

DSO STRATEGY REPRODUCTIVE HEALTH COMMODITIES

Study report

Final version Volume I

June 2020

www.hera.eu

Tel +32 3 844 59 30
hera@hera.eu

Laarstraat 43
B-2840 Reet
Belgium



TABLE OF CONTENTS

Acknowledgements	vii
Executive summary	viii
1 Introduction	1
1.1 Objectives	1
1.2 Methodology	1
1.2.1 Definitions	1
1.2.2 Study questions.....	2
1.2.3 Study components.....	3
1.3 Coronavirus Disease 2019 (COVID-19) pandemic.....	6
1.4 Limitations and challenges.....	6
2 Findings.....	8
2.1 Contextual findings	8
2.2 Product specific information.....	10
2.3 Recent trends and developments in relation to RHC availability	10
2.3.1 Study question 1 – Recent trends and developments.....	11
2.3.2 Summary study question 1.....	20
2.4 The role of the Netherlands.....	20
2.4.1 Study question 2 - Role of the Netherlands in RHCs.....	20
2.4.2 Summary study question 2	23
2.5 Priority interventions	23
2.5.1 Study question 3 – Priority interventions.....	23
2.5.2 Summary study question 3.....	43
2.5.3 Study question 4 – Private sector	44
2.5.4 Summary study question 4.....	50
2.5.5 Study question 5 - Main players in RHCs procurement and technical assistance.....	51
2.5.6 Summary study question 5.....	57
3 Conclusion	59
3.1 Many interventions, limited evidence	59
3.2 Recent developments	59
3.3 Key areas identified provide opportunities for support.....	59
3.3.1 Last mile distribution	60
3.3.2 Domestic resource mobilisation	60
3.3.3 Private sector	60
3.4 Support of the Netherlands remains relevant	61
4 Policy options	62

4.1 Introduction	62
4.2 Policy options to increase availability of RHCs	64
4.2.1 Strategic support at global, regional and country level	64
4.2.2 RHCs research	68
4.2.3 Last mile distribution	71
4.2.4 Domestic resource mobilisation	73
4.2.5 Private sector	74

LIST OF FIGURES

Figure 1. Current spending on contraceptive supplies (source: CGA 2019).....	34
--	----

LIST OF TABLES

Table 1. Study questions (grouped by topic) and data sources used to answer these questions	2
Table 2. Stakeholders interviewed	5
Table 3. Current spending by sector, segmented by GNI Group (source: CGA 2019).....	35
Table 4. Policy options.....	62

ABBREVIATIONS

3PL	Third Party Logistics
ACAME	Association Africaine des Centrales d’Achats de Médicaments Essentiels (African Association of Procurement Centres)
AFD	Agence Française de Développement
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonisation
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
ARC	African Resource Centre
ARV	Antiretroviral
BFM	Bridge Funding Mechanism
BMGF	Bill & Melinda Gates Foundation
CBD	Community Based Distribution
CCP	Central Contraceptive Procurement
CGA	Commodity Gap Analysis
CGD	Centre for Global Development
CHAI	Clinton Health Access Initiative
CIP	Costed Implementation Plan
CMS	Central Medical Stores
CRT	Commodity Requirement Tool
CSO	Civil Society Organisation
CSP	Coordinated Supply Planning
CYP	Couple Years of Protection
DFID	Department for International Development
DHIS	District Health Information Software
DRC	Democratic Republic of Congo
DRM	Domestic Resource Mobilisation
DSO	Directorate Social Development
EAC – MRH	East African Community Medicines Regulatory
ECOWAS	Economic Community of West African States
eLMIS	electronic Logistic Management Information Systems
EML	Essential Medicines List
EOI	Expression of Interest
ERP	External Review Panel
FDA	Food and Drug Administration
FP2020	Family Planning 2020
FPET	Family Planning Estimation Tool
FY	Financial Year
GBV	Gender-Based Violence
GFF	Global Financing Facility
GHSC-PSM	Global Health Supply Chain Program – Procurement and Supply Management

Global FP VAN	Global Family Planning Visibility and Analytics Network
GMP	Good Manufacturing Practices
HIP	High Impact Practices
HPV	Human Papilloma Virus
HRP	Human Reproduction Programme
HSC	heat stable carbetocin
IAP	Implant Access Program
ICPD	International Conference on Population and Development
IPM	Informed Push Model
IPPF	International Planned Parenthood Federation
IUD	Intra-Uterine Device
JSI	John Snow Inc
KII	Key Informant Interview
L-MIC	Lower Middle-Income Country
LAPM	Long Acting and Permanent Method
LARC	Long Acting Reversible Contraceptive
LMD	Last Mile Distribution
LMIC	low- and Middle-Income countries
LMIS	Logistic Management Information Systems
LNG-IUS	Levonorgestrel Intra-Uterine System
MHRA	Medicines and Healthcare products Regulatory Agency
MOF	Ministry of Finance
MOH	Ministry of Health
MPT	Multipurpose Prevention Technology
MSH	Management Sciences for Health
MSI	Marie Stopes International
MVA	Manual Vacuum Aspiration
NDA	New Drug Application
NEML	National Essential Medicines List
NEPAD	The New Partnership for Africa's Development is the development agency of the African Union
NGO	Non-Governmental Organisation
NHIS	National Health Insurance Scheme
NMRA	National Medicines Regulatory Authority
NRA	National Regulatory Authority
OOP	Out of Pocket
OP	Ouagadougou Partnership
P4P	Payment for Performance
PATH	Program for Appropriate Technology in Health
PPH	Post-Partum Hemorrhage
PPIUD	Postpartum Intra-Uterine Device
PPM	Pooled Procurement Mechanism
PPMR	Procurement Planning and Monitoring Report

DSO strategy in relation to Reproductive Health Commodities

PSB	Procurement Services Branch
PSI	Population Services International
PVR	Progesterone Vaginal Ring
R&D	Research and Development
RFM	Regional Financing Mechanism
RHC	Reproductive Health Commodity
RHI	Reproductive Health Interchange
RHSC	Reproductive Health Supplies Coalition
RMNCAH	Reproductive Maternal Newborn, Child and Adolescent Health
RMNCAH-N	Reproductive, Maternal, Newborn, Child and Adolescent Health and Nutrition
RMNCH	Reproductive, Maternal, Newborn and Child Health
SC	Subcutaneous
SCM	Supply Chain Management
SDG	Sustainable Development Goal
SECONAF	Forum pour la Sécurité Contraceptive en Afrique Francophone
SMO	Social Marketing Organisation
SRA	Stringent Regulatory Authority
SRH	Sexual and Reproductive Health
SRHR	Sexual and Reproductive Health and Rights
STM	Short Term Method
SWEDD	Sahel Women's Empowerment and Demographic Dividend
The Global Fund	The Global Fund to Fight Aids, Tuberculosis and Malaria
TMA	Total Market Approach
TOR	Terms of Reference
TPP	Third Party Procurement
U-MIC	Upper Middle-Income Country
UAV	Unmanned Aerial Vehicle
UHC	Universal Health Coverage
UNFPA	United National Population Fund
US	United States
USFDA	US Food and Drug Administration
WAHO	West African Health Organisation
WASH	Water, Sanitation and Hygiene
WB	World Bank
WHO	World Health Organisation
WISH	Women's Integrated Sexual Health

ACKNOWLEDGEMENTS

The review was conducted by Ana Villen Gonzalvo and Ingeborg Jille Traas from hera.

Quality assurance for the report was provided by Marianne Schürmann. Lianne Vreeke provided administrative support from the hera office in Belgium.

The hera team is grateful to the team from the Directorate Social Development for its dedicated involvement and support throughout the study, and to all key informants who provided their time for answering questions and enriching the study findings. The team also thanks all colleagues within and outside hera who were willing to share their valuable views and experiences on topics related to reproductive health commodities availability.

Reet, Belgium

June 2020

EXECUTIVE SUMMARY

Introduction

The Terms of Reference (TOR) identified the following objectives of this study:

1. Mapping of the most recent (last two years) trends and developments in relation to reproductive health commodities (RHCs). In this context, scientific, programmatic as well as policy trends in relation to donor support will be studied.
2. Based on the policy choices already made and the mapping mentioned under 1, provide an overview of priority interventions for the Directorate of Social Development (DSO) of the Dutch Ministry of Foreign Affairs in each of the following areas: (1) last-mile distribution (LMD), (2) West-Africa (3) domestic resource mobilisation (DRM) and (4) facilitating the private market for RHCs.

The study consisted of a literature review (71 peer reviewed articles, 84 documents from grey literature and 39 websites were reviewed) and Key Informant Interviews (KII) (26 people from 22 organisations). The list of key informants was developed in collaboration with DSO. An interview guide was applied for all interviews.

Throughout the study, several consultations and discussions were held with DSO and technical experts from several Dutch Embassies in Sub-Saharan Africa. Data collection took place between December 2019 and May 2020.

The study questions were elaborated in collaboration with DSO. The table below shows the main study questions:

Trends	1	What can be learned from recent strategic review processes undertaken at global level by important stakeholders?
	2	What is the view of international stakeholders on the role of the Netherlands?
Priority interventions	3	What is current evidence regarding impact of interventions on the availability of RHCs?
	4	What are the main vulnerabilities, risks and/or barriers of the private sector for RHCs?
	5	Who are the main players in RHCs procurement and technical assistance in public and private sector?

After the development of the summary report of key findings from literature review and KII (March 2020), the COVID-19 pandemic broke out. This report therefore does, for the most part, not consider COVID-19 in its analysis and policy options.

Context

The RHC market in Low- and Middle-Income Countries (LMIC) is complex: involving actors from multiple sectors, a broad product range, insufficient integration of RHCs in the overall national public health supply chains and in the Ministry of Health budgets of many countries, and demand that is difficult to estimate due to hidden needs and unreliable consumption data. Reproductive health remains, to a large extent, a socially and culturally sensitive matter particularly contraception for young (unmarried) girls and abortion. all this affects RHC availability. RHCs, especially family planning supplies, are available through the private sector (full price paid by the users, mainly short-acting methods), social marketing programmes (subsidised prices,

mainly short-acting methods), and the public sector (mostly free of charge, broad range of methods, but focus on long-acting reversible contraceptives).

The global unmet need for family planning in 2019 is estimated at 12% with variances between the developed and least developed region (10 and 21% respectively). The number of family planning users is expected to grow from 487 million users in 2020 to 569 million users in 2030, a 17% increase. The global funding gap for contraceptive supplies for 2020 is USD 178 million, increasing to a cumulative gap over five years (2021-2025) of up to USD 1.17 billion, unless changes occur in donor and/or domestic funding (values) and/or demographic developments.

Study results

Study question 1 - *What can be learned about the availability of RHCs (at global, national and peripheral level) from the recent strategic review processes that have been undertaken at global level by important stakeholders like UNFPA, FP2020, USAID, the RHSC and others?*

In the lead up to the post (FP)2020 era, several of the main stakeholders have strategized or are in the process of reviewing their current strategies. Main changes observed in the RHC landscape include:

- The demand for RHCs is likely to increase considerably due to growing population overall and higher expressed needs
- Overall improving method mix, but the benefit of the noticed shift noticed from predominantly short-acting methods to long-acting reversible contraceptives is being debated, including in relation to the freedom of choice of the users
- Expected decreasing trend in external funding of RHCs which will lead to considerable changes in procurement arrangements with more countries procuring RHCs with domestic funding using national procurement guidelines and quality standards
- Increased requests from countries for technical assistance expected to support the strengthening of their national health systems (including national supply systems); with decreasing donor support, RHCs will likely be integrated in the national supply chains
- A greater realisation that the private sector must (and will) play a more important role for RHC availability. Sufficient capacity for adequate regulation of the private sector will be required to ensure maximum benefit (e.g., quality of services and products)
- Investigation, by a group of key stakeholders, of a configuration for a so-called global market manager; an entity that would have full and up to date information of RHC markets, and that could take timely action in case of anticipated changes or problems

Study question 2 – overarching question: *What is the view of international stakeholders (including main global health actors, private sector in program countries, government counterparts in program countries, manufacturers and technical experts in the field of RHCs) on the specific role of the Netherlands in ensuring availability of RHCs?*

Overall, support from the Netherlands in RHCs is appreciated. It is considered thoughtful and consistent and adds to the diversification of existing donor support. Some interviewees question whether enough support is provided to private sector development and expressed some concerns related to decreased funding for RHCs. The Netherlands' role in the reform of UNFPA Supplies is valued.

Alignment and harmonisation of efforts at global level is considered adequate, with the note that less coordination mechanisms might lead to more efficiency. At country level, where governments are

responsible for coordination and alignment of efforts related to RHC availability among other ministries and partners, this remains a challenge.

Study question 3 – overarching question: *What is current evidence regarding impact of interventions on the availability of RHCs (e.g. strengthening private sector, enhancing last-mile distribution etc)?*

There is no consensus on which interventions contribute to increased availability of RHCs. General descriptions of the broad range of existing projects and (pilot) interventions are available, but the body of evidence about the results and impact of these projects and interventions remains limited. Without in-depth understanding of why an intervention works or not in a certain context, its replication or scaling may not be successful. Scaling up of successful (small) pilot interventions is stated as a major undertaking requiring considerable investments.

From our assessment based on available literature and interviews the most promising interventions include:

- The Informed Push Model as successfully implemented (and evaluated) in Senegal. It involves a collaboration of public and private sector that managed to achieve a stable supply of RHCs in the public sector. The model is being implemented in other countries as well, for RHCs and for other medicines and health commodities (e.g., Zambia).
- The Prime Vendor System which is implemented in several countries (e.g. Tanzania). It involves contracting of a private supplier where public sector actors can purchase medicines and health commodities in case of stock out in the public sector.
- Online sales of a range of health and personal hygiene commodities, including family planning supplies, through social enterprises. It involves online platforms through which commodities can be ordered. Orders are either delivered to doctor's offices (e.g. Doctorstore in India), at end-user's homes or at pick up locations (e.g., Kasha in Rwanda and Kenya, MYDAWA in Kenya)
- Sales of commodities by Community Health Promoters (in Uganda), Village Midwives (in Indonesia) and similar professionals in several other countries showed increased availability of key RHCs at the end-user level and promising results for health outcomes.
- Co-financing as implemented by GAVI and the Global Fund has the interest of the RHCs community, but it is still in its early stages. As donor funding is decreasing, there is pressure on countries to increase domestic resources which will require changes in the current financing systems for RHCs.

Volume guarantees are still being negotiated but seem controversial; after the initial successes (e.g., lower prices, additions to the method mix), doubts have risen about long-term consequences including a weakening of the vulnerable market. Other interventions are being explored such as long-term agreements that focus on long term commitments rather than volume guarantees, but no consensus exists on what the best approach is.

Interventions that have facilitated innovation at product level and for last mile distribution could not be identified.

Social marketing is under pressure; questions and doubts related to its sustainability are raised, and funding is decreasing. But the RHCs community is divided and strong promoters continue to believe in the strength of social marketing. Meanwhile social marketers are exploring approaches that would provide sufficient revenue to cover (a larger part of) the costs related to a non-interrupted supply chain for subsidised commodities. With pressure for cost reduction, strong regulatory bodies are required to ensure all commodities provided to the population comply with (inter)national standards.

The lack of opportunity for health facilities to generate revenue for medicines/health commodities that are dispensed for free affects their last mile distribution unless governments and/or donor agencies provide the necessary funding.

Study question 4 – overarching question: *What are the main vulnerabilities, risks and/or barriers of the private sector for RHCs?*

The RHC market is a challenging market with few manufacturers and few buyers. Main challenges for manufacturers include difficulties to comply with the buyers' quality standards (WHO prequalification requirement) and mandatory registration in most countries, processes that are cost and labour intensive.

In recent years several market shaping interventions (e.g. volume guarantees) have been implemented by key actors in an attempt to create a healthier market that supports the availability of RHCs. As a result, the family planning supplies method mix increased in many countries, but there has also been criticism of this approach and some even say that it has made the market more vulnerable. Manufacturers lost appetite to enter the market because of the low prices paid and because existing agreements limited their business opportunities.

At country level, the private sector is not well organised and its participation in the national or local health system remains limited for different reasons (e.g., lack of market information, unclear requirements). Nevertheless, consensus exists that the private sector should be more involved to ensure all future needs can be met.

The following interventions to strengthen the private market at country level could be considered:

- Improve public stewardship required to involve the private sector in health systems in an efficient and sensible way
- Support the TMA to obtain an in-depth understanding of the market and identify opportunities to make use of the different sectors to reach different users
- Explore collaboration with relevant private sector institutions such as national federations, associations of private practitioners, and associations of pharmacists; these, when well organised, can act as focal point for the private sector and in that role facilitate collaboration with the public sector

Limited written information is however available on the results of such interventions.

Study question 5 – overarching question: *Who are the main players in RHCs procurement and technical assistance in public and private sector?*

There are only 2 main actors in procurement of RHCs, UNFPA Supplies and USAID. These organisations apply different procurement procedures, including different quality standards. One of the main challenges of UNFPA Supplies is the unpredictability of funding combined with the fact that the funds have to be on UNFPA's account before orders can be placed. Since 2015, USAID's supply program has been facing numerous challenges including decreasing on-time delivery rates and increasing stock-outs in the supported countries. Smaller buyers include NGOs (e.g., MSI, IPPF). For condoms, the Global Fund is an important buyer who provides the online platform wambo.org for procurement by its principle recipients.

A variety of organisations provide technical assistance in aspects related to RHC availability with a focus on general aspects of supply chain management (e.g., Chemonics, JSI, Village Reach, MSH). ACAME is a regional organisation with 22 member countries in West Africa with the objective to contribute to better performance of its members' central medical stores in order to improve the availability of affordable quality assured medicines and health commodities. Their involvement can be interesting for interventions related to strengthening of public health supply chains.

Through literature review and KII we identified two organisations that support manufacturers with WHO prequalification and registration at country level, namely the Concept Foundation and WCG.

Other organisations active in quality assurance are FHI360 and QUAMED. The development agency of the African Union (NEDAP) supports AMRH, a program working on regulatory issues including harmonisation of registration in regional economic communities of the African Union.

CGD is a research organisation working on, among other things, global health, and recently published, through its working groups, articles on the future of procurement and funding for family planning that provide interesting insights from a scientific perspective. Other research institution involved in RHCs related topics include HRP, the Guttmacher Institute and the William Davidson Institute.

Conclusion

Many different interventions to increase availability of RHCs are being implemented, yet information found on these interventions is restricted to brief descriptions on what the interventions entail, and does not include information on what works, what not, and why. As such, the body of evidence related to impact of these interventions and their scalability is limited.

The three key thematic areas identified by DSO are in line with latest thinking in the global RHC space and provide opportunities for support (the fourth key area, West Africa, is a geographic focus area):

- The main supply chain management issue for RHCs is related to last mile distribution, which is in some countries partly caused by the fact that these commodities are dispensed for free in the public sector.
- Domestic resource mobilisation is an emerging topic in the RHC space. Overall donor funding is decreasing, which increases the responsibility of receiving countries to allocate domestic funding for procurement and in country handling of RHCs.
- There is consensus in the global RHC community that the private sector will have to be more involved in order to meet the growing demand for RHCs. Social marketing organisations are slowly but successfully shifting their set up from charity towards social enterprises. In less developed countries (e.g. several countries in West Africa) however, the need for subsidies remains.

The focus of the Netherlands' support to West Africa is considered relevant. The region's key SRHR indicators are the lowest in the world. The context is complex with high levels of insecurity and related humanitarian crises. Innovative solutions to increase RHC availability that were successful in other regions may not work in this particular context or may require major adaptations (e.g., online sales, social marketing). With the long term presence of health experts in several countries in this region and a proven fairly flexible approach, the Netherlands is well placed to play an important (coordinating) role in RHCs provision and/or broader supply chain management in selected countries.

Policy options

Key principles applied include:

- Ensure a balanced mix of interventions at the different levels that allows the Netherlands to maintain the opportunity to be involved in policy making at global and regional level, and to understand what the effects of global level input are on the availability of RHCs at country level.
- The various options proposed can work on their own, but reinforce each other when more or all are implemented.
- The options for research can be directly linked to options for implementation of specific interventions.

- As strengthening health systems is a requirement to support SRH interventions, the overall strategy of the Netherlands to improve availability of RHCs should be to strengthen national procurement and supply chain systems and to avoid, to the maximum extent, the establishment and use of parallel systems.
- In West Africa, focus region of the Netherlands, several countries are unstable and the evolution of the situation is hard to predict and expected to be different in each country. Implementation of options in this region must therefore be flexible, ensuring adaptive interventions that can be implemented by different organisations, while continuing to focus on building resilient health systems including in humanitarian settings.
- In several countries in West Africa, demand is weak and interventions to increase availability of the RHCs therefore have to be accompanied with interventions to increase access and generate demand, particularly for adolescents, hard to reach and other vulnerable populations. These interventions are not directly linked to RHCs availability and therefore not further elaborated.
- Options proposed for country level have to be contextualised.

Priority raking is based on the following indicators:

- To what extent does the proposed option contribute to the main objectives of the Dutch Policy for Foreign Trade and Development Cooperation related to SRHR?
- Within which period can the proposed option show attributable results/impact (short, medium or long term), thereby assuming a preference for short to medium term results/impact?
- How do the costs of this option relate to the potential (short, medium, or long term) benefits of the proposed option?
- To what extent is the existing context favourable to implement the proposed option? Can interventions be added on existing interventions with existing infrastructure? Do new structures/infrastructures have to be established, requiring additional investment?
- Does the proposed intervention cover more than one of the focus areas identified by DSO (last mile distribution, domestic resource mobilisation, private sector, West Africa)?

Category	Option	Priority ranking
Strategic support at global, regional and country level	Option 1 - Continue support to UNFPA Supplies, at least during the period of the transition of the organisation: funding for procurement of RHCs and technical and financial support for the transition	High
	Option 2 - Support the RHSC	Medium
	Option 3 - Continue support to the Regional Financing Mechanism Fund coordinated by WAHO	Low/Medium
	Option 4 - Support specific product categories that globally have less attention and funding, e.g., supplies for menstrual health and hygiene, and safe abortion	4a: Low 4b: Medium/high
RHCs research	Option 5 - Fund independent (operational) research to add to the limited body of evidence on interventions that can contribute to increased availability of RHCs	Low/Medium
	Option 6 - Conduct studies to better understand existing national RHC markets (supply and demand) and identify possible roles for actors of all sectors for increasing availability of RHCs	Medium

DSO strategy in relation to Reproductive Health Commodities

Category	Option	Priority ranking
	Option 7 - Support (independent) evaluations and impact assessments of promising models and interventions to ensure availability of RHCs at the last mile	Low/Medium
	Option 8 - Support a feasibility study for the development and implementation of a co-financing strategy to facilitate agreement among donors	Low
Last mile distribution	Option 9 - Support models and interventions involving entrepreneurial approaches that have proven successful to ensure availability of RHCs at the last mile in Sub-Saharan Africa (particularly anglophone countries in Southern and Eastern Africa)	High
	Option 10 - Consider, based on results of recent assessments, to provide general financial and technical support to the national public health procurement and supply chain system, including last mile distribution	Medium
Domestic resource mobilisation	Option 11 - Support countries to develop resource mobilisation plans or transition plans with a focus on increasing domestic resources and decreasing dependency on external funding	Low
Private sector	Option 12 - Support initiatives to harmonise medicines registration processes	Low/Medium
	Option 13 - Support social marketing organisations (SMO) to set up a sustainable supply chain that is independent from external support	Medium/High
	Option 14 - Assess barriers related to regulation and policy for private sector actors to participate in the RHC market, and advocate for lifting unreasonable restrictions	Medium/High

1 INTRODUCTION

1.1 OBJECTIVES

The Terms of Reference (TOR) identified the following objectives of this study:

1. Mapping of the most recent (last two years) trends and developments in relation to reproductive health commodities (RHCs). In this context, scientific, programmatic as well as policy trends in relation to donor support will be studied.
2. Based on the policy choices already made and the mapping mentioned under 1, provide an overview of priority interventions for the Directorate of Social Development (DSO) of the Dutch Ministry of Foreign Affairs in each of the following areas: (1) last-mile distribution (LMD), (2) West-Africa (3) domestic resource mobilisation (DRM) and (4) facilitating the private market for RHCs.

This report describes the findings of the literature review and the Key Informant Interviews (KIIs) and provides policy options for DSO to contribute to increased availability of RHCs. Feedback received from DSO has been incorporated. The report structure follows the (adapted) study questions as proposed by hera and approved by DSO on 27 November 2019.

1.2 METHODOLOGY

1.2.1 DEFINITIONS

Several concepts and terms used in this study might be understood in different ways. In order to achieve a common understanding, we describe below how the main concepts will be interpreted and used throughout the study.

- **RHCs:** As per the TOR these include all commodities for family planning, safe deliveries (e.g. oxytocin) and safe abortion. Multi-purpose technologies to prevent pregnancy as well as sexually transmittable infections (e.g. dapivirine vaginal ring) are also included, although technically these do not fit within the categories above. The human papilloma virus (HPV) vaccine is excluded.
- **Availability:** A commodity is (easily) obtainable in the public/private market open to the population. It involves all logistics activities required to reach the end-user. Other related terms are often used interchangeably, such as use (a commodity is actually consumed by the population) and access (a commodity can be obtained and used when and where the population needs it without financial and geographic barriers, and often used as the overarching term covering availability, affordability, and adoption). Affordability relates to the costing aspects, ensuring that commodities are not too costly for the people who want and need them. Adoption mainly relates to acceptance and demand at the different levels of the society (global, national, district, and community).¹ As per the TOR, this study mainly covers availability of RHCs at the user level. Nevertheless, affordability is discussed as a side issue.
- **West Africa:** The current Dutch Development Policy for RHCs focusses on Mali, Burkina Faso and Niger. The Netherlands also supports regional programs such as the Ouagadougou Partnership (OP) and the West African Health Organisation (WAHO). In addition, the Netherlands, through multilateral support, is also involved in the UNFPA Supplies program and the Global Financing Facility (GFF). In line with the focus regions of the Dutch Development Policy, countries in West Africa are covered by

¹ Laura J. Frost & Michael R. Reich. Access: how do good health technologies get to poor people in poor countries? 2016.

this review, including the Francophone countries and fragile regions in the Sahel where a number of (regional) programmes are being supported.

- **Private market:** The RHCs' private market involves the pharmaceutical industry, manufacturers, importers/wholesalers at national level (e.g. suppliers), and retailers at peripheral level (e.g., private pharmacies, private clinics).
- **Country supply chain:** A network of interconnected organisations or actors that ensure(s) the availability of pharmaceuticals and health commodities to the people who need them. This network of actors is nested within a country's health system and the operational and contextual environments in which they operate. Supply chains can be public, private or mixed.
- **Supply chain management (SCM):** Several definitions, theories and models are used, yet the common understanding is that supply chain management is responsible for 'the six rights': the right product, in the right quantities, in the right condition, delivered at the right place, time and cost. The following elements are considered part of supply chain management: product selection, forecasting and quantification, procurement, inventory management, distribution, and rational use. Quality assurance and reporting are overarching elements.
- **Last-Mile distribution (LMD):** The movement of goods (usually) from an intermediate transportation hub to the dispensing location (e.g., health facilities or community clinics/community health workers).
- **Domestic Resource Mobilisation (DRM):** The process through which countries raise and spend their own funds to provide for their people. It is seen as a critical step on the path out of aid dependence.

1.2.2 STUDY QUESTIONS

Table 1 below lists the study questions. The questions are grouped around the following topics:

- Recent trends and developments in relation to RHCs availability (scientific, programmatic as well as policy trends in relation to donor support)
- Role of the Netherlands (past and present)
- Priority interventions (in last-mile distribution, West-Africa, domestic resource management, facilitating the private market for RHCs)

For questions 1, 3, 4 and 5, results from the literature review were complemented with the results from the KIIs. For answering study question 2, the study team relied on KIIs only. Table 1 also indicates the data sources used to answer the study questions.

Table 1. Study questions (grouped by topic) and data sources used to answer these questions

#	Study question	Data source
Recent trends and developments in relation to RHCs availability		
1	What can be learned about the availability of RHCs (at global, national and peripheral level) from the recent strategic review processes that have been undertaken at global level by important stakeholders like UNFPA, FP2020, USAID, the Reproductive Health Supplies Coalition (RHSC) and others?	Main data source: literature review
Role of the Netherlands in RHCs		
2	What is the view of international stakeholders (including main global health actors, private sector in program countries, government counterparts in program	Main data source: KIIs

#	Study question	Data source
	<p>countries, manufacturers and technical experts in the field of RHCs) on the specific role of the Netherlands in ensuring availability of RHCs?</p> <ul style="list-style-type: none"> Which of these views are relevant when making choices for specific priority interventions? What is the risk at global level of duplication of efforts to increase availability of RHCs by interventions from the Netherlands, and how can this be avoided? How can the Netherlands facilitate alignment of initiatives at global level and in its focus countries? 	
Priority interventions		
3	<p>What is current evidence regarding impact of interventions on the availability of RHCs (e.g., strengthening private sector, enhancing last-mile distribution etc.)?</p> <ul style="list-style-type: none"> What are the interventions with most impact on the availability of RHCs? Which interventions have facilitated innovation at product level, and for last mile distribution? What are successful interventions to stimulate domestic resource mobilisation for RHCs? What is the impact of interventions by INGO's (PSI, MSI etc.) on the availability of RHCs, and which interventions implemented by INGOs to increase availability of RHCs could be supported by the Netherlands? 	Main data source: literature review complemented by KIIs
4	<p>What are the main vulnerabilities, risks and/or barriers of the private sector for RHCs?</p> <ul style="list-style-type: none"> How can the Netherlands support the development of a sound private market for RHCs considering the present vulnerabilities, risks and barriers? 	Main data source: literature review complemented by KIIs
5	<p>Who are the main players in RHCs procurement and technical assistance in public and private sector?</p> <ul style="list-style-type: none"> Which of these organisations are best positioned to align interests of the private sector (this concerns global manufacturers, local wholesalers and importers of RHCs)? Which organisations can facilitate increased availability of RHCs, quality assurance, including registration processes globally and in the Netherlands priority countries? 	Main data source: literature review complemented by KIIs

1.2.3 STUDY COMPONENTS

1.2.3.1 Literature review

The TOR requested a systematic review, but also stated that the review was not to be limited to published research and studies, but should also include other relevant (non-scientific) documents. A traditional 'systematic review' according to its definition² was therefore not feasible and would not have provided the necessary information to answer the study questions. Therefore, the literature review conducted is a combination of a narrative and a systematic review. In this report we use the term literature review. More information can be found in Annex 1 (Volume II).³

² The purpose of a systematic review is to deliver a meticulous summary of all the available research results in response to a specific research question. It uses all existing research on a certain topic and follows generally a rigorous and clearly documented methodology in both the search strategy and the selection of studies in order to minimise bias in the results.

³ The methodology applied is explained in detail in the 'Approach for the systematic review' submitted to DSO in November 2019.

We applied several strategies to search for and select relevant publications for review of the literature: search in the Pubmed/Medline (for peer reviewed articles) and Google Scholar, review of existing literature included as Annex to the TOR, and simultaneous cross-referencing to identify other relevant publications. For each of the study questions, specific search strategies were developed to search the peer reviewed literature. For non-scientific or grey literature, the regular search engine Google was used. We also searched for documents at relevant websites (e.g., the Reproductive Health Supplies Coalition/RHSC, Program for Appropriate Technology in Health/PATH, United Nations Population Fund/UNFPA). Furthermore, relevant documents (e.g., policy and strategy documents) were requested from DSO, from key informants interviewed and from our own network. More details on the literature review can be found in Annex 1 (Volume II).

After the screening, 68 peer reviewed articles published in scientific journals, and 9 non-scientific or grey literature reports were found relevant and shortlisted for the full-text review. Additionally, 2 articles from the bibliography suggested in the TOR by DSO were included, and 1 article was added following the KIIs. All selected documents were downloaded in PDF format and imported to MAXQDA software. Once reviewed, 11 articles were excluded from the analysis, since they were not capturing any data related to the study questions. The final number of studies used for the initial analysis was 60.

Several types of articles were found: evaluations of interventions, pilot studies, case studies, and quantitative, qualitative and mixed methods research studies. Geographically, 14 countries were represented. Among all the studies, 25 referred to interventions or policies in more than one country. Democratic Republic of Congo (DRC) was the most represented country with 7 studies, followed by Ethiopia, Tanzania, and Uganda. Countries in West Africa were also represented, but not strongly, in the selected studies (e.g., Burkina Faso, Mali, Niger). When analysing the main topic, the majority of studies (41) referred to family planning supplies, while 8 discussed RHCs in general, 4 referred to safe abortion supplies and 6 to medicines and medical products related to safe delivery.

The selection of the grey literature directly obtained from stakeholders' websites was done as documents were read and analysed in MAXQDA.⁴ In total, 154 documents were reviewed, of which 70 peer reviewed articles and 84 documents from grey literature.

A total of 40 websites were visited and searched.

The initial literature review was conducted between November 2019 and February 2020. After this period, additional relevant literature was searched for and reviewed to complement the review where needed, and to provide the necessary supportive documents for the development of the policy options.

The list of documents reviewed, and websites searched can be found in Annex 1 (Volume II).

1.2.3.2 1.2.3.2 Key informant interviews

Key informant interviews were conducted to complete and enrich the information obtained through the literature review. The selection of informants has been made in close collaboration with the DSO team. Initially, 20 stakeholders were selected, including Dutch Embassies in Sub Saharan Africa, and 2 were added at a later stage. In total the team interviewed 26 people from 22 different organisations. One selected stakeholder did not reply (on time) to the request sent by DSO.

Table 2 below shows a summary of the stakeholders interviewed.

⁴ <https://www.maxqda.com>

Table 2. Stakeholders interviewed

#	Name	Type	Countries involved
1	Private sector actor	Private sector	Mali
2	Association des Centrales d'Achat des Medicaments Essentiels (ACAME)	Network of central medical stores in West/Central Africa	West/Central Africa
3	Association of Support in the Development of Activities of Population	National NGO	Mali
4	Bill and Melinda Gates Foundation	Donor	Global; also involved in matching fund in West-Africa
5	Clinton Health Access Initiative	INGO	Global
6	DFID	Donor	Different countries
7	Dutch Embassy in Ethiopia	Embassy	Ethiopia
8	Dutch Embassy in Mali	Embassy	Mali
9	Dutch Embassy in Uganda	Embassy	Uganda
10	Family Planning 2020	Partnership	Global
11	Global Financing Facility	Financing mechanism / partnership	Global; Starting in Mali and Niger, implementing in Burkina Faso
12	Global Healthcare Supply Chain Expert	Independent consultant	Global
13	i+ solutions	Consultancy firm/procurement agent	Different countries
14	MSD	Manufacturer	Global
15	NORAD	Donor	Global
16	Ouagadougou Partnership Coordination Unit	Partnership	West Africa - Benin, Togo, Cote d'Ivoire, Guinea, Senegal, Mauritania, Mali, Burkina Faso, Niger
17	Population Services International (PSI)	INGO	Senegal, Guinea, Cote d'Ivoire, Burkina Faso, Benin, Mali, Niger
18	Pregna International Limited- Managing Director	Manufacturer	India
19	Reproductive Health Supplies Coalition	Partnership	Global
20	United Nations Population Fund Supplies	UN thematic program	Global
21	West African Health Organisation	Regional health agency Economic Community of West African States (ECOWAS)	ECOWAS member states (Benin, Burkina Faso, Cabo Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo)

#	Name	Type	Countries involved
22	William Davidson Institute	Research and educational organisation	Different countries

The study team conducted the KIIs in February and March 2020 and used a standard interview guide which was then adapted to the knowledge and experience of each informant. All interviews except for 5 were conducted by the two study team members. When only one team member could participate, support for note taking was provided by the hera office. All interviews were recorded with the permission from the interviewees. The notes taken during the interviews were completed with a transcription of the recordings and analysed in MAXQDA. Interviewees were given the opportunity to provide feedback to sections of the report that include information directly traceable from the interviews.

The list of people interviewed can be found in Annex 2 (Volume II). The interview guide can be found in Annex 3 (Volume II).

1.3 CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC

After the development of the summary report of key findings from literature review and key informant interviews (March 2020), the COVID-19 pandemic broke out. This report therefore does, for the most part, not consider COVID-19 in its analysis and policy options. Meanwhile, effects of this pandemic on RHCs (e.g., reported longer lead times for procurement, increased prices) cannot be denied, and wherever possible, the study team considered this aspect.

1.4 LIMITATIONS AND CHALLENGES

Several limitations and challenges were faced with regards to the literature review. These include:

- It is difficult to find literature on recent trends, particularly in peer reviewed journals; it takes time for interventions to be implemented, evaluated, and have the results published.
- Most literature found refers to family planning supplies in particular. Some documents did not specify which of the RHCs were discussed.
- Detailed information on countries in West Africa or other priority countries for the Netherlands was not found through the current search, but we found relevant articles from other Sub Saharan African countries (e.g. Ethiopia).
- Due to the specificity of the study questions, a large part of the selected literature reviewed to answer these questions is grey literature. This comes with certain challenges:
 - Many articles describe projects implemented in a general way, e.g. the interventions and the implementing partners. Details on coverage (e.g. predefined provinces and districts or the entire country) and the level of the use of country systems vs vertical systems are often lacking. Results are often not described at all or only partially, and the necessary background and methodology to judge whether the results recorded are measured through a robust and objective evaluation are missing.
 - The majority of available documents was developed by a limited number of organisations (e.g., UNFPA, UNFPA Supplies, Population Services International (PSI), Reproductive Health Supplies Coalition (RHSC), FP2020).

- The sources for grey literature are almost unlimited. To set boundaries to our search, we performed searches in the websites of the key organisations and stakeholders working in RHCs (see for more information Annex 1, Volume II). When considered useful (e.g. in case our initial search resulted in little information on a certain topic) we conducted additional searches. Nevertheless, we are aware that other relevant documents are available, which we accessed on an as needed basis during the study phases following the literature review and KIIs.
- Procurement and supply chain related topics relevant to this study are not (yet) widely researched. The number of peer reviewed articles focusing on availability of RHCs as key topic is therefore limited. Most articles selected do not have availability of RHCs as their main study topic. As a result, it was difficult to find detailed evidence and information to answer all the specific study questions. As in several countries RHCs follow (to a certain extent) the national public health supply chain, information this chain was also assessed.

No particular constraints were encountered with KIIs. Selected interviewees were interested to talk to the study team and information provided was rich. A common challenge of KIIs is that validity is hard to establish; in this case, results from the KIIs were mainly used to complement the key results from the literature review, and to triangulate data collected through different data collection methods. The study team therefore is confident that the combined findings provide sufficient reliable information to answer the main study questions.

The views of the receiving countries were underexposed. There may be various reasons for this: 1) the study did not focus on specific countries but on a large and diverse region (West Africa), and 2) relatively few stakeholders from the recipient countries have been interviewed (e.g. no representatives of the receiving governments). Most of the interviewees indicated the main challenges with regards to RHCs are at country level.

Several topics related to RHCs availability were not well covered by the literature study (e.g., universal health coverage, health insurance, drone deliveries, free vs paid commodities) but were considered important and therefore additional research was conducted. Available time for such additional research was however limited, and these topics could not be explored in great detail.

2 FINDINGS

2.1 CONTEXTUAL FINDINGS

Note: Information that is not supported by a reference to the literature has been sourced through KIIs.

RHCs have some particularities that make the market complex and challenging: actors from multiple sectors are involved (e.g., receiving country's ministries of health, donors, national and international non-governmental organisations (NGO), partnerships, manufacturers, private pharmacies, transport companies), the product range is broad, RHCs are not sufficiently integrated in the overall national public health supply chains and in the Ministry of Health (MOH) budgets, and in many countries reproductive health remains to a great extent a social and culturally sensitive matter, particularly contraception for young girls and abortion. Demand for some RHCs is difficult to quantify due to hidden needs and unreliable consumption data.

At global level, the unmet need for family planning (women aged 15-49 married or in union) was estimated at 12%, with variances between the different regions (10% in the more developed regions and 21% in the least developed ones).⁵ The proportion of demand satisfied with modern methods, among women aged 15-49 was estimated at 78% with variances between 79 and 59% in more developed and least developed regions respectively. Furthermore, substantial changes in strategy, set-up, and funding arrangements are expected to take place for several of the main stakeholders including FP2020, USAID and UNFPA Supplies.⁶ We therefore first provide a quick overview of the current global RHCs landscape before addressing the study questions in the next sections.

Towards the end of the 2010s, many key stakeholders in sexual and reproductive health (SRH) summarised results achieved and challenges ahead to achieve the Sustainable Development Goals (SDG) by 2030. The inclusion of SRH including RHCs in Universal Health Coverage (UHC) strategies is high on the agenda and provides important opportunities to realise fulfilment of sexual and reproductive health and rights (SRHR) and to ensure more equitable access to RHCs.⁷

Although considerable disparities remain between countries as well as between different populations within countries, the use of contraceptives globally increased considerably over the years (from 36% in 1970 to 64% in 2015 for married or in-union women).⁸ Donors played an important role through financial support and a range of interventions at national as well as at global level (e.g., support the development of systems for logistics data, coordination and alignment of purchases, price negotiations with manufactures, and bridging finance schemes).⁹

The overall demand for RHCs is expected to grow considerably in the coming decade; not only because of the current demographic developments (increasing number of people in reproductive age), but also because of the expected greater use by the population.^{10,11} The RHSC Commodity Gap Analysis of 2019 estimates that there will be up to 569 million family planning users in 2030 as compared to 487 million users in 2020, a growth of 17%.

At the same time, a considerable gap between funding needs and funding provided by donors and governments already exists today, and this is expected to increase.¹² The 2019 Commodity Gap Analysis

⁵ UNFPA State of World Population 2019. Unfinished business- the pursuit of rights and choices for all. 2019

⁶ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

⁷ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

⁸ UNFPA State of World Population 2019. Unfinished business- the pursuit of rights and choices for all. 2019

⁹ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹⁰ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹¹ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹² Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

estimates a funding gap of USD 178 million in 2020, increasing to a cumulative gap over five years (2021-2025) of up to USD 1.17 billion, unless changes occur in donor funding (values) and/or demographic developments.

In the RHC community different perspectives regarding the development of donor funding in the years ahead exist, but the overall understanding is that funding for procurement of RHCs is decreasing and that this trend will continue, or at best plateau¹³. Overall, the United States (US) remains the biggest donor for family planning commodities, but the reinstatement and expansion of the Mexico City Policy (or 'Global Gag Rule') put global funding for SRHR interventions under pressure (e.g., contraception, safe abortion). US funding to UNFPA also decreased.¹⁴ Several European countries continue or increase their substantial support to SRHR including to RHCs (e.g., UK, the Netherlands, Germany), although overall support from European countries for SRHR and family planning decreased considerably between 2014 and 2016 (from EUR 1.229bn to EUR 1.035bn).¹⁵ Declining donor funding is likely to increase users' Out of Pocket (OOP) expenditure, unless domestic funding increases considerably in the future. Currently nearly all OOP spending goes to non-subsidised products in the private sector (98%). Two percent is spent on subsidised products.¹⁶ Currently, in low- and middle-income countries (LMIC), financing for RHCs comes from end-users (82%), donors (10%) and national governments (8%), yet with considerable variances between the low-income countries (LIC), lower and upper middle-income countries (L-MIC and U-MIC).¹⁷

Recent literature classifies RHCs as follows:

- **Maternal health commodities** - This product category is the least controversial product category of RHCs as compared to the FP and abortion commodities. Needs are likely to increase in response to demographic growth and an increasing number of assisted deliveries across the globe, and expansion of the current range of supplies seems necessary to be able to respond to the increasing needs.

Examples of products in this category: oxytocin, magnesium sulphate, misoprostol

- **Family planning commodities** – This category can be divided in short-term methods (STM), and Long Acting and Permanent Methods (LAPM).¹⁸ The latter is primarily provided through the public sector as it involves medical services, and has an overall lower annual cost (couple year of protection – CYP) than the short-term methods. The private sector focuses primarily on the provision of STMs.¹⁹ This general division by type of product and sector is particularly clear in countries with economies in transition (e.g. Nigeria). The demand for family planning commodities is expected to increase considerably in the coming years, mainly caused by an increasing number of people in reproductive age.

Examples of products in this category: combined oral contraceptive pill, progesterone-only pill, implant, injectables, Intra-Uterine Device (IUD), male and female condoms.

- **Safe abortion commodities** – The legal status of abortion is an important factor for the market. This category has never been a priority of donor support to SRH. Limited data on the market for safe abortion commodities are available, and misoprostol (one of the medicines used for medical abortion)

¹³ RHSC. Commodity Gap Analysis 2019

¹⁴ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹⁵ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹⁶ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁷ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹⁸ LAPM methods include the intrauterine device (IUD) and the progestogen implant (Jadelle®, Implanon®, etc), as well as female and male sterilization. The IUD and progestogen implant are reversible and are also called long-acting reversible contraception (LARC). These are methods recommended for couples intending to space pregnancies. On the other hand, sterilization is a permanent method for couples who have completed childbearing and do not wish to have more children. LAPM is used broadly to refer to all methods.

¹⁹ RHSC. Commodity Gap Analysis 2019

can be used for several other conditions as well.²⁰ The demand for safe abortion supplies is expected to increase as more countries legalize abortion, and the use of safe methods is therefore likely to increase.²¹

Examples of products in this category: misoprostol, mifepristone, manual vacuum aspiration (MVA) set.

- **Supplies for menstrual health and hygiene** – The market for menstrual health and hygiene supplies is large, and with rising income levels globally, this market is expected to grow fast in all regions. In many countries, regulation for this product category is being developed. In the global supplies community, discussions are ongoing whether or not this product category should be added to the category of RHCs. In line with the TOR, the present study does not cover menstrual health supplies.

Examples of products in this category: menstrual cup, sanitary pads.

The main new topics and areas of interest emerging in the RHC landscape include menstrual health or menstrual hygiene supplies (described above), and adolescents younger than 15 years old (a population group about which relatively little is known in terms of needs, attitudes, and use). RHCs in humanitarian and fragile settings remains on the agenda; in these settings, the right to SRH services, particularly for adolescents, is often compromised.²²

Other RHC topics that remain high on the global agenda are reproductive health services for adolescents (aged 15-19 years) and private sector involvement. Adolescents are considered a priority group in SRHR because of their vulnerability, special needs, and limited use of regular public health services.²³ Private sector involvement in all its forms remains an important and much debated topic. Results of collaboration with the private sector in procurement and supply chain management are being published, and involvement of the private sector in program planning and implementation has been noticed in some countries.²⁴ Another theme being discussed for a few years already is product development e.g., new products, existing products in other forms (e.g. Sayana Press self-injection), and related quality issues.

2.2 PRODUCT SPECIFIC INFORMATION

The RHCs landscape comprises several commodities, including medicines, medical devices and consumables; some of those deserve special attention in this report because of their relation to innovation, their contribution to the method mix, or their prevalence of use in LMICs.

Examples of such commodities are the dapivirine vaginal ring, that allows women to take control of HIV prevention in a discrete way; the subcutaneous medroxyprogesterone acetate, suitable for self-injection or injection by less skilled staff and providing 3 months of contraceptive protection; heat-stable carbetocin, an uterotonic effective in the prevention and treatment of post-partum haemorrhage that does not require cold chain like the currently used oxytocin; or a combination pack of misoprostol and mifepristone for medical abortion. Detailed information on what is currently known about these and other relevant RHCs can be found in Annex 5 (Volume II).

2.3 RECENT TRENDS AND DEVELOPMENTS IN RELATION TO RHC AVAILABILITY

Note: Information that is not supported by a reference to the literature has been sourced through KIIs.

²⁰ RHSC. Commodity Gap Analysis 2019

²¹ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

²² Castle S. Intersections between Youth and Reproductive Health Supplies A Report to the Reproductive Health Supplies Coalition. May 2016

²³ PATH. Advances in reproductive health. September 2016

²⁴ UNFPA State of World Population 2019. Unfinished business- the pursuit of rights and choices for all. 2019

2.3.1 STUDY QUESTION 1 – RECENT TRENDS AND DEVELOPMENTS

Study question 1:

What can be learned about the availability of RHCs (at global, national and peripheral level) from the recent strategic review processes that have been undertaken at global level by important stakeholders like UNFPA, FP2020, USAID, the RHSC and others?

Information available in the public domain on recent strategic review processes of key stakeholders (e.g., USAID, FP2020, UNFPA Supplies) is limited. We first summarise highlights from strategic documents and KIIs. To complement, we then describe other relevant information on availability of RHCs obtained through both literature review and KIIs.

Summary from strategic documents (available in the public domain) and interviews with representatives from key stakeholders

- *Reproductive Health Supplies Coalition (RHSC)*

The report *Creating an effective & sustainable ecosystem for reproductive health supplies by 2030* developed by the RHSC established ‘an ecosystem aim for 2030’ that is described as follows: ‘*Our aim during the next decade is to develop a sustainable, inclusive and equitable reproductive supplies ecosystem which contributes to achievement of the Sustainable Development Goals (SDG) in low- and middle-income countries*’. Strategic focus areas are: ensure broad participation and cooperation among all actors involved in the RHC space – from different sectors, support to a healthy market, ensure equity, improve efficiency, focus on quality of supplies. Ten key recommendations are formulated for the next decade, and cover forging broad partnerships, promotion of equity, reduction of vulnerabilities of the public sector supplies market, inclusion of RHCs in the Universal Health Coverage (UHC) strategies, and strengthened quality assurance mechanisms.²⁵ As several key stakeholders in the RHC space are currently in the process of re-strategizing and re-thinking their plans (e.g., FP2020, UNFPA Supplies, the Bill & Melinda Gates Foundation - BMGF), it is not unlikely the landscape will (again) undergo considerable changes in the near future.

The RHSC 2019 Commodity Gap Analysis Report notes a stagnation in donor funding in the coming decade, and estimated the cumulative 5 year funding gap to reach USD 1.17 billion in 2025, expecting that the amount spent on family planning supplies remains the same, and the number of users grows.²⁶ According to the report the private sector already plays an important role in providing family planning supplies but will not be able to close this gap; the private sector serves a different market than the public sector (e.g., STM versus LARMS, different user groups), and the two are not fully interchangeable. Subsidies in the private sectors will continue to play a considerable role through different models (market driven and supported by the public sector). In LMIC however, only 12% of private sector users receive subsidised products. Some of these products are distributed through social marketing channels as well as through commercial channels. Similarly, many social marketing programs distribute non-subsidised products. A considerable growth of contraceptive users is expected in the coming decade, but the growth varies between countries. Therefore, support and funding needed to sustain these growth patterns vary per country as well.²⁷

The RHSC is involved in initial discussions and elaboration of options to create a (virtual) procurement platform, possibly through a joint platform with the Global Family Planning Visibility and Analytics Network (Global FP VAN) (more details are provided in Annex 7, Volume II). Furthermore, the establishment of a so called ‘market manager’ is an emerging topic within the RHSC and several key stakeholders including BMGF and the UK’s Department for International Development (DFID). There are several challenges and

²⁵ Braddock M., Skibiak J. *Creating an effective & sustainable ecosystem for reproductive health supplies by 2030*. October 2019

²⁶ The CGA provides the likely consequence of continued trends, both in terms of funding or demand.

²⁷ RHSC. *Commodity Gap Analysis 2019*.

weaknesses in this market, and stakeholders search for means to better understand this market in order to be able to take measures that can support strengthening it, and to timely foresee important and/or urgent problems (e.g., decreased production capacity, quality issues related to the Active Pharmaceutical Ingredient (API)). There seems indeed a need to identify and address existing challenges in the RHC market, but to manage a market is a complex intervention, and the RHSC fears that related efforts are seriously underestimated. An independent entity (Dalberg) has been contracted to provide first options for a market manager configuration.²⁸

- *Family Planning 2020 (FP2020)*

FP2020, a global partnership, was established after the 2012 London Summit on Family Planning with the goal to enable 120 million more women and girls to use contraceptives by 2020. The focus is on 69 countries across the globe. The partnership collaborates with governments, multilateral organisations, donors, private sector, research institutions, and civil society organisations.

Throughout 2019, FP2020 and the Core Conveners (USAID, UNFPA, BMGF, DFID) engaged the global family planning community to create a shared vision for the next decade. Through a global consultation, stakeholders from across the globe have provided their input on the future of family planning that will inform the next family planning movement. The FP2020 Reference Group discussed key strategic choices to be made by the partnership, including the current nomenclature (family planning), scope (maintaining a family planning vision, or rather including family planning in broader SRHR strategies), goal settings (quantitative and qualitative), focus and prioritisation (reach everyone and everywhere, or focus on specific geographic or other areas), financing (in line with the longstanding debate on vertical versus horizontal approaches), and the role of the partnership.²⁹

The vision framework was finalised in the first quarter of 2020 with the vision statement articulating a partnership *‘working together for a future where all women and girls everywhere have the freedom and ability to make their own informed decisions about using modern contraception and whether or when to have children, lead healthy lives, and participate as equals in society and its development’*. The vision framework includes the following focus areas: expansion of the narrative and shaping of the policy agenda, increased use of data and evidence for informed decision making, diversification and efficient use of financing, and transformation of social and gender norms. Guiding principles are defined to form the basis for the next movements’ activities. These principles are: voluntary, person-centred, rights-based approaches; empowering women and girls and engaging men, boys and communities; engaging and counting on adolescents, youth and marginalised populations to meet their needs; country-led global partnerships, with shared learning; and mutual accountability for commitments and results.

An architecture to support this common vision, including a transition roadmap and partnership approach, is being developed. The launch of the next family planning movement will be in 2021 including a new name for the movement, with transition activities to happen between 2020 and 2022.^{30,31}

- *UNFPA*³²

Three overall results are formulated by UNFPA: eliminate unmet need for family planning, eliminate preventable maternal deaths, and eliminate gender-based violence (GBV). For RHCs, the UNFPA strategy 2018-2021 foresees interventions related to capacity strengthening to effectively forecast, procure,

²⁸ <https://dalberg.com/what-we-do/dalberg-advisors/>

²⁹ FP2020 Reference Group Meeting - Report. April 2019, FP2020 Reference Group Meeting – Young People’s Perspective Post 2020 (presentation). April 2019, FP2020 Reference Group Meeting – The Global Early Adolescent Study (presentation). April 2019

³⁰ Family Planning Post 2020 Vision Framework. September 2019

³¹ <http://www.familyplanning2020.org/Beyond2020>

³² We did not conduct an interview with UNFPA.

distribute and track the delivery of sexual and reproductive health commodities ensuring resilient supply chains. The strategy emphasises that for the provision of (integrated) SRHR services, the health systems strengthening approach is recommended. It is assumed, this also applies for the supply systems although this is not specified in the strategy.

The strategic interventions listed above are covered under outcome 1 of the strategy which aims for all women, adolescents and youth anywhere on the globe to have used integrated sexual and reproductive health services and have exercised reproductive health rights, free of coercion, discrimination and violence.³³

- *UNFPA Supplies thematic programme*

The UNFPA Supplies thematic program provides RHCs to 46 countries and supports these countries with the strengthening of their national supply chains to improve access to a broad range of contraceptives. They also support reproductive health services in humanitarian settings. In collaboration with the BMGF and DFID, the so-called Bridge Funding Mechanism was set up with as main objectives to improve value for money, improve distribution to avoid stock outs, and facilitate price negotiations. In 2018 the Bridge Funding Mechanism has been instrumental to meet urgent commodity needs and close supply gaps in almost 50 countries.³⁴

UNFPA Supplies' key achievements reported for the year 2018 included: 1) better forecasting systems that led to more accurate procurement and related cost savings, as well as to an improved response to user needs, 2) the launch of the Commodity Requirement Tool (CRT) that provides an overview of consumption trends and inventory levels, 3) the roll out of the maturity model, and 4) last mile audits that provide information on the management of commodities along the supply chain (see also section 2.5.1.2 – study question 3b, and Annexes 6 and 7, Volume II).³⁵

UNFPA Supplies will start to support governments in the development of policies that enable them to gradually take over funding for procurement and management of RHC. It also reports an increased focus on supply chain strengthening to ensure that the commodities procured reach the beneficiaries, whereby the challenge is to create strong and sustainable national supply chains that have the capacity to handle all medicines and health commodities from any source or fund.

The Mid-Term Evaluation conducted in 2018 reported the following key findings: the program contributed to higher rates of contraceptive use, improved efficiency of procurement and supply management of RHC, and the set-up of government-led coordination platforms; it showed leadership in diversifying market approaches at global level, but less so at country level; the program has achieved a strong leader position as procuring entity for family planning supplies with the capacity to use its procurement power and influence global markets; and the program provided support to the supply of RHCs in humanitarian crises. The evaluation recommends that the Commodity Security Branch and country offices develop adequate processes to estimate needs and assess funding gaps.³⁶

A transformation of the UNFPA Supplies program is taking place, supported by its main donors. It involves three components:

1. *Country engagement* - Country engagement involves services provided by the UNFPA Supplies program in country. A model is being developed that includes information on how these services will be funded and measured, and how support provided by UNFPA Supplies can be transitioned in a sustainable manner. The country support operation model will include a Commodity and

³³ UNFPA. Strategic Plan 2018-2021

³⁴ More information about the Bridge Funding Mechanism can be found in Annex 6. (key interventions)

³⁵ UNFPA Supplies. Annual report 2018

³⁶ UNFPA Evaluation Office. Mid-Term Evaluation of the UNFPA Supplies Programme (2013-2020). 2018

Supplies Management Fund and a High Impact Transformative Action Fund, and overarching elements such as ‘Programme Countries and Sustainable Transition Guidance’ and a ‘Measurement and Performance Framework’.

2. *Governance* – Governance involves the new model that will be set up to support UNFPA Supplies with the implementation of the new program and to ensure the necessary changes are made for UNFPA to act as the global partner for RHC commodity security related topics. The proposed governance structure includes three thematic committees (strategy and planning, finance and risk, and personnel) and an overarching Steering Committee. The Steering Committee will involve members from donor agencies, civil society, implementing countries and UNFPA Supplies, and will be directed by an independent chair.
3. *Strategy for 2020–2030* – The strategy is still under development. It will integrate elements from components 1 and 2.

During the remainder of 2020 the proposed model and operational plan will be finalised and approved. First pilots are foreseen to start towards the end of 2020, and roll-out in 2021.³⁷³⁸³⁹

- *Bill and Melinda Gates Foundation (BMGF)*

The BMGF is a relatively new player in the family planning space. Its support to family planning programmes started in 2009 and by 2015 financial support reached over USD 200 million on an annual basis. In the initial years of program support, considerable amounts were invested in strengthening UNFPA Supplies, aiming at increasing availability of quality commodities. The longer-term goal is to achieve universal access to voluntary family planning. The current restructuring and re-strategizing of UNFPA Supplies is considered a key intervention to realise this goal.

The Foundation, in collaboration with its partners, supports governments that committed to the FP2020 goals to develop and implement their country plans. This support includes needs assessments, identification of funding gaps, testing of interventions, performance monitoring, and data collection and coordination platforms. Other topics the BMGF works on include policy improvement for family planning, and establishment of public-private partnerships in order to increase access to and options for new contraceptives and research. The proposed budget for new contraceptive technology and innovation in contraceptives foresees an increase to up to USD 60 million annually. Other long-term investments (e.g. for development and distribution of new technologies) focus on addressing the contraceptive needs beyond 2020 through improved acceptance and continued use among priority user groups.⁴⁰

BMGF also funds technical support to manufacturers to obtain the necessary WHO prequalification, and to ensure their market entry strategy is adequate. The Matching Fund, under the Ouagadougou Partnership, is also funded by the BMGF. Through this fund, the BMGF allocates two US Dollars for every additional US Dollar invested in family planning by each of the nine Ouagadougou Partnership countries’ governments.⁴¹

At the end of April 2020, Bill Gates announced his Foundation will fully focus on COVID-19 preparedness and response and that this might put other public health interventions of the Foundation at risk. Further details were not known at the time this report was finalised (June 2020).

³⁷ UNFPA Supplies Steering Committee. Strengthening the Governance and Decision-making of UNFPA Supplies. 17 October 2019

³⁸ UNFPA Supplies. Transition Oversight Group Meeting – 4

³⁹ UNFPA Supplies. UNFPA Supplies Country Support Operating Model and Operational Plan – Draft for review. January 2020

⁴⁰ <https://www.gatesfoundation.org/what-we-do/global-development/family-planning> and <https://www.gatesinstitute.org/our-work> (limited information found in the public domain)

⁴¹ Benin, Burkina Faso, Côte d'Ivoire, Guinea, Mali, Mauritania, Niger, Senegal, and Togo

- *USAID*⁴²

USAID's Office of Population and Reproductive Health supports family planning and reproductive health programs in the countries supported by USAID, focusing on access to voluntary family planning (supplies, services and information). Overall USAID's programmes contribute to the FP2020 goal of reaching an additional 120 million women by 2020. Legislative and policy restrictions are ruling family planning and reproductive health programmes funded by the US.⁴³ USAID has strict legislative and policy restriction on support for abortions.

USAID reports it achieved, in collaboration with other donors and manufactures, price reductions of up to 50% for injectables and implants. USAID is the largest bilateral donor in family planning with an overall budget of USD 607.5 million for financial year (FY) 2019, of which an estimated USD 50 million were spent on contraceptives in 2018.⁴⁴

The commodity component of USAID is managed by the Global Health Supply Chain Program (GHSC) (Chemonics). GHSC works in 15 priority countries and focuses on leveraging global procurement and logistics to improve availability of health commodities, technical leadership to strengthen global demand and financing, and foster stronger markets.

SHOPS Plus is a USAID supported project that focuses on provision of health services through public-private partnerships. The Central Contraceptive Procurement (CCP) project was developed to set up a stable and strong system for the supply of contraceptives for family planning programs (see Annex 7, Volume II for more information on this project).⁴⁵

- *DFID*

The Women's Integrated Sexual Health (WISH) program is the DFID flagship SRHR program that is currently being implemented in 27 countries by two consortia, led by Marie Stopes International (MSI) and International Planned Parenthood Federation (IPPF). The program is delivering lifesaving integrated sexual and reproductive health services, enabling women and girls, including young, poor and marginalised women, to program plan their pregnancies and have choice on whether, when and how often to have children. The program includes work with communities to increase awareness and accessibility of family planning, and work with national Governments to bolster longer-term capacity to provide services and foster a supportive policy environment for SRHR.

The Reproductive Health Supplies program (2020-2025) is a new program funded by DFID with a budget of GBP 600 million. It aims to provide access to family planning supplies to more than 20 million women and girls per year in the world's poorest countries, including in humanitarian settings and for hard to reach populations. Safe abortion supplies will be provided in countries that legalised abortion. In collaboration with partners from different sectors, the program focuses on improving the availability of family planning commodities by expanding the methods mix, rolling out new RHCs, reducing prices, and supporting the increase of domestic funding in order for governments to build capacity to procure and distribute RHCs without external donor support. Additionally, the program includes a contribution to UNFPA Supplies, particularly for the restructuring of this program.^{46,47}

⁴² The study team has not been able to obtain an interview with a USAID representative

⁴³ <https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-and-international-family-planning-reproductive-health-efforts/>

⁴⁴ Clinton Health Access Initiative, Reproductive Health Supplies Coalition. Family planning market report. December 2019

⁴⁵ <https://www.usaid.gov/global-health/health-areas/family-planning/partnerships-projects>

⁴⁶ <https://dfidnews.blog.gov.uk/2019/09/25/uk-aid-stands-strong-on-womens-rights/> and <https://www.devex.com/news/uk-announces-600m-for-srhr-amid-us-opposition-95684>

⁴⁷ DFID. RH Supplies Business Case, Summary Sheet. November 2019

DFID reproductive health program business case emphasises as rationale for its continuous support to RHCs: 1) current limited availability of these commodities remains an obstacle to achieve universal SRHR; 2) donors have a comparative advantage in the funding of RHCs; and 3) donor funding delivers Value for Money as it pools funding and demand, and procurement is conducted through global mechanisms that benefit from economies of scales and secured affordable prices.

DFID supports the establishment of a market manager (see also the section on the RHSC above). DFID acknowledges the efforts required for the design of the market manager's configuration and its implementation, but is convinced the existing support and motivation from several key actors in the RHC landscape will lead to positive results in the long term, and ultimately to less need for active engagement from DFID in the RHC arena.⁴⁸

- *Global Financing Facility (GFF)*

GFF was established in 2015 to close the financing gap for reproductive, maternal, newborn, child and adolescent health and nutrition (RMNCAH-N). The GFF secretariat is based at the World Bank (WB). GFF leverages domestic government resources, WB financing as well as other external funding, and resources from the private sector.⁴⁹⁵⁰

GFF focuses on efficient resource utilisation (rather than on resource mobilisation as the fiscal space in most countries supported by GFF is limited), and on opportunities for prioritisation. The process of prioritisation is supposed to be a consultative process which includes the full range of actors in a country (e.g., actors from the public sector, private sector, multi- and bilateral donors, civil society). The result of the consultative process is an investment case in which priorities are articulated, and which is in line with the available budget. Current policies and strategic documents, if compliant with the GFF requirements, can also serve as a country's investment case.

The investment cases include the cost of commodities required to deliver the prioritised services. For commodity procurement, supported countries must adhere to the WB procurement guidelines. Procurement is commonly conducted by the countries and includes certain control mechanisms from GFF/WB, for example the requirement to obtain a 'no objection' for key steps in the procurement process.

Private sector involvement is an important pillar of GFF because of the amount of financing flowing through this sector and the role of this sector in service delivery. GFF has a limited role in supporting development of innovation in service delivery or related areas. Instead, it facilitates scaling up of (innovative) interventions that prove to be efficient and provide value for money.

- *The Clinton Health Access Initiative (CHAI)*

CHAI's main work on RHCs aims to develop healthy and accessible markets for RHCs in LMICs. Important topics include product introduction, product commercialisation and to market strategies, and ensuring sufficient supply to satisfy current and future demand. Other activities involve collaboration with manufacturers to increase access to affordable quality commodities, technical support to governments to strengthen existing (national) supply systems and/or other actors involved in RHC supply related issues, and to improve their overall management and finance systems. Country programmes also include support to service provision; CHAI developed an integrated strategy for maternal, newborn, and reproductive health that accompanies women through their reproductive lives. CHAI currently operates in 36 countries and is actively engaged in reproductive health in 18 of those.

⁴⁸ DFID. RH Supplies Business Case, Summary Sheet. November 2019

⁴⁹ Global Financing Facility, Technical briefing for FP2020, - Financing for Family planning (presentation). Date unknown

⁵⁰ Global Financing Facility, Adolescent sexual and reproductive health and rights: the GFF's support to accelerate action. May 2019

CHAI is an important actor for increasing access to health commodities for LMICs and has supported the negotiation of over 120 agreements that have significantly lowered the price and increased availability of health commodities such as best-in-class HIV regimens and contraceptive implants.

For the past 5 years CHAI has been publishing the annual Family Planning Market Reports where it aggregates supplier shipment data for greater visibility. The 2019 Family Planning Market Report covers the FP2020 public sector market (volumes purchased by institutional buyers (USAID, UNFPA, Social Marketing Organisations, etc.) and MOHs), or government-affiliated procurers for the 69 FP2020 focus countries. It showed an overall decrease from 2014, but an increase in market volume, value, and CYPs shipped from 2017 to 2018 from a historic low in 2017. These market trends coincide with a fluctuating annual value of contraceptives procured and distributed by USAID over the years, with a considerable increase from 2017 to 2018 reaching USD 50 million in 2018. Also for UNFPA the values of contraceptives procured have fluctuated in recent years: in 2018, USD 11 million more were spent on commodity procurement as compared to 2017.⁵¹ Similar to other information retrieved in the public domain the report states that longer-term donor funding is uncertain.⁵²

CHAI is member of the Coordinating Supply Planning Group, one of two workstreams of the RHSC System Strengthening Working Group. This workstream supports the coordination of shipments and the allocation of resources within and among countries, as well as the development of global forecasts and funding gap analyses.

- *West African Health Organisation (WAHO)*

The WAHO is a regional agency with the responsibility of safeguarding the health of the peoples in the Economic Community of West African States (ECOWAS) through the initiation and harmonisation of the policies of Member States; pooling of resources; and fostering cooperation between Member States and with others for collectively and strategically addressing the health problems of region. An important initiative managed by WAHO related to RHCs is the Regional Financing Mechanism (RFM) for family planning supplies. The main objectives of this mechanism, funded by KfW Development Bank, the French Development Agency (AFD), BMGF and the Netherlands, are to contribute to reducing maternal and child mortality, to contribute to behaviour changes with regards to SRH among youth, and to cover commodities gaps. Since 2011, over USD 22.5 million was spent in 7 countries (Benin, Burkina Faso, Ghana, Guinea Bissau, Niger, Sierra Leone, and Mali).

Support (both financial and technical) is based on proposals submitted by the countries, for which strict requirements were established (e.g., governments have to collaborate with NGOs, proposal has to be based on Costed Implementation Plan (CIP) for family planning).⁵³ Procurement is conducted by the national procurement agencies, based on guidance from WAHO. For the technical assistance component, WAHO collaborates with the Swiss Tropical and Public Health Institute. The RFM includes an exchange of stocks between countries in the region that helps to avoid expiries and stockouts of family planning supplies. None of the interviewees did refer to this initiative.

Additional findings on availability of RHCs

Issues raised with regard to RHCs availability are related to product categories and populations. The UNFPA Supplies 2018 report notes that in their program countries the gap in access to contraceptives between rural and urban areas is narrowing, but that the method choice in rural areas remains limited, and more limited than in urban areas. While the report does not mention specific reasons for this narrowing gap, it is likely

⁵¹ UNFPA Supplies. Annual report 2018

⁵² Clinton Health Access Initiative, Reproductive Health Supplies Coalition. Family planning market report. December 2019

⁵³ A Costed Implementation Plan (CIP) is a multi-year actionable roadmap designed to help governments achieve their family planning goals—goals that when achieved will save millions of lives and improve the health and wellbeing of women, families and communities

partly the result of an improved availability of RHCs in rural areas. Through better access to services and supplies in rural areas, access increased for population groups that were (more) deprived of using contraception in the past.⁵⁴

Availability of family planning supplies, often reported as the number of different methods available, varies considerably by sector.⁵⁵ Despite differences between countries, overall the public sector (through public health facilities) mainly provides LARC (often free of charge) while the private sector predominantly offers, at a cost, STM to the population.^{56,57} LARC are methods that provide contraception for a longer period of time and do not require specific action from the user during that period. Examples include injections, IUDs and subdermal contraceptive implants. STM provide contraception for a short period only and effectiveness depends on their correct use by the end-user. Examples include the different types of pills, (male and female) condoms, and vaginal ring.

This different availability of methods in the different sectors implies equity issues because users without access to public health services are obliged to use private services for which they have to pay, and where choices are generally limited (e.g. mainly STM). In some countries, subsidised family planning supplies, mainly STMs, are provided through interventions supported by (international) NGOs through a diverse network of providers. Per CYP, STM are more expensive than LARC.⁵⁸, which may have a potential impact on the users choice and may cause pressure from donors on NGOs (and country governments) that are expected to deliver results measured in CYP.^{59,60} UNFPA Supplies comments that in 2018 some of the countries they support offered a wider variety of methods than in previous years, and that fewer countries offered only one main method.⁶¹

Availability of RHCs is under pressure. The Countdown 2030 Europe report on contraceptive supplies financing confirms donors made important efforts to increase RHCs availability with the existing (decreasing) budgets by making procurement processes more efficient, negotiating prices with manufacturers, and improving information flows.⁶² The report however also warns that these interventions may have a negative impact and do not solve one of the key issues related to decreasing funding at country level, namely the increasing share of OOP spending and related inequities: interventions in RHC markets may distort the market and eliminate competition, and funding mechanisms using loan funds (e.g. GFF) to procure RHCs may increase countries debts.

Literature mentions quality standards as an influencing factor on RHC availability. Several manufacturers are reluctant to apply for prequalification by the World Health Organisation (WHO) and/or approval by a Stringent Regulatory Authority (SRA) because of the complexity of the process and the high costs involved. This causes a challenge for commodity availability; countries and procurement agencies who apply the WHO prequalification and/or SRA requirement for their procurement processes may have limited procurement choices, pay high prices, and face long delivery times, with potential risks for stock outs or interrupted supplies in-country. At the same time however, manufacturers of non-WHO prequalified products are likely

⁵⁴ UNFPA Supplies. Annual report 2018

⁵⁵ A more appropriate term is “method mix”, but in the literature it is sometimes referred to as “availability”.

⁵⁶ The public sector consists of government- financed health facilities (hospitals, health centres, health posts); the private sector comprises a range of outlets, including hospitals, clinics, pharmacies and shops. There is a third sector, social marketing, which involves distribution of subsidised supplies through private sector entities, or socially marketed products sold through pharmacies (source: Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019)

⁵⁷ RHSC. Commodity Gap Analysis 2019

⁵⁸ CYPs is a measure that estimates the protection from pregnancy provided by contraceptive methods during a one-year period (per couple).

⁵⁹ <https://decorrespondent.nl/11005/op-pad-met-de-racende-dokters-die-een-heel-land-van-anticonceptie-willen-voorzien/5217144983105-002097a1>

⁶⁰ <https://decorrespondent.nl/11010/wat-er-gebeurt-als-bill-en-melinda-gates-zich-niet-op-software-maar-spiraaltjes-storten/5219515335210-cd01ecf9>

⁶¹ UNFPA Supplies. Annual report 2018

⁶² Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

to continue supplying countries with less stringent regulation, at costs lower than those charged for the prequalified commodities. With decreasing donor funding, it is likely that procurement of non-prequalified commodities will increase with an implied risk of substandard quality commodities being distributed in countries with weak quality assurance systems. The Ecosystem 2030 report highlighted the need for a quality control framework feasible for manufactures to comply with.

Because of unstable and/or late donor fund disbursement for procurement, UNFPA Supplies, the largest procuring entity for family planning supplies, faced considerable challenges to ensure a non-interrupted supply chain as per the countries' needs. Rules and regulations of the UN oblige UNFPA Supplies to procure supplies only when the funds are available (in hand). To bridge the gap between actual disbursement and cash needed to timely procure supplies, the Bridge Funding Mechanism (BFM) was set up.⁶³ Through this mechanism more efficient procurement processes are possible, allowing for multiple year commitments, and leading to less delays, reduced delivery times, and lower supplier prices.⁶⁴

In many countries the procurement and supply chains for health commodities in general and for RHCs in particular were heavily supported by donors (both technically and financially). Vertical and/or parallel systems, motivated or not by donors, were set up with varying national level leadership and governance. Because of decreasing donor investments, countries are forced to take more leadership in managing the supply chain. Integration of vertical and/or parallel systems in the national health products supply chain belongs to the options that are explored in several countries⁶⁵ and is in line with the fundamental principles of the Paris Declaration on Aid Effectiveness, which promotes the use of existing national systems.⁶⁶

Donor funding has long focused on the public sector, but recently tends to shift to support the private sector; evidence suggests that the public sector alone is not capable to adequately respond to the demand. This is not only due to the increasing number of users. Also, the different preferences for certain methods or brands, product availability and other factors determine the decision of users to use the services of either the public or private sector.

With the involvement of the private sector, challenges to adequately estimate the needs for RHCs and the related resources required to procure and supply them increase; in most countries the private sector is not connected to existing logistics data management systems, and crucial data for forecasting and quantification from the private sector are therefore largely unavailable. Adequate involvement of the private sector in the health system is therefore required.^{67,68}

New tools and models

Many documents reviewed refer to tools and models developed to provide insights in RHCs stock availability, to estimate existing and future needs, and to collect, consolidate and share available data from different sources on procurement and supply chain related issues that influence availability of RHCs (e.g., CRT, Global FP VAN, Coordinated Supply Planning Group).⁶⁹ An overview with the main tools is provided in Annex 7.

⁶³ FP2020. Women at the centre – A call to action from FP 2020's 2018-2019 annual progress report.

⁶⁴ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A guide for advocates. June 2018

⁶⁵ HIP/Family Planning High Impact Practices. Supply Chain Management: Investing in contraceptive security and strengthening health systems. November 2012

⁶⁶ The Paris declaration on aid effectiveness and the Accra agenda for action. Organisation for Economic Co-operation and Development; 2008.

⁶⁷ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

⁶⁸ USAID/SHOPS Plus. Stewarding the Private Sector for Family Planning. January 2019

⁶⁹ UNFPA Supplies. Annual report 2018; Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019; and FP2020. Women at the centre – A call to action from FP 2020's 2018-2019 annual progress report

2.3.2 SUMMARY STUDY QUESTION 1

In the lead up to the post (FP)2020 era, several of the main stakeholders have strategized or are in the process of reviewing their current strategies. Main changes observed in the RHC landscape include:

- The demand for RHCs is likely to increase considerably due to growing population overall and higher expressed needs
- Overall improving method mix, but the benefit of the noticed shift noticed from predominantly short-acting methods to long-acting reversible contraceptives is being debated, including in relation to the freedom of choice of the users
- Expected decreasing trend in external funding of RHCs which will lead to considerable changes in procurement arrangements with more countries procuring RHCs with domestic funding using national procurement guidelines and quality standards
- Increased requests from countries for technical assistance expected to support the strengthening of their national health systems (including national supply systems); with decreasing donor support, RHCs will likely be integrated in the national supply chains
- A greater realisation that the private sector must (and will) play a more important role for RHC availability. Sufficient capacity for adequate regulation of the private sector will be required to ensure maximum benefit (e.g., quality of services and products)
- Investigation, by a group of key stakeholders, of a configuration for a so-called global market manager; an entity that would have full and up to date information of RHC markets, and that could take timely action in case of anticipated changes or problems

2.4 THE ROLE OF THE NETHERLANDS

2.4.1 STUDY QUESTION 2 - ROLE OF THE NETHERLANDS IN RHCS

Study question 2 – overarching question:

What is the view of international stakeholders (including main global health actors, private sector in program countries, government counterparts in program countries, manufacturers and technical experts in the field of RHCs) on the specific role of the Netherlands in ensuring availability of RHCs?

To answer this question, the study team only drew from information gathered through KII. Published, grey and peer reviewed literature are not an adequate source of information for this type of questions.

Overall, key informants interviewed consider the Netherlands as a committed partner in the area of SRHR in general and RHCs specifically. Informants were generally positive about the role of the Netherlands in ensuring availability of RHCs, and in the RHC landscape in general; the support is found to be steady, thoughtful and consistent. The Netherlands are independent and flexible, and ensure some 'biodiversity' in the commodities spaces by supporting interventions that are not supported by other donors; they do not have a 'favourite' country or a political agenda in LMIC, which is considered a comparative advantage. Several informants mentioned the importance of the support from the Netherlands, including its critical voice.

Furthermore, 'integrated support' (e.g., support complementary to other projects and/or partners) was considered positive. An example mentioned is the support to demand generation for RHCs in addition to the supply of RHCs. Stakeholders interviewed from Francophone countries in West Africa mentioned the Dutch support to overall development of the health sector (as opposed to support to one specific aspect of the health sector) as a positive approach for donor support.

Continuous input provided by the Netherlands to the functioning of UNFPA Supplies, and particularly now with a restructuring and/or reform underway, is appreciated. Also, the particular attention paid by the Netherlands to countries ('what is happening and how to ensure the situation at country level improves') is valued by the stakeholders interviewed.

Some mentioned that the Netherlands seem to become overshadowed by several donors who are putting considerable (and additional) funding into RHCs (e.g., DFID) and it might therefore slightly lose its significant role in strengthening access to RHCs and services at global level.

A minority of stakeholders mentioned the Netherlands' focus on support to UNFPA Supplies while providing (too) limited support to private manufacturers and interventions to strengthen national supply chains. Furthermore, one stakeholder raised critical notes related to the increasing amount of funding that is made available for advocacy at the expense of funding for commodities.

There is consensus among stakeholders that the Netherlands should continue to support RHCs. There was however less agreement on whether or not future support should be focused on the supplies, or include or be redirected to other aspects related to RHCs (e.g., demand generation)

2.4.1.1 Sub question 2a – Relevant views for decision making

Sub question 2a:

Which of these views are relevant when making choices for specific priority interventions?

The main aspects for the Netherlands to consider are the elements that are most appreciated by the stakeholders regarding past and present Dutch support: consistency, flexibility, complementarity, and diversity of support.

Critiques DSO might need to reflect on include the (perceived) imbalance between commodities and advocacy, and (perceived) limited support to manufacturers. In this context it should be noted that this section of the report reflects issues raised by stakeholders, positive and negative. The study team did not have sufficient documentation and data to verify whether these are justified and well-founded, but a comparison of funding for RHCs and the SRHR fund for NGOs, where the focus is on advocacy, could provide a definite answer as to whether this is the case.

2.4.1.2 Sub question 2b – Risks of duplication of efforts

Sub question 2b:

What is the risk at global level of duplication of efforts to increase availability of RHCs by interventions from the Netherlands, and how can this be avoided?

The RHC landscape is a crowded space, particularly at global level. It involves a broad range of organisations and individuals, from large and influential donors to powerful big pharmaceutical companies.

At present, several key stakeholders are rethinking their strategies and developing new programmes to improve availability of RHCs (e.g., BMGF, UNFPA Supplies, FP2020), which implies an increased risk of duplication of efforts just because it is unknown and/or unclear on which specific topics and/or interventions these organisations will focus in the (near) future, and how much funds will be spent.

"... there are so many coordination mechanisms even so that a coordination mechanism is needed for the coordination mechanisms..."

Source: stakeholder in interview

Nevertheless, on a global level, coordination and consultation between the main (and biggest) stakeholders and actors seems fairly robust, and it is expected that these stakeholders will keep each other sufficiently informed of the general developments within and outside their own organisations. The collaboration

between key stakeholders for the reform of UNFPA Supplies was mentioned as a good example of productive interaction and coordination.

For coordination of operational elements such as data sharing, common structures or tools (e.g. the Coordinated Supply Planning (CSP)) are used, both at global and at country level. The CSP is a working group of the RHSC that coordinates donor procurement of family planning supplies for the public sector, fosters dialogue and mutual trust between supply chain participants and facilitates adjustments to prevent stock-outs and/or over-stocks.

While details on strategies and programming from several stakeholders are currently still unknown, we noticed that some of the bigger stakeholders tend to focus their new strategies and programmes on the trends and recommendations described in recently published leading documents on RHCs such as the Ecosystem 2030 report. Some of the current novelties or innovative approaches attract the attention of many stakeholders (e.g., the market manager, the development of heat stable carbetocin, market launches of new products, roll out of successful pilot projects), and duplication of efforts in these areas is not unlikely.

Duplication of data collection efforts also poses a certain risk. Data often have an ownership issue; some programmes or projects are reluctant to share data, although data should be considered public good and indispensable for improvement of health outcomes. Both at global and at country level several parallel reporting systems for programmatic and logistics data co-exist (e.g., for RHC, for vaccines), which is an additional burden to the health system (health workers in particular), and reduces opportunities for overall health systems strengthening.

Alignment and harmonisation in procurement and supply chain management at global level is considered challenging. For procurement it was mentioned that the big international procuring entities of medicines and health commodities (mainly UN entities) could make efficiency gains by harmonising their procedures and processes. Currently, each entity focuses on its own mandate (e.g., UNICEF procures vaccines, UNFPA procures RHCs) without looking for opportunities for harmonisation and/or collaboration.

Coordination at country level remains problematic. Almost all interviewees agree coordination and alignment of partners and interventions at this level is the responsibility of the country, but mechanisms put in place are not always adequate. Coordination of bilateral support seems particularly challenging for countries. The GFF puts considerable efforts in the development of business plans by jointly defining priorities in RMNCAH at country level.

Alignment and harmonisation of in-country supply management continues to be challenging in many countries. Most supply chains show considerable weaknesses, yet interventions to address these weaknesses are often isolated interventions and lack the holistic approach necessary to strengthen the entire system.

Apart from possible duplication of efforts, some stakeholders referred to a certain competition by implementers in relation to obtaining donor funding. In some cases, competing projects and programmes have led to distraction in implementation of national programmes, such as for the – simultaneous - introduction of new products on the market that were supported by different donors.

The strengths of the Dutch support, as noted by the stakeholders interviewed and described in the previous section, provide good potential to avoid duplications. Additional consultation might be needed with the stakeholders that are still in the process of strategizing to ensure initiatives are well aligned and duplications avoided. This might be particularly the case for initiatives in line with the new trends as those will probably be the focus of most stakeholders. At country level, there are usually less partners that provide (hands-on) support than at global level.

2.4.1.3 Sub question 2c – Facilitation of alignment of initiatives

Sub question 2c:

How can the Netherlands facilitate alignment of initiatives at global level and in its focus countries?

As described above initiatives at global level seem rather well aligned, in particular between the big players. More efficiency may be achieved by decreasing the number of or by harmonising existing tools and platforms (e.g., Procurement Planning and Monitoring Report/PPMR, RHInterchange/RHI, Coordinated Supply Planning Group/CSP). The Netherlands could advocate for this harmonisation to take place.

Suggestions from interviewees for interventions to be supported by the Netherlands

We also asked the informants whether they had suggestions for interventions that could be supported by the Netherlands.

General suggestions were in line with the identified strengths of the support provided by the Netherlands, e.g. the flexibility of the Dutch funding mechanisms that allow for adapting funding to the ever-changing environment. Interviewees also suggested to include the development of strong partnerships and relations with countries supported by the Netherlands. It is believed that such relationship building will considerably improve and enrich the relationship and collaboration between the supported countries and the Netherlands, and consequently lead to better results. Several interviewees recommended to foster the private sector, as opposed to the more traditional focus on the public sector.

It goes without saying that interviewees from the different sectors have different opinions about what best to invest in, and self-interest plays a certain role in this as well.

All suggestions and responses are summarised in Annex 8. We have not investigated the feasibility and advisability of these suggestions.

2.4.2 2SUMMARY STUDY QUESTION 2

Overall, support from the Netherlands in RHCs is appreciated. It is considered thoughtful and consistent and adds to the diversification of existing donor support. Some interviewees question whether enough support is provided to private sector development and expressed some concerns related to decreased funding for RHCs. The Netherlands' role in the reform of UNFPA Supplies is valued.

Alignment and harmonisation of efforts at global level is considered adequate, with the note that less coordination mechanisms might lead to more efficiency. At country level, where governments are responsible for coordination and alignment of efforts related to RHC availability among other ministries and partners, this remains a challenge.

2.5 PRIORITY INTERVENTIONS

Note: Information that is not supported by a reference to the literature has been sourced through KIIs.

2.5.1 STUDY QUESTION 3 – PRIORITY INTERVENTIONS

2.5.1.1 Sub question 3a – High impact interventions

Study question 3 – overarching question:

What is current evidence regarding impact of interventions on the availability of RHCs (e.g. strengthening private sector, enhancing last-mile distribution etc)?

Sub question 3a:

What are the interventions with most impact on the availability of RHCs?

Main findings from the literature review

Most of the literature we found describes impact of interventions on availability of and access to family planning and/or reproductive health services, without specifying information on availability of RHCs. Three peer reviewed articles provide some details and are described below.

A study conducted at population and health facility level in Burkina Faso on the introduction of subcutaneous (SC) injections (Sayana Press®), piloted in a selection of regions in 2014, and rolled out to national level in 2016, showed an increased availability of SC injections at public health facilities from 50 to 85% after 6 months.⁷⁰ In Tanzania, a study on a prime vendor system (a public-private partnership to engage a supplier from the private sector as prime vendor to complement the national public sector supplier) reports an increased availability of tracer medicines from 69% to 94% in 2018. Details on the tracer products were not provided, thus it is unknown whether this is also applicable to RHC, but it gives an indication of the potential of the intervention.⁷¹ Also in Tanzania, a project based on payment for performance (P4P) resulted in a substantial increase of the availability of RMNCH commodities including medicines and equipment (8.4 percentage point, $p=0.002$) and a less significant effect on the availability of medical supplies (8.3 percentage point, $p=0.05$) within 13 months.⁷²

The Ecosystem 2030 report was one of the few documents that provided information on impact of interventions focusing on availability of RHC. The use of a dedicated (vertical or parallel) supply chain is mentioned as an intervention that has supported the success of family planning programs, particularly in reaching lowest service levels of the health system. The report refers to the successes of the vaccine and HIV programmes that were achieved because of dedicated supply chains.⁷³ Nevertheless, the use of vertical or parallel supply chains is being debated. Some argue that vertical systems weaken the national supply chains and distort the functioning of the national central medical stores, but others claim that vertical systems help to improve the quality of medicines and health commodities overall, support joint quantification exercises and increase national storage capacity.⁷⁴

Initiatives to integrate those chains are underway in several countries. Since several years, UNICEF for example, has been supporting the integration of nutrition commodities supply chain management in several countries. In close collaboration with governments and other development partners, several initiatives were initiated to facilitate the process of integration, whereby the strengthening of existing systems plays an important role. This is in keeping with the fundamental principles of the Paris Declaration on Aid Effectiveness, which promotes the use of existing systems.⁷⁵ In 2011, UNFPA and WHO noted the need for

⁷⁰ Guiella G, Turke S, Coulibaly H, Radloff S, Choi Y. Rapid Uptake of the Subcutaneous Injectable in Burkina Faso: Evidence from PMA2020 Cross-sectional Surveys. *Glob Heal Sci Pract* [Internet]. 2018 Mar 21;6(1):73–81. Available from: <http://www.ghspjournal.org/lookup/doi/10.9745/GHSP-D-17-00260>

⁷¹ Wiedenmayer K, Mbwasi R, Mfuko W, Mpuya E, Charles J, Chilunda F, et al. Jazia prime vendor system- A public-private partnership to improve medicine availability in Tanzania: From pilot to scale. *J Pharm Policy Pract*. 2019;12(1):1–10.

⁷² Binyaruka P, Borghi J. Improving quality of care through payment for performance: examining effects on the availability and stock-out of essential medical commodities in Tanzania. *Trop Med Int Health* [Internet]. 2016/12/07. 2017 Jan;22(1):92–102. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27928874>

⁷³ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

⁷⁴ Jille Traas, C.C. Effects of Global Health Initiatives on country supply systems. Thesis submitted in partial fulfilment of the requirements for the degree of Master of Science in Public Health – Diseases Control. July 2014.

⁷⁵ The Paris declaration on aid effectiveness and the Accra agenda for action. Organisation for Economic Co-operation and Development; 2008.

strong health systems to support SRH interventions, and provided guidance on SRHR in the context of aid effectiveness.⁷⁶

Despite a few good examples, there is no consensus on whether or not the use of private sector providers in (different elements of) the supply chain has an impact (positive or negative) on availability of commodities. The Informed Push Model (IPM) implemented in Senegal, also known as the IPM-3PL (third party logistics) project, is complimented by many to have considerably improved availability of RHCs and other health commodities, particularly at the dispensing level. It involves a third-party logistics provider, selected through a competitive bidding process, managing logistics with the government providing oversight. In regions with insufficient storage space, large transport trucks were converted to 'mobile stores' and serve as mobile regional distribution channels.⁷⁷

Results from an evaluation of the IPM were presented at the RHSC meeting in Brussels in March 2018. The evaluation found that the availability of contraceptives in health facilities improved from 13% in 2012-2013 up to 94% in 2016 for 8 contraceptives⁷⁸, but there was no impact on contraceptive use at national level. Main lessons learned include the importance of supervision and adaptation to the health system, the inclusion of auxiliary products, and the need to strengthen other supply-side as well as demand-side interventions.⁷⁹ The model was also criticised; investment was shifted from the public sector to private sector, whereas some argue national public health systems should be strengthened. More information about this model can be found below (section 2.5.1.2 - question 3b). The IPM was also referred to by several interviewees, and one interviewee mentioned that during scale up and change of financing arrangements (from donor to government supported), operational challenges were faced. We did not find detailed information on this issue in the literature.

In 2014, Doctorstore was launched in India, an e-commerce portal with a small section of RHC, and has now expanded its product range to 81 commodities. The platform, currently managed by DKT International, focuses on improving access to RHCs for doctors and ultimately users by keeping sales prices low through bypassing middlemen. For shipment of the orders the national post offices are used. Similar initiatives exist in Rwanda and Kenya.

Kasha, a for-profit social enterprise, supplies a range of women's health products including supplies for family planning and personal hygiene through an e-commerce platform and a distribution network. The platform is available online (through a retail website and mobile application) and offline (through a call centre). Orders are either delivered at home (in urban areas), or at 'pick-up' locations in both rural and urban settings. Kasha sells (short-acting) family planning methods that are allowed to be sold through pharmacies, but only to women who can proof they used these methods before. In any other case, a counselling session can be provided through health facilities with which Kasha partners, after which the method can be sold to the counselled women. Kasha currently operates in Rwanda and Kenya and plans to expand to three other countries in Sub-Saharan Africa and Asia by 2024.⁸⁰

MYDAWA is a licenced e-retail pharmacy in Kenya, established in 2017. It offers family planning supplies as well as quality medicines and health and wellness products for women and delivers these at the women's

⁷⁶

https://apps.who.int/iris/bitstream/handle/10665/70737/WHO_RHR_11.29_eng.pdf;jsessionid=7D4FF33B75016371E7C7882607CE10EE?sequence=1

⁷⁷ Brunner, Bettina, Jeffrey Barnes, Andrew Carmona, Arsène Kpangon, Pamela Riley, Erin Mohebbi et Leslie Miles. 2016. Evaluation du secteur privé de la santé au Senegal a travers quelques exemples d'offres de produits et de prestations de services. Bethesda, MD: Projet Strengthening Health Outcomes through the Private Sector, Abt Associates Inc.

⁷⁸ Combined pill, progesterone-only pill, injection, implant, IUD, male condom, female condom and collier

⁷⁹ Cavallaro, F et al. Presentation Lessons learned from the evaluation of the Informed Push Model in Senegal. RHSC meeting, Brussels, 22 March 2018.

⁸⁰ Warren, April, Sean Callahan, and Ali Lauer. 2020. Social Enterprise Innovations in Family Planning: Case Studies. Brief. Rockville, MD: Sustaining Health Outcomes through the Private Sector Plus Project, Abt Associates.

home or another location of their choice. Ordering, for over the counter and prescription medicines and health commodities, can be realised through the MYDAWA website or a mobile application. Family planning supplies available at MYDAWA currently include several brands of condoms, oral contraceptive pills, emergency contraceptives, and the Sayana Press injectable. Plans for the future include expansion to more rural and remote areas, increase of the number and range of products offered, and collaboration with (private) health insurance companies and microfinance groups.⁸¹

The website of the Family Planning High Impact Practices (HIPs)⁸² provides information on evidence-based family planning interventions and practices that were assessed by experts following a predefined set of criteria. Results are documented in short briefs, which are published. A few HIP publications touch upon the study question but refer to long known interventions. These include mobile outreach services and social marketing. Through mobile outreach services reliable systems for supplies of RHCs, related medical supplies and equipment needed to provide quality services are set up. Social marketing programmes increased RHCs availability through collaboration with service providers from different sectors. A brief from 2012 emphasises the importance of an effective supply chain management system. This, according to the brief, will improve quality of care and lead, by reducing stock out of commodities and related equipment, to a better method mix and thus more choice for the users. Recommendations to improve supply chains include the implementation of a robust Logistics Management Information System (LMIS), regular quantification exercises, partnerships and/or outsourcing to private sector, strengthening of last mile distribution, and strong coordination mechanisms between stakeholders. The evidence provided in all briefs referred to is slightly outdated (2012-2014).⁸³

In Nigeria drugs shops are popular and an important place for youth, mainly young and unmarried women, to purchase contraceptives. Through expansion of the different methods for sale in these drug shops a larger population could be reached. These shops fill an important gap in the market.⁸⁴

Partnering with the private sector through corporate sector workplace programs was reported to provide promising opportunities to reach high numbers of (young) women. Large companies, often located in major cities, employ many people who usually have come from rural areas to find a job, and can therefore be an appropriate entry point to provide SRH services including provision of contraceptives and related commodities. In Ethiopia encouraging results in the uptake of contraception were achieved (from 11% to 90% between 1997 and 2000).⁸⁵

We found information on other interventions related to RHCs in general that could potentially be interesting to increase availability as well. These are listed in Annex 6.

Additional findings from the KIIs

The interviews provided information on a few more interesting interventions in addition to those mentioned in the previous section. These are listed below. Nevertheless, informants also confirmed the overall limited body of evidence for interventions implemented to increase availability of RHCs. Some argued that several of the large projects have just started and are therefore not yet in a position to report on results (e.g., last mile distribution supported by the Sahel Women's Empowerment and Demographic Dividend SWEDD,⁸⁶ the

⁸¹ Warren, April, Sean Callahan, and Ali Lauer. 2020. Social Enterprise Innovations in Family Planning: Case Studies. Brief. Rockville, MD: Sustaining Health Outcomes through the Private Sector Plus Project, Abt Associates.

⁸² <https://www.fphighimpactpractices.org>

⁸³ High Impact Practices in Family Planning (HIP). Supply chain management: investing in contraceptive security and strengthening health systems. Washington, DC: USAID; 2012 Nov. Available from: <http://www.fphighimpactpractices.org/briefs/supply-chain-management/>

⁸⁴ Riley C, Garfinkel D, Thanel K, Esch K, Workalemahu E, Anyanti J, et al. Getting to FP2020: Harnessing the private sector to increase modern contraceptive access and choice in Ethiopia, Nigeria, and DRC. *PLoS One*. 2018;13(2):e0192522.

⁸⁵ Karen Hardee, Population Council; David Wofford, Meridien Group International; Nandita Thatte, World Health Organisation. Family Planning Evidence Brief – Partnering with the private sector to strengthen provision of contraception. July 2017

⁸⁶ https://wcaro.unfpa.org/sites/default/files/pub-pdf/SWEDD_ENG.pdf

WISH program supported by DFID), yet others agreed that the community could do better in documenting results of tested and piloted interventions, and then share relevant information with the community.

In Indonesia, a public private partnership established midwives as independent clinicians and entrepreneurs. The intervention, part of the Village Midwife Programme, included the usual counselling and clinical care provided by the midwives plus sales of contraceptives by these midwives as a new service. The government was involved in this intervention, and regulated procurement and sales prices. The intervention was considered useful, particularly because of the accessible prices charged by the midwives.⁸⁷ A study on the effects of the program published in 2014 did not find changes in overall contraceptive prevalence, but noted a change in the method choice; the use of injectables increased whereas use of oral contraception and implants decreased.⁸⁸

A similar intervention was piloted in Uganda focusing on child mortality; Community Health Promoters were trained and equipped to provide medical advice, referral and sale of commodities, which led to reduced child mortality (27 percent reduction after 3 years of implementation). The pilot included family planning supplies, but the published article does not provide information on results related to this component.⁸⁹

Healthy Entrepreneurs, a Dutch organisation, implements similar interventions mainly in the great lake region; health workers trained by Healthy Entrepreneurs sell health commodities and health care products in their own little pharmacies in their villages. Interventions by Health Entrepreneurs were however not mentioned in interviews nor were they referenced in the literature reviewed.⁹⁰

Stakeholders interviewed who are engaged in country level program implementation indicated that improved quantification exercises combined with regular supply planning resulted in better availability of RHCs and in better use of available resources. Specific documentation on these interventions are not available, but literature also referred to the importance of reliable quantification to improve availability of RHCs. In this light, strong in-country presence from supporting agencies was mentioned as an advantage to support countries in their efforts to improve RHCs availability. It was however added that some donor and implementing agencies lack the capacity and skills in supply chain management that is necessary to provide meaningful support to countries. It is not uncommon, according to stakeholders interviewed, that technical support on supply chain related topic is provided by health experts whereas a different skills set/additional skills would be required.

Models similar to the prime vendor model described above are being tested in several countries in Sub Saharan Africa (e.g., Uganda, Cameroon, Liberia, Tanzania) but documentation on results is not yet available. GFF expressed interest in such models as they promote involvement of the private sector.

Price negotiations and price policies

Several examples exist for volume related price reductions negotiated between manufacturers and donors;⁹¹ these reductions led to wider availability of several RHCs resulting in a more comprehensive method-mix,

⁸⁷ Healthy Entrepreneurs (<https://www.healthyentrepreneurs.nl>) a Dutch organisation, implements similar interventions mainly in the great lake region; health workers trained by Healthy Entrepreneurs sell health commodities and health care products in their own little pharmacies in their villages. Interventions by Health Entrepreneurs were however not mentioned in interviews nor were they referenced in literature reviewed.

⁸⁸ Weaver, E.H et al. Effect of Village Midwife Program on Contraceptive Prevalence and Method Choice in Indonesia. *Stud Fam Plann.* 2013 December; 44(4): 389–409. doi:10.1111/j.1728-4465.2013.00366.x

⁸⁹ Björkman Nyqvist M, Guariso A, Svensson J, Yanagizawa-Drott D. Reducing Child Mortality in the Last Mile: Experimental Evidence on Community Health Promoters in Uganda. *American Economic Journal: Applied Economics* 2019, 11(3): 155–192. 2019. <https://doi.org/10.1257/app.20170201>

⁹⁰ <https://www.healthyentrepreneurs.nl>

⁹¹ There are also examples of collaboration between manufacturers and donors and/or country governments to introduce new products and to reduce prices. Carbetocin for example, a heat-stable uterotonic medicine that has the potential to be widely used to prevent and treat post-partum haemorrhage (PPH), will be offered by Ferring Pharmaceuticals at a maximum price of USD 0.35 per ampoule for low- and middle-income countries (LMICs).

more products for the same amount of funding, and optimisation of production and reduction of cost and lower prices for manufactures.⁹²

Positive results of negotiated prices (through advance purchase commitments) are reported in a study on the uptake of implants conducted in 12 countries in Sub-Saharan Africa between 2003 and 2017. The negotiated price allowed for cost savings by donors of up to USD 230 million between 2013 and 2017, permitting the procurement of larger quantities and thus serving more users. Several donors and manufactures were involved in this intervention, including BMGF, USAID, Bayer and Merck. Their collaboration resulted in the Implant Access Program (IAP) launched in 2012-13. The study argues furthermore that task shifting, in this case inserting of implants by lower level health workers and community workers, validated by WHO, supported the access to implant use at the lower levels.⁹³ Long term effects of the IAP are yet unknown as the program ended only in 2019.

During the KIIs, the IAP was often mentioned, and most of the interviewees noted the initiative was positive: prices went down and access increased, and manufacturers involved (Merck and Bayer) committed to maintain the low price for a longer period of time. Some however were critical to the fact that the IAP mainly improved availability for the users that obtain their implants through the public sector. Others argued all efforts were directed to promote demand, supply and availability of one single family planning method, which could potentially reduce the freedom of choice for users. This comment was not only made with regards to the IAP but also related to other volume guarantee agreements. Others argued that instead of reducing the freedom of choice, these approaches supported one method at global level but added a method to the mix at country level. The challenges of the manufacturer to respond to the unexpectedly high demand were also raised and need to be addressed in case volume guarantees would be applied for other commodities in the future.

Some argue volume guarantee related price reductions may present a threat for the market as they limit opportunities for market entry for other manufacturers with interest and capacity to sell their commodities; the market is locked. Negotiated or reduced prices with big international suppliers furthermore make the market unattractive for small(er) suppliers, thereby limiting competition and thus opportunities to create a healthy market.

Interviewees were divided on the success of volume guarantees whereby prices were fixed based on the procurement of a certain quantity in a certain period of time. Manufacturers claim forecasting of RHCs is a major challenge and seek for guarantees. In reality, forecasts are hardly ever accurate and estimating sales is part of the entrepreneurship of a manufacturer. Interviewees therefore thought such guarantees are inappropriate and unnecessary. Furthermore, in their view, several of these agreements lacked clear conditions. For example, they did not clarify what the consequence would be if sales were higher than agreed or indeed less than expected. Contingency plans to face under- or overestimation of demand were suggested for future volume guarantees.

Strong price competition between the small group of manufacturers selling WHO prequalified commodities was also raised as a threat for the market; profit margins are said to be very low, which will limit the interest of new manufacturers to enter the market. Sales at low margins can only be interesting if the volumes are high enough. Agreements made in the past have now fully locked up the already limited market.^{94,95}

Another consequence of price negotiations and strong competition mentioned is the decreased profit of manufacturers. Several of the Research and Development (R&D) manufacturers now charge additional costs for services that were initially included in the product price, such as costs for training and transport. The

⁹² Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A guide for advocates. June 2018

⁹³ Jacobstein R. Liftoff: The Blossoming of Contraceptive Implant Use in Africa. *Glob Heal Sci Pract*. 2018 Mar;6(1):17–39.

⁹⁴ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

⁹⁵ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

report on the ecosystem for RHCs states that some LMIC already requested for more flexible pricing agreements, whereby the services expected from these manufacturers would be again included.⁹⁶

Furthermore, for commercial companies low (or reduced) profit margins may limit the appetite to serve markets in LMICs. Generally, high(er) income countries provide more opportunities for higher profits for manufacturers as in these countries higher prices can be charged.⁹⁷ According to one interviewee, manufacturers, particularly for implants, already start to pull back and charge higher prices in non FP2020 countries to compensate for the limited revenues they obtain in those FP2020 countries. Product specific information on negotiated prices can be found in Annex 5.

Market interventions for RHCs considered innovative in the past are partly responsible for current challenges; the donor community successfully supported the development of generic alternatives for branded products and in this way managed to increase product availability and affordability. Presently however, several generic manufacturers are reluctant to apply for prequalification by WHO or registration by an SRA because of the high investment involved. Nonetheless, a number of generic reproductive health products are currently included on the WHO prequalification list.⁹⁸

Some countries remain reluctant to procure generic RHCs. When these countries increase procurement volumes with domestic resources, they might opt to procure the originator products (particularly when branded commodities are also offered) which will probably lead to a decrease in sales for the generic manufacturers. For generic manufacturers, of which several supply prequalified products, to sustain their business interest, it is suggested that support from the international supplies and donor community is needed; manufacturers of generic products do not always have the financial means to generate demand and promote their products on their own.⁹⁹

Interviewees referred to volume guarantees as a rudimentary instrument to decrease prices and make quality assured commodities available, while creating incentives that are not per se correct; the market does indeed not react to demand signals. There is a general view that price agreements are not the silver bullet to increase availability of RHCs in the long term. Instead, overarching solutions that strengthen the overall RHC market and stable funding are mentioned as the key aspects that need to be worked on in the near future.

Despite challenges and critiques from actors in the RHC landscape, the study team understood volume guarantee agreements are still being negotiated, most recently with three manufacturers for medical abortion pills. Details of these agreements are not known. New or adapted approaches are also explored: the BMGF and UNFPA Supplies are discussing new mechanisms to use the current Bridge Funding Mechanism as a mechanism to secure multiple year orders to achieve price reductions. Long term contracts or framework agreements are common strategies used in the procurement of other health commodities to obtain good prices and ensure these are valid for a long(er) period of time.

2.5.1.2 Sub question 3b – Interventions that facilitated innovation

Sub question 3b:

Which interventions have facilitated innovation at product level, and for last mile distribution?

⁹⁶ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

⁹⁷ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

⁹⁸ [https://extranet.who.int/prequal/content/prequalified-](https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=&field_medicine_applicant=&field_medicine_fpp_site_value=&search_api_aggregation_1=&field_medicine_pq_date%5Bdate%5D=&field_medicine_pq_date_1%5Bdate%5D=&field_therapeutic_area=18&field_medicine_status=&field_basis_of_listing=All)

[lists/medicines?label=&field_medicine_applicant=&field_medicine_fpp_site_value=&search_api_aggregation_1=&field_medicine_pq_date%5Bdate%5D=&field_medicine_pq_date_1%5Bdate%5D=&field_therapeutic_area=18&field_medicine_status=&field_basis_of_listing=All](https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=&field_medicine_applicant=&field_medicine_fpp_site_value=&search_api_aggregation_1=&field_medicine_pq_date%5Bdate%5D=&field_medicine_pq_date_1%5Bdate%5D=&field_therapeutic_area=18&field_medicine_status=&field_basis_of_listing=All)

⁹⁹ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

The term innovation is used in several ways in the literature. In some documents it refers, although not explicitly, to new and creative ideas, and in other documents it refers to improvements or better solutions to existing challenges or needs that are not per se new. The literature reviewed and KII did not provide useful information on interventions that facilitated innovation, and the actual study questions can therefore not be fully answered. We however found information on innovation and innovative interventions; these are described below.

This section is further subdivided into 3 subsections: innovation at product level, innovation in last mile distribution and other innovations.

Innovation at product level

Most of the literature we found describes ‘innovative’ interventions to market a new product, rather than interventions that facilitated product development. These interventions include social marketing which, through the collaboration between service providers from different sectors, provides commodities via non-traditional channels, and task shifting which allows for less trained health workers to be able to prescribe or carry out the necessary interventions (e.g., injections, implants) for new products to be used at the lower levels. Most of the reviewed literature focuses on the self-injectable Sayana Press and, to a lesser extent, on community-based distributions (CBD). For example, CBDs of misoprostol through traditional birth attendants to treat post-partum haemorrhage (PPH) at the community level are reported in different settings in sub-Saharan Africa. More information on social marketing can be found in this section under sub-question 3d (2.5.1.4) below.

Other documents and studies found on innovation at product level were linked to the marketing of the product, to the administration of the product, or improvements made to facilitate adequate administration. Clinical studies and trials were excluded from the literature review. We first elaborate on global level aspects of innovation at product level, and then list country level studies.

Despite a decrease in donor interest to support product specific innovations allowing for more efficacy, longer continuation, and better responsiveness to user needs (Ecosystem 2030 report), donors continue to play an important role in innovation in product development, alongside R&D companies and NGOs. These actors are also actively involved in demand creation for the new products they develop.¹⁰⁰ There are also examples of collaboration between manufacturers and donors and/or country governments to introduce new products and to reduce prices. Carbetocin for example, a heat-stable uterotonic medicine that has the potential to be widely used to prevent and treat PPH, will be offered by Ferring Pharmaceuticals at a maximum price of USD 0.35 per ampoule for LMICs. Heat-stable carbetocin was recently tested in the largest clinical trial of uterotonics for PPH ever performed, in order to prove its safety and non-inferiority in relation to other uterotonics. Part of the agreement between the manufacturer, MSD For Mothers, and WHO was that if the clinical trial came out with positive results, Ferring would supply the product for the public market at a very low price.¹⁰¹¹⁰²

Two studies found in peer reviewed journals describe experiences with innovative products that were put on the market recently. Innovation here refers to products that have been slightly modified or have been released in a new form:

¹⁰⁰ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁰¹ Theunissen FJ, Chinery L, Pujar Y V. Current research on carbetocin and implications for prevention of postpartum haemorrhage. *Reprod Health*. 2018;15(Suppl 1).

¹⁰² Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

- A recent small-scale study assessing the introduction of a postpartum intrauterine device (PPIUD) inserter by Population Services International Mali (PSI Mali) in a limited number of selected health facilities suggested potential for improving access to PPIUD.¹⁰³
- Robust evidence shows injectable contraceptives can be distributed by community health workers in a safe, effective and acceptable manner, and can help to reach more women, and particularly young girls. However, only a few African countries allow community health workers to administer injectables. A new injectable contraceptive—subcutaneous depot medroxyprogesterone acetate (subcutaneous DMPA or DMPA-SC) facilitates administration as compared to the traditional intramuscular DMPA (DMPA-IM), and therefore provides options to overcome existing barriers to community health workers providing injectables.¹⁰⁴

Interviews provided additional insights on manufactures' perspectives with regards to innovation and product development. Introduction of new products in the market is challenging and costly (e.g., WHO prequalification, country regulatory issues, marketing) and manufacturers therefore tend to opt to improve existing products that can provide added value to the users and the service providers involved (e.g., better loading systems, simpler and safer insertion devices, products adjusted to postpartum needs).

The Population Council was mentioned as an important player in the development of contraceptives. This organisation supports the design of effective family planning services, including supplies, around the world and has a strong focus on research covering all aspects (identification of drugs and delivery systems, conducting preclinical studies and clinical trials, and obtaining approvals from the national regulatory authorities necessary for market introduction of new products). Recent developments include Anovera™ (segesterone acetate and ethinyl estradiol vaginal system), a contraceptive that protects against unintended pregnancy for the period of one year and is fully under a woman's control). Contraceptive, microbicide, and multipurpose prevention technology (MPTs) products are currently in different stages of development and licensing. The Population Council collaborates with a range of partners, e.g., RHSC's Market Development Approaches Working group, FP2020, CHAI and WHO's Department of Reproductive Health and Research.¹⁰⁵

¹⁰³ Burke E, Dakouo ML, Glish L, Moon P, Blumenthal PD. Helping Postpartum Women in Mali Achieve Their Fertility Intentions: Perspectives from Introduction of the Dedicated Postpartum IUD Inserter. *Glob Heal Sci Pract* [Internet]. 2018 Oct 3;6(3):515–27.

¹⁰⁴ Stout A, Wood S, Barigye G, Kaboré A, Siddo D, Ndione I. Expanding Access to Injectable Contraception: Results From Pilot Introduction of Subcutaneous Depot Medroxyprogesterone Acetate (DMPA-SC) in 4 African Countries. *Glob Heal Sci Pract* [Internet]. 2018 Mar 21;6(1):55–72.

¹⁰⁵ <https://www.popcouncil.org>

Innovations in supply chain management / last mile distribution

Most innovations in supply chain / last mile distribution reported on in the literature are innovations led by the public sector, or a combination of public and private sector such as the IPM in Senegal (see question 3a (section 2.5.1.1) and below).

Mobile outreach programs or services are often mentioned as innovation in last mile distribution. It can however be questioned whether mobile outreach can still be considered as innovation; this approach exists for several decades and has proven its benefits for improving access to health services in rural and/or remote areas. Nevertheless, outreach programs evolve according to their context, opportunities, and lessons learned, and focus is shifting from increasing access to services to increasing variety of methods.¹⁰⁶¹⁰⁷¹⁰⁸

(Electronic) Logistic Management Information Systems (eLMIS) are also often mentioned in the innovation discussion. For many years, countries have been making progress with the implementation of LMIS or eLMIS to manage logistics data. Yet, not all countries have a functional (e)LMIS that is able to generate (close to) real-time logistics data of all product categories and at all levels of the supply chain. RHCs are usually among the prioritised categories for inclusion in (e)LMIS systems.¹⁰⁹¹¹⁰

More recent is the use of mobile technologies for logistics reporting, e.g., reporting on stock levels and consumption through mobile phones. Reporting by means of mobile application is technically feasible and has several interesting benefits (e.g., increased data visibility), but scaling up these systems is an enormous undertaking, requiring considerable resources. These interventions are therefore usually implemented for particular product categories (e.g., nutrition commodities, antimalarials), and implemented in particular circumstances (e.g., emergency settings).¹¹¹¹¹²

The IPM implemented in Senegal (also referred to in section 2.5.1.1 above) used a different approach for logistics data collection and management by implementing a national LMIS run by the concerned directorate of the MOH. Results of this approach presented in different documents reviewed are positive. The country applied vendor managed inventory, which involves quantification, transport, data collection and data management. Real time consumption data, collected each month in all health facilities, were made available to key actors through an internet platform, and used to estimate the needs. Availability of reliable data increased, and stock outs decreased considerably. IPM is considered an important step towards professionalisation of the supply chain in Senegal, with the additional advantage that it allowed health workers to concentrate on service provision as the burden of supply management is taken over by logistic experts. Other countries applied similar strategies for RHCs and other medicines/health commodities, based on lessons learned from Senegal. Zambia reports that availability of the antimalarials doubled since professionalisation of district logistics management.¹¹³¹¹⁴

¹⁰⁶ HIP/Family Planning High Impact Practices. Mobile Outreach Services: Expanding access to a full range of modern contraceptives. May 2014

¹⁰⁷ Hernandez JH, Akilimali PZ, Muanda MF, Glover AL, Bertrand JT. Evolution of a Large-Scale Community-Based Contraceptive Distribution Program in Kinshasa, DRC Based on Process Evaluation. *Glob Heal Sci Pract* [Internet]. 2018 Dec 27;6(4):657–67.

¹⁰⁸ PSI. Developing Family Planning Markets in Francophone West Africa 2017-2020.

¹⁰⁹ Mukasa B, Ali M, Farron M, Van de Weerd R. Contraception supply chain challenges: a review of evidence from low- and middle-income countries. *Eur J Contracept Reprod Health Care* [Internet]. 2017/10/31. 2017 Oct;22(5):384–90.

¹¹⁰ USAID | DELIVER PROJECT, Task Orders 4 and 7. 2016. USAID | DELIVER PROJECT Final Country Report: Ethiopia. Arlington, Va.: USAID | DELIVER PROJECT, Task Orders 4 and 7.

¹¹¹ USAID | DELIVER PROJECT, Task Orders 4 and 7. 2016. USAID | DELIVER PROJECT Final Country Report: Ethiopia. Arlington, Va.: USAID | DELIVER PROJECT, Task Orders 4 and 7

¹¹² FP2020. Women at the center – A call to action from FP 2020's 2018-2019 annual progress report

¹¹³ Hasselback L, Dicko M, Viadro C, Ndour S, Ndao O, Wesson J. Understanding and addressing contraceptive stockouts to increase family planning access and uptake in Senegal. *BMC Health Serv Res* [Internet]. 2017 Dec 26;17(1):373

¹¹⁴ Merck For Mothers. Providing Reliable Last Mile Access to Contraceptives and Other Essential Medicines: The Informed Push Model with Third Party Logistics Providers in Senegal. October 2017

Because of reduced funding and increased RHCs demand foreseen in the coming years, adequate forecasting becomes an urgent issue. UNFPA Supplies intensified collaboration with governments to improve estimations of future needs and emphasises the importance of including the real needs as compared to needs based on past consumption.¹¹⁵ A good example of adequate needs forecasting is the IPM project in Senegal.

The latest innovation in data management is the development of international platforms compiling logistics data from diverse sources from different countries, such as the Global FP VAN, and the CRT as described in Annex 7 (Volume II).

A novelty of UNFPA Supplies are 'last mile audits' that were conducted for the first time in 2019. These were audits of implementing partners in 16 countries which were selected based on the volume and value of commodities managed. The audits assess how commodities are handled from point of entry to the dispensing point. Based on assessment results, strategies to mitigate identified risks are developed.¹¹⁶

Several interventions are tested, but information on results remains limited. An example worth mentioning is the Sahel Women's Empowerment and Demographic Dividend (SWEDD) project. This project, supported by the WB, is piloting different models for last mile distribution in collaboration with the central medical stores in seven countries. Bulk purchases are conducted by the central medical stores and the commodities are delivered at health facility level. No additional information on this approach is yet available. For more information about SWEDD see Annex 6 (Volume II).

The use of unmanned aerial vehicles (UAVs), the formal name for drones, for the delivery of RHCs has not been mentioned in the literature found through the systematic approach and did not come up during the interviews. A fast internet search provided us with basic information and background; it teaches us that contraceptives do not belong to the product categories that are considered ideal for drone delivery. Contraceptives are relatively cheap, and drone deliveries are mainly used for expensive products which is related to the cost of the flights. Combining deliveries of contraceptives with other (high value) health commodities could be a way forward. Drone deliveries can be cost-competitive when they compensate costs, including staff time, of alternative transportation methods, usually motorcycles that are used for the last mile delivery in remote areas. Another important factor is the need for (continuous) adequate counselling for and follow up of users of contraceptives that requires health workers contact with users.¹¹⁷¹¹⁸

Other innovative interventions

The UNFPA State of World Population 2019 report describes options to obtain more, better and new data through the application of new technologies that could help increase RHCs availability. The use of geospatial information or handheld electronic devices is mentioned as well as modelling tools that can provide useful information on population sizes and location, interaction between populations, SRHR, and sustainable development. Market interventions for RHCs considered innovative in the past are discussed in section 2.5.1.1 above (Price negotiations and price policies).

Another innovative intervention to improve RHC availability that was referred to in one of the interviews is sales through apps or online stores. The Doctorstores established in India in 2014 was established as an online shop for doctors. Similar concepts for online sales of RHCs to end-users are emerging, e.g., Kasha in Rwanda and Kenya, and MYDAWA in Kenya (see section 2.5.1.1 above).

¹¹⁵ UNFPA Supplies. Annual report 2018

¹¹⁶ UNFPA Supplies. Annual report 2018

¹¹⁷ <https://www.prb.org/can-drones-help-avert-contraceptive-stockouts-maybe/>

¹¹⁸ Wright, C. et al. What should you deliver by unmanned aerial systems? The role of geography, product, and UAS type in prioritising deliveries by UA. JSI Research & Training Institute, Inc. January 2018

The Innovation Fund from RHSC provides grants to a variety of organisations that explore new or better ideas to support the RHSC goals. The fund focuses on projects that explore means to improve availability of RHCs at the level of the end user. Since 2009, 67 small awards were approved for over USD 6 million.

More interventions described in the literature reviewed and that we consider promising and providing interesting solutions to existing problems and challenges related to RHCs are listed in Annex 6 (Volume II).

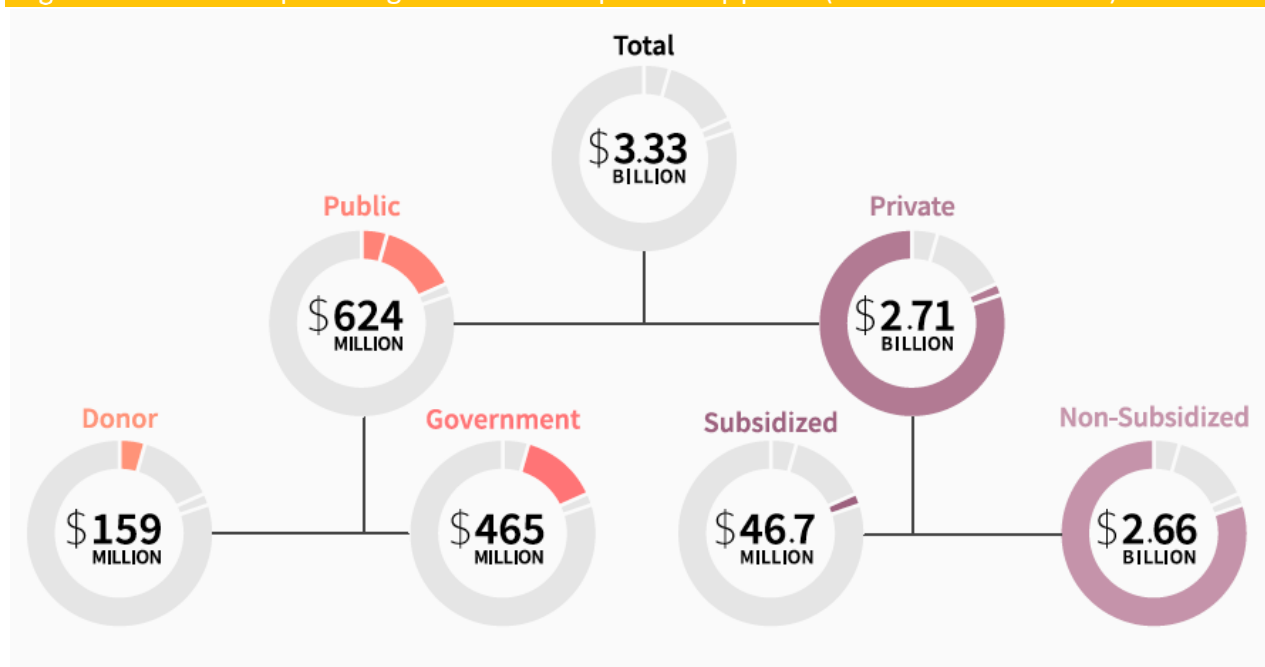
2.5.1.3 Sub question 3c – Interventions to stimulate domestic resource mobilisation

Sub question 3c:

What are successful interventions to stimulate domestic resource mobilisation for RHCs?

The most recent figures on contraceptive supplies financing as presented in the Commodity Gap Analysis (CGA) 2019 report indicate that in 135 LMICs a total of USD 3.33 billion is currently spent.¹¹⁹ Figure 1 below shows the current spending.

Figure 1. Current spending on contraceptive supplies (source: CGA 2019)



The CGA 2019 specifies that of the total of USD 3.33 billion, USD 191 million is spent in Low Income Countries (LIC), USD 905 million in Lower Middle-Income Countries (L-MIC), and USD 2.24 billion in Upper Middle Income Countries (U-MIC).¹²⁰ These amounts are divided among the different sources as shown in Table 3 below.

¹¹⁹ Reliable information about spending on other RHC categories (e.g., maternal health commodities, safe abortion commodities) could not be found in the literature.

¹²⁰ This segmentation of countries is based on the World Bank's categories of Gross national Income per Capita

Table 3. Current spending by sector, segmented by GNI Group (source: CGA 2019)

	TOTAL	PUBLIC	WITHIN PUBLIC		PRIVATE	WITHIN PRIVATE	
			DONOR	GOVERNMENT		SUB	NON-SUB
LIC	191,000,000	126,000,000	94,000,000	32,400,000	64,300,000	10,100,000	54,200,000
L-MIC	905,000,000	321,000,000	58,400,000	263,000,000	584,000,000	36,600,000	547,000,000
U-MIC	2,240,000,000	177,000,000	6,850,000	170,000,000	2,060,000,000	43,700	2,060,000,000
Total	3,330,000,000	624,000,000	159,000,000	465,000,000	2,710,000,000	46,700,000	2,660,000,000

Although clear figures are not available, there is consensus that donor funding for RHCs (family planning supplies mainly) is likely to decline in the coming years. With this decline and an overall increasing global funding gap, the need to improve domestic resource mobilisation for RHCs is emerging. Simultaneously, RHCs stakeholders are aware that increased domestic funding alone will not be able to close the current and future gap. A clear vision is required to align financing strategies with the global values and principles in reproductive health and with the SDG and International Conference on Population and Development (ICPD) targets that aim to increase access to SRH services and UHC.¹²¹

While costing exercises are in place and lobbying for increase of domestic funding for RHCs has been ongoing for several years, numerous challenges exist to mobilise domestic funding for RHC. These include limited fiscal space, competing priorities of governments, and poor accountability and tracking of domestic contributions. Also, the existence of a budget line for RHCs does not per se mean that the budget will be allocated or spent, nor that it will be spent on commodities.¹²² Some also believe that the provision of free contraceptives disincentivises receiving countries to allocate domestic resources to RHCs procurement, and more generally discourages these countries to design insurance schemes that cover all SRH interventions out of fear of the high costs involved that will have to be funded with domestic resources in the future when donors are pulling out.¹²³

As countries grow economically it is anticipated that expenditure on health per capita will increase; more maturing tax systems and expansion of the fiscal space will allow for increasing domestic funding and a proportional decline in donor funding and funding through OOP. Such trends are not yet shown for RHCs but are expected to occur in the long term. Particularly low-income countries, however, will need donor support for many years.¹²⁴

The increase of domestic funding for procurement of RHCs also raises concerns; it is expected that countries that have access to considerable national funding will procure by themselves. Most likely however, they will not have access to the bulk purchasing discounts that the two major procuring entities for RHCs (USAID and UNFPA Supplies) manage to obtain.¹²⁵ Unless price agreements can be negotiated with manufacturers such as through tiered pricing policies,¹²⁶ this will deprive countries from reduced prices negotiated between manufacturers and the large procuring entities, and quantities they are able to purchase will decrease. Countries then may explore other procurement options, whereby quality might become a less important factor.¹²⁷ Using domestic funding for RHC procurement requires capacities and systems that might not yet

¹²¹ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹²² Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹²³ Pharos Global Health Advisors. Transitions in Family Planning: Challenges, Risks, and Opportunities Associated with Upcoming Declines in Donor Health Aid to Middle-Income Countries. 2019

¹²⁴ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹²⁵ Pharos Global Health Advisors. Transitions in Family Planning: Challenges, Risks, and Opportunities Associated with Upcoming Declines in Donor Health Aid to Middle-Income Countries. 2019

¹²⁶ GAVI managed to negotiate tiered pricing policies with pharmaceutical industry who apply lower prices for lower income countries than for higher income countries. These agreements are feasible as funding from GAVI is predictable and the demand is relatively easy to estimate and to pool (source: <https://www.gavi.org/news/media-room/gavi-approach-creates-tiered-pricing-vaccines>)

¹²⁷ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

be available in all countries, and some believe it will be a challenge to prepare national (and decentralised) governments for procurement and management of RHCs that are required to provide SRH services to a growing population in reproductive age.

Based on existing evidence it is difficult to estimate whether or to what extent these concerns are justified, and what the actual effects will be; analysable data is lacking. It is however clear that procurement capacity within the national procurement centres / central medical stores exists; these organisations procure large volumes of medicines and health commodities, including RHCs in some countries, following national procurement laws and quality requirements. The WAHO, through the Regional Funding Mechanism, provides technical assistance to countries for procurement of family planning supplies, and in several countries, the national central medical stores are supported by donor agencies, both financially and technically (e.g. support from the USAID/DELIVER Project to the Ethiopian public sector health supply chain managed by the Pharmaceuticals Fund and Supply Agency).¹²⁸ Other initiatives to prepare governments to conduct procurement of RHCs include the support from ForoLAC who supports national procurement officers in Latin America to obtain relevant and up to date knowledge on prices and procurement strategies.

Risks during the transition period highlighted in the literature reviewed include the potential need for loan funds during that period and limited access to technical support - risks that if not mitigated can have catastrophic consequences. Transition therefore should be well planned, and preferably happen gradually.¹²⁹

A range of interventions and initiatives are reported in the literature reviewed, most of which are supported by the main players in RHCs – UNFPA Supplies, USAID, GFF and FP2020. Nevertheless, clear and objective information on the results did not become available for most of the interventions. We list the most important and/or promising interventions below.

- The matching fund for Ouagadougou Partnership countries in West Africa; this fund, supported by the BMGF, doubles each USD spent on RHCs by national governments (for each additional US Dollar invested by the national government, BMGF allocates two US Dollars). All nine countries from the Ouagadougou partnership committed to invest in RHCs with their own funding, and in 2018 five countries made use of the Fund; these countries spent USD 2.3 million, resulting in the provision of matching funds of USD 4.7 million. It remains unclear though what countries would have invested without the incentive of the fund.¹³⁰
- The partnership between UNFPA Supplies and the European Parliamentary Forum for Population and Development aims at motivating governments, both country and donor governments, to increase resources for RHCs through engagement with parliamentarians. Advocacy remains an important tool to convince countries to include RHCs in their health budgets.¹³¹
- The development of a business case for investment in reproductive health (or family planning) including for supplies. Business cases, although variable in format and content, usually provide background information on the project or program (e.g. objectives), an overview of the available options (e.g., for interventions, implementation), expected costs, a gap analysis, and an overview of challenges and risks and measures to mitigate these. Business cases are often requested by DFID for countries or programmes they support. UNFPA provides support to countries for the development of such plans. GFF requests countries to develop an investment case, and defines an investment case as *'a description of the changes that a country wants to see with regard to reproductive, maternal,*

¹²⁸ USAID | DELIVER PROJECT, Task Orders 4 and 7. 2016. USAID | DELIVER PROJECT Final Country Report: Ethiopia. Arlington, Va.: USAID | DELIVER PROJECT, Task Orders 4 and 7.

¹²⁹ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹³⁰ UNFPA Supplies. Annual report 2018

¹³¹ UNFPA Supplies. Annual report 2018

newborn, child, and adolescent health (RMNCAH) and a prioritised set of investments required to achieve these results.' The development process of these investment cases differs per country, depending on the country's context. GFF aspiration is that the investment case becomes a harmonisation tool for countries to use, and discussions with other global financing actors have started to try to reduce transition costs for these initiatives. Thus far, no outcomes of the investment case development process in the different countries are available.

- UNFPA Supplies' support to countries in the transition towards financial sustainability through three interlinked approaches: development of a business case for investment in family planning, diversification of sources and increase of amount of funding including domestic resource mobilisation, and most efficient use of available funding. The development of a roadmap for the transition period is also supported by UNFPA Supplies.¹³²
- Global Citizen is an online community of people engaged to end extreme poverty by 2030 through different actions including the action platform and global campaigns (e.g. to support the #ShelsEqual campaign to empower girls and women). Since 2011, the community managed to achieve political commitments for a total amount of over USD 35 billion, yet details on the realisation and impact of these commitments could not be found.¹³³

UNFPA Supplies reports on several interventions and initiatives they support, of which some are included in the list above.¹³⁴ The 2018 mid-term evaluation of UNFPA Supplies reported that results achieved in strengthening sustainable financing had little visibility (the approaches to support the countries to encourage sustainable funding were developed shortly before the evaluation).¹³⁵

The Countdown 2030 report mentions co-financing as a potential for funding of contraceptives including the transition towards increased use of domestic resources. Co-financing as implemented by GAVI for procurement of vaccines involves the release of their donations when the receiving country has achieved the contribution it had committed to. Specific in the vaccine space is the fact that the majority of funding and interventions for vaccines are channelled through GAVI, facilitating development and implementation of policies for co-financing; this is considerably different for the RHCs environment.

The Global Fund also includes co-financing as a condition in their grants. To be eligible for funding, countries have to be able to demonstrate progressive government expenditure on health, and progressive uptake of costs related to specific health programs, including programs supported by the Global Fund. As an additional incentive, at least 15% of the approved grant becomes available if countries make additional commitments for domestic funding during grant implementation.¹³⁶ Interviewees emphasised that, in order to achieve increased domestic resources for RHCs, all donors should apply the same approach; currently UNFPA Supplies provides RHCs for free, which makes it a challenge to motivate countries to invest themselves as well.

Increase of domestic funding for RHCs and particularly family planning supplies might be challenging in countries where there is strong religious or cultural resistance to contraceptive use.¹³⁷

Several documents reviewed note the importance for countries to develop sustainable funding mechanisms that are human rights based and promote equity.¹³⁸ This could include measures to use tax revenues to subsidise target populations, increase of health insurance packages and coverage, and decrease of OOP

¹³² UNFPA Supplies. Annual report 2018

¹³³ <https://www.globalcitizen.org/en/info/campaigns/sheisequal/>

¹³⁴ UNFPA Supplies. Annual report 2018

¹³⁵ UNFPA Evaluation Office. Mid-Term Evaluation of the UNFPA Supplies Programme (2013-2020). 2018

¹³⁶ <https://www.theglobalfund.org/en/funding-model/throughout-the-cycle/co-financing/>

¹³⁷ UNFPA State of World Population 2019. Unfinished business- the pursuit of rights and choices for all. 2019

¹³⁸ UNFPA State of World Population 2019. Unfinished business- the pursuit of rights and choices for all. 2019

expenditure. Donors should support countries in this direction as well, which can be achieved by funding UHC strategies and national health insurance schemes that include RHCs.¹³⁹

Literature review and KIIs have yielded little information the link between RHCs availability and UHC; the topic being current and important, we performed an additional search. Target 3.8 of the SDGs calls for the achievement of UHC, which includes *'financial risk protection, access to quality essential health-care services, and access to safe, effective, and affordable essential medicines and vaccines for all.'* Reproductive health services and commodities are widely accepted to be essential and should therefore be included in UHC related interventions. In many countries, UHC includes national health insurance and entitlement schemes, such as free maternal and child health services. For countries implementing UHC programs, defining health benefit packages is crucial since they are often challenged with competing priorities and limited resources. This may involve risks of neglecting RHCs. The RHSC has advocated to include RHCs as an integral part of the basic packages in UHC reforms.

According to a recent WHO evidence brief on UHC for SRH, there are significant evidence gaps on providing SRH services in the context of UHC, and there is particularly limited evidence on the effectiveness of different financing mechanisms (e.g., community-based health insurance, cash transfers, changing OOP or user fees, results-based financing and social protection programs working with vouchers). There is a need to build the evidence base on financing a comprehensive range of SRH services in a health benefit package, on the implementation of strategic purchasing, and on engagement with the private health sector. The evidence brief concluded that tax-funding health services to provide free key services may be more appropriate than giving exemptions.¹⁴⁰

A study conducted in 2017 in Latin America and Caribbean countries examined family planning services within social health insurance schemes and demonstrated these services have been relatively well-integrated into UHC-oriented schemes. Enrolment in government supported insurance schemes was associated with improved access to and uptake of modern family planning methods, and, among the poorest quintile of women, insured women had a modern contraceptive prevalence rate 16.5 percentage points higher than those that were uninsured.¹⁴¹

Another study, carried out in seven countries (Ethiopia, Ghana, Indonesia, Kenya, Kyrgyzstan, Nigeria and The Philippines) in 2018, concluded that despite the formal inclusion of family planning services in national benefits packages, issues such as unauthorised fees, lack of capacity, and limited political will, have limited the availability of family planning services in practice. The study report furthermore mentioned that inclusion of family planning supplies in insurance schemes remains challenging because of the lack of supplies, and included the example of Indonesia, where poor supply chain management was noted.¹⁴²

Ghana is in the process of including access to a wide range of modern contraceptive methods in the National Health Insurance Scheme (NHIS) benefit package. To warrant good results from an expanded benefit package it is important to ensure broad coverage, particularly amongst the informal sector and poorest population. In Peru, Honduras and Guatemala, OOP spending for family planning remained substantial despite the inclusion of family planning in health benefit packages. This implies that complementary strategies are needed.¹⁴³

Generally, KIIs confirmed the key findings of the literature review and brought a few new insights. Most interviewees acknowledge that the donor community has not (yet) been very successful in supporting countries to increasing domestic resources. For many years, all RHCs were provided for free to the supported

¹³⁹ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹⁴⁰ <https://apps.who.int/iris/bitstream/handle/10665/331113/WHO-SRH-20.1-eng.pdf?ua=1>

¹⁴¹ <https://www.ghspjournal.org/content/5/3/382>

¹⁴² http://www.healthpolicyplus.com/ns/pubs/10253-10458_FPUHCRReview.pdf

¹⁴³ <https://blogs.worldbank.org/african/taking-stock-financing-family-planning-services-to-reach-ghanas-2020-goals>

countries, and only recently discussions emerged on co-financing and other conditions for receiving governments to fulfil their obligations to make RHCs available in their countries (e.g., strengthening their health systems, ensuring last mile delivery, allowing for free choice, and assuming the responsibility to allocate domestic resources for the procurement of RHCs). One interviewee referred to the costs for clearance of RHCs procured abroad by donors; these costs can be relatively high and are usually absorbed by the receiving countries (as per prior arrangements or not). This is also a form of domestic funding, but it is unclear to which extent this is included in calculations and expenses tracking.

Some interviewees were sceptical about the effectiveness of advocacy to increase investment in RHCs by governments in LMICs, as they believe many other factors play a (more important) role in decision making on budget allocation by governments. Nevertheless, successes were also reported, e.g. Burkina Faso has been investing at least USD 1 million in RHC procurement each year since 2009.

Issues on procurement processes and quality standards for the commodities to be procured were also raised by interviewees. Countries make their own choices; for procurement with domestic funding the country's regulations and procedures have to be followed, including for quality standards. However, cases of procurement of inferior quality commodities with donor funding have been reported. For countries starting procurement of RHCs with domestic resources, UNFPA Supplies recommends the use of Third-Party Procurement (TPP) services to ensure commodities of assured quality are procured. Countries make their own decision whether or not to follow this recommendation, which comes with a cost. UNFPA Procurement Services charge 5% administrative fee for non-UNFPA clients.¹⁴⁴

The BMGF supports efforts to track resources to obtain a better understanding of the costs of RHCs. It uses different sources such as Countdown 2030 and costing studies for SRH conducted by UNFPA and others. Their intention is to develop better instruments for adequate tracking and data analysis.

Free dispensing of RHCs to the population comes with another challenge that is, to a certain extent, also linked to domestic resources. Almost all interviewees (from global, regional and country level) emphasised that, although supply chain arrangements and conditions at central and regional/district level are improving, last mile distribution remains a major challenge in most countries they work with. Reportedly, the fact that RHCs are dispensed free of charge is likely to contribute to this, particularly in countries with a cost recovery system where health facilities sell medicines. The small revenue obtained through sales contributes to payment of handling and transport from the district or province. In addition, this revenue provides incentives to maintain sufficient stocks. However, if commodities are provided free of charge, there is no source of income and incentive to cover handling and transport of these commodities, unless the government or donors compensate for these costs.

¹⁴⁴ We assume the fee is calculated on the cost of the goods but this is not clearly described (<https://www.unfpaprocurement.org/budget-planner>)

2.5.1.4 Sub question 3d – Impact of interventions by INGO's

Sub question 3d:

What is the impact of interventions by INGO's (PSI, MSI etc) on the availability of RHCs, and which interventions implemented by INGOs to increase availability of RHCs could be supported by the Netherlands?

The literature reviewed did not provide an answer to this question, nor did the KIIs. A considerable number of interventions are described and discussed, but their impact is either not measured or results obtained and measured through independent studies are not presented in the public domain.

Social marketing has played an important role in RHC availability since many years and is currently subject of discussions and debate. In this section we first provide an overview of the main activities of the two leading INGOs in social marketing (PSI and DKT International),¹⁴⁵ and then summarise the latest deliberations on social marketing in the RHC space. Information for this section was obtained through searches in the public space (mainly on the websites from PSI and DKT International and a recent publication on the transitioning from DKT towards a social enterprise) and through KIIs.¹⁴⁶

Population Services International (PSI)

PSI, established in 1970, is a global not for profit organisation, and is currently active in more than 50 countries including several in West Africa. In its early years PSI focused on family planning but has expanded to a broad range of areas including HIV, malaria, non-communicable diseases and sanitation. An important pillar of PSI's work is the use of commercial marketing strategies. Main donors include the United States, United Kingdom, Germany, and the Netherlands; the Global Fund; United Nations agencies; private foundations; and individuals. In the RHCs space, PSI primarily plays a role in market shaping, contraceptives provision through different channels, including social marketing and franchising, and influencing global and national priorities (e.g., for UHC, resource mobilisation). The overall aim is to support the achievement of the FP2020's goal.¹⁴⁷

PSI has been involved in social marketing since its establishment, but has noted, since 5 or 10 years, decreasing interest from donors to fund RHCs for this approach. Their global budget for donated commodities decreased considerably over the last years, which is, according to PSI, related to the following general opinions among donors: preference for free distribution, non-sustainability of the model in many LMICs, and the (perceived) undercutting of the private market by social marketing.

PSI implements global programs as well as country specific programs.¹⁴⁸ Other interventions include product development (e.g. the creation of a low-cost IUD inserter to facilitate postpartum IUD insertion), product promotion and introduction of new products (SILCS diaphragm - a non-hormonal and reusable barrier contraceptive, levonorgestrel intra-uterine system (LNG-IUS), a popular LARC in the US and Europe).

PSI considers health insurance as an opportunity to implement its social franchising models and collaborates with PharmAccess to support private providers to invest in their own clinics and linking them to the insurance schemes. PharmAccess is a Netherlands based organisation focusing on affordable health care

¹⁴⁵ Other important international organisations active in social marketing are Marie Stope International (MSI) and the International Planned Parenthood Federation (IPPF). At country level several national NGOs are involved.

¹⁴⁶ It should be noted that we conducted an interview with PSI but not with DKT International. The study's TOR did not allow to interview all stakeholders in the RHC space

¹⁴⁷ <https://www.psi.org>

¹⁴⁸ <https://www.psi.org>

through mobile technology.¹⁴⁹ In most (low and middle income) countries, contraceptives are not yet included in the health insurance schemes.

In several countries (e.g., Zimbabwe, Kenya), PSI uses an adapted version of District Health Information Software (DHIS) tools to compile and analyse data collected through PSI supported projects which ensures alignment with government systems that are based on the DHIS open source software. The PSI DHIS includes data from social franchise clinics and from a limited number of private sector clinics with whom PSI have agreements for data sharing. Plans exist to expand the use of DHIS to countries in West Africa (including Sahel) in a next phase.

DKT International

DKT International, established in 1989, is a not for profit organisation working on family planning and HIV/AIDS prevention. DKT International has a strong focus on the private sector and entrepreneurship in most of its interventions. It has offices in 24 countries, and a sales presence in 60 countries. In West Africa, DKT International has an office in Ghana that covers Anglophone West Africa, and country offices in Cameroon and Côte d'Ivoire. Since 2015, DKT International has been operating in Francophone Africa through a regional platform and sells condoms and RHCs in Senegal, Burkina Faso, Cameroon and Côte d'Ivoire. The regional approach was chosen as it decreases the required financial resources as compared to in-country presence, and benefits from the common language, culture and regulatory requirements.

Currently, DKT International covers up to 70% of its operating costs through revenue from sales from products and services, making the organisation less dependent on donor funding and more autonomous.¹⁵⁰

The current debate on social marketing

Social marketing is challenged. Organisations involved sense a certain donor fatigue: enthusiasm to fund social marketing is decreasing, and questions are raised on the sustainability of the model. PSI and DKT International note a decreasing interest from donors to fund RHCs for this approach.

Stakeholders we interviewed were generally positive about the results that can be achieved through social marketing. It is not the solution for all availability issues, but it provides opportunities to engage the private sector and to increase availability through this channel. Successes however vary from country to country, and there is no consensus about the (measured) impact of this intervention. Study results are mixed and it is believed that this is influenced by the different methods used for evaluations, of which some might not be adequate to measure impact of social marketing programs (e.g. studies that compare free distribution and social marketing).

Using attractive packaging and appealing communication, social marketers have been successful in generating demand, creating markets and increasing availability of good quality commodities at affordable prices. Through social marketing channels different users are reached than through the traditional public and private sector - users that probably would otherwise not have been reached at all (e.g. sex workers working in night clubs and bars; anonymity is important for this group, and they might therefore avoid the public sector where anonymity and privacy is not always evident). Issues such as privacy and convenience (e.g., location and opening hours) play an important role for users in their decision where to obtain their contraceptives, and social marketing pays attention to these issues.

Concerns are however also expressed. For the social marketing model to be sustainable, a certain purchasing power of the population is required. This applies to a few countries in Sub Saharan Africa (e.g. South Africa), countries in Latin America and in Asia. In these countries, social marketers can make a healthy profit, and become independent of donor funding. In countries without such level of purchasing power, it remains a

¹⁴⁹ <https://www.pharmaccess.org>

¹⁵⁰ <https://www.dktinternational.org/about/>

challenge for social marketing organisations to generate sufficient turnover to be able to operate independently in the near future.

Therefore, in many West African and several other Sub Saharan African countries additional (donor) funding is required to pay for the expenses not covered by sales. Organisations like PSI and DKT International are currently looking at options to expand commercial models and establish social enterprises that allow to cover these costs.

A recent publication on the transitioning of DKT International from '*charity to social enterprise*' describes the main changes that enabled DKT International to become less donor dependent. These include cost recovery (e.g. charging slightly higher prices while maintaining affordability) and cross-subsidisation strategies (e.g. price segmentation through which profits from higher priced products could be used to offset subsidies for lower priced products)¹⁵¹ that allowed to serve different populations (in different market segments) and generate revenues from these sales that could cover the cost, and in some countries even generated some profit. Facilitating factors included the increased interest from customers to purchase DKT International products (e.g., because of their reputation and availability), higher incomes in several countries in the South and consequently increased ability and willingness to pay for contraceptives, and decreasing prices of contraceptives over the last 30 years as a result of a larger number of manufacturers. In all countries, new models explored and implemented are geared towards entrepreneurial types of social marketing in order to become independent of donor funding. The publication identifies as main success factors the application of innovative financing mechanisms and a balanced mix of staff (covering experiences from different sectors).¹⁵²

Also, PSI is considering new strategies for income generation in order to become less dependent on donor funding. An important change taking place is the use of a unique brand in a certain region, rather than country specific brands. This reduces costs considerably and is in line with the way pharmaceutical companies operate. Information provided on the website of DKT International points in the same direction.

Critics of the social marketing model argue that social marketing is undercutting the market, particularly the private sector. Others however argue that currently there is enough space in the contraceptive market for all types of sales, including for social marketing; different sectors can easily co-exist. Also, interviewees argue, the private market aims to maximise profit, whereas social marketing is mainly interested in volume share. A manufacturer interviewed noted social marketers succeed in generating demand and investing in the market but are limited in their activities because of the funding arrangements. One interviewee brought up the fact that subsidised commodities limit the potential for the private market to develop. Issues were also raised about the type of users of the subsidised commodities. These are in many countries not necessarily the people who need them most, but people with a certain ability to pay.

A Total Market Approach, currently applied in many countries, helps to understand the market and its players and supports productive involvement of all these players in order to increase availability of RHCs in a sustainable manner.

Interviewees also pointed to other issues related to donor dependency; every time a project ends there is a risk of stock out because of interrupted funding, and in some occasions the brand changed with the change of funding. Branding is an important pillar of social marketing. Sales can decrease considerably if the brand to which users are accustomed and attached to is (temporarily) not available. This applies particularly to

¹⁵¹ The principle of cross-subsidization is based on the use of revenues earned from products sold at a higher prices to offset subsidies on other products or for other parts of program operations.

¹⁵² Purdy, C. How One Social Marketing Organisation Is Transitioning From Charity to Social Enterprise. Sage Journals. April 2020. DOI: 10.1177/1524500420918703

condoms. Local social marketing organisations are therefore eager to establish their own brands and a stable supply that could ideally operate independently from donor funding.

With the current changes noted in the social marketing space the role of social marketing organisations becomes somewhat blurred. Apart from acting more like a social enterprise which must be financially autonomous and independent in order to survive, some are also moving more towards service delivery where their status is not fully clear (private, public, or hybrid). In the (near) future it will be important for these organisations to define what type of organisations they are or will be, how they can be financially sustainable, and which (new, additional) role they can play in commodity and/or service provision (e.g. provision of LARC that require a service in addition to the provision of a commodity only).

We list general interventions that potentially could be interesting for the Netherlands in Annex 6 (Volume II).

2.5.2 SUMMARY STUDY QUESTION 3

There is no consensus on which interventions contribute to increased availability of RHCs. General descriptions of the broad range of existing projects and (pilot) interventions are available, but the body of evidence about the results and impact of these projects and interventions remains limited. Without in-depth understanding of why an intervention works or not in a certain context, its replication or scaling may not be successful. Scaling up of successful (small) pilot interventions is stated as a major undertaking requiring considerable investments.

From our assessment based on available literature and interviews the most promising interventions include:

- The Informed Push Model as successfully implemented (and evaluated) in Senegal. It involves a collaboration of public and private sector that managed to achieve a stable supply of RHCs in the public sector. The model is being implemented in other countries as well, for RHCs and for other medicines and health commodities (e.g., Zambia).
- The Prime Vendor System which is implemented in several countries (e.g., Tanzania). It involves contracting of a private supplier where public sector actors can purchase medicines and health commodities in case of stock out in the public sector.
- Online sales of a range of health and personal hygiene commodities, including family planning supplies, through social enterprises. It involves online platforms through which commodities can be ordered. Orders are either delivered to doctor's offices (e.g. Doctorstore in India), at end-user's homes or at pick up locations (e.g., Kasha in Rwanda and Kenya, MYDAWA in Kenya)
- Sales of commodities by Community Health Promoters (in Uganda), Village Midwives (in Indonesia) and similar professionals in several other countries showed increased availability of key RHCs at the end-user level and promising results for health outcomes.
- Co-financing as implemented by GAVI and the Global Fund has the interest of the RHCs community, but it is still in its early stages. As donor funding is decreasing, there is pressure on countries to increase domestic resources which will require changes in the current financing systems for RHCs.

Volume guarantees are still being negotiated but seem controversial; after the initial successes (e.g., lower prices, additions to the method mix), doubts have risen about long-term consequences including a weakening of the vulnerable market. Other interventions are being explored such as long-term agreements that focus on long term commitments rather than volume guarantees, but no consensus exists on what the best approach is.

Interventions that have facilitated innovation at product level and for last mile distribution could not be identified.

Social marketing is under pressure; questions and doubts related to its sustainability are raised, and funding is decreasing. But the RHCs community is divided and strong promoters continue to believe in the strength of social marketing. Meanwhile social marketers are exploring approaches that would provide sufficient revenue to cover (a larger part of) the costs related to a non-interrupted supply chain for subsidised commodities. With pressure for cost reduction, strong regulatory bodies are required to ensure all commodities provided to the population comply with (inter)national standards.

The lack of opportunity for health facilities to generate revenue for medicines/health commodities that are dispensed for free affects their last mile distribution unless governments and/or donor agencies provide the necessary funding.

2.5.3 STUDY QUESTION 4 – PRIVATE SECTOR

2.5.3.1 Overarching question 4 – Main vulnerabilities, risks and barriers of the private sector for RHCs

Study question 4 – overarching question:

What are the main vulnerabilities, risks and/or barriers of the private sector for RHCs?

The private sector plays an important role in the RHC landscape, covering a broad range of actors. We found literature about manufacturers at global level, and distributors and service providers at the national level. Information obtained through KIIs is incorporated in the sections below.

Global level

Both literature review and KIIs confirm that the RHC market is fragile and delicate; it is fragmented, the number of manufactures of quality assured products is limited, and visibility into and transparency of the market is low. The unanticipated withdrawal of Pfizer, Merck, and Daré for some commodities in 2019 is an example for the uncertainty of this market, causing stock outs and nervousness in the RHC donor community.¹⁵³ Furthermore, there is a limited number of procuring entities for RHCs for the public sector, mainly USAID and UNFPA, who have a strong market position with much power and influence.

The number of products that comply with the required quality standards (WHO prequalification for UNFPA and approval from the Food and Drug Authority/other stringent regulatory authority/UNICEF for USAID) is limited. We were informed by an interviewee that, when Pfizer had to interrupt production of DMPA, alternatives were limited. One of the alternatives was registered in only few countries, and another alternative was registered in several donor dependent countries, but this commodity was not prequalified.

Several commodities have many suppliers but the products of only a few are prequalified by WHO. Prequalification of the API is also of concern; for mifepristone for example, a commodity used for medical abortion, three products are prequalified, but only one API source, which makes the market very vulnerable.¹⁵⁴ Several manufacturers use the same raw material source, and in case of failure of this supplier the production of most manufacturers will be affected.

The increase of the number of prequalified commodities depends on the manufacturers' interest and capacity to apply for prequalification of their products, and to invest in the required quality improvements. The cumbersome, lengthy and costly process to obtain WHO (or SRA) prequalification discourages many manufacturers from embarking on this process.

Manufacturers interviewed noted that most donors require products to be WHO prequalified yet do not provide any guarantee for business for these products. WHO prequalification also does not automatically

¹⁵³ We have not been able to obtain information on the commodities concerned.

¹⁵⁴ The limited number of WHO prequalified API sources is a general problem in the pharmaceuticals market.

provide access to countries' (private) markets since at country level registration is required. Despite ongoing attempts and efforts, harmonisation of registration requirements and procedures in the African region is progressing slowly, which implies registration usually has to be obtained for each country where the manufacturer wants to sell its products.

Interviewees furthermore draw attention to the common perception among manufacturers that family planning commodities are low profit commodities and therefore not attractive. They added that in many – mainly donor dependent – countries commodities offered by the private sector have to compete with those provided for free in the public sector, and those subsidised for social marketing. Once commodities are offered for free or sold at a subsidised price, it becomes difficult to charge prices allowing maintain a sustainable business.

In addition to the challenges faced by manufacturers to obtain WHO prequalification, compliance with country regulation is said to be subject to obstacles and delays as well. When more countries will conduct procurement in the future due to the decline in donor funding and the related increase of domestic funding for RHCs, the need for a quality framework to control non-WHO prequalified products becomes a priority. The ideal framework should be able to assure quality of RHCs without putting an additional 'burden' on manufacturers. Protocols and tools for quality assurance for products that are not WHO pre-qualified developed by a group of NGOs is considered an important step towards a full quality framework (e.g., MSI QARMA matrix).¹⁵⁵¹⁵⁶

Interviewees noted that investments (recent and expected) for innovator products are limited, which affects the possibilities to strengthen the market through the availability of a wider range of products in the short term. It would therefore be unlikely that the variety or products available will considerably change at short to medium term.

Many stakeholders are aware of the vulnerability of the market and undertake efforts to diversify the manufacturing base for the main contraceptives and to improve commodity security. Meanwhile, Mylan has recently been acquired by Pfizer which reduces the supplier base.¹⁵⁷ Merck/MSD on the other hand announced the splitting-off of their women's health unit to become a new company with the working name 'NewCo'.¹⁵⁸

Country level

At country level the private sector for RHCs becomes increasingly important. Although the situation varies per country, globally more people are obtaining their family planning supplies in the private sector, including the social marketing sector. The RHSC Gap Analysis of 2019 estimates that over 40% of family planning users in LMICs get products through the private sector. The private sector is often preferred to the public sector because it is more flexible and convenient (e.g., longer opening hours, suitable locations, provides more privacy for users, and a larger variety and better availability of supplies).¹⁵⁹ Youth and adolescents are among the main clients of the private sector.

In many countries however, the challenges existing in the private RHC market limit its unique possibilities and leaves existing opportunities largely unexploited. An important challenge to develop a healthy market for RHCs is related to free dispensing to the population through the public sector and the distribution at

¹⁵⁵ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁵⁶ The study team did not find updated information on this tool in the public domain.

¹⁵⁷ https://www.pfizer.com/news/press-release/press-release-detail/mylan_and_upjohn_a_division_of_pfizer_to_combine_creating_a_new_champion_for_global_health_uniquely_positioned_to_fulfill_the_world_s_need_for_medicine

¹⁵⁸ <https://www.mrknewsroom.com/news-release/corporate-news/merck-focus-key-growth-pillars-through-spinoff-womens-health-trusted-leg>

¹⁵⁹ PATH. How can we accelerate women's access to beneficial innovations, and keep learning? The ongoing story of subcutaneous DMPA and self-injection. November 2018

subsidised prices (usually through social marketing). This type of dispensing and distribution may distort the existing market and inhibits its development assuming private sector actors are not interested to invest in commodities that are available for free to the population through the public sector.¹⁶⁰

Unless the private sector gets a more sustainable role in RHCs, it will be difficult for the market to mature. Yet, the private sector is needed to ensure RHCs become and remain available to people who need and want to use them, and a common approach to free distribution of RHCs will therefore be required. Options could include incorporating RHCs in national insurance packages so that the products can be provided for free or at subsidised prices through the private sector, who will then be refunded by the insurance scheme. Such options require a shift of donor funding from products to system strengthening (in this case, national health insurance).

While private sector may have less interest in commodities that can also be obtained for free through the public sector, price is not the only factor that determines where the population obtains RHCs. There are several reasons why people prefer to pay for medicines/health commodities in the private sector: privacy, opening hours, service, availability, trust, and branding of products (which is confirmed by social marketing interventions).¹⁶¹ For the private sector however, keeping stock of medicines/health commodities that are available for free in the public sector involves a higher risk; demand is partially influenced by the performance of the public sector, i.e. its ability to ensure uninterrupted RHCs availability, something the private sector has little influence on.¹⁶²

Literature reviewed (mainly the Ecosystem 2030 report) and KIIs provided important insights in the complexity of the private market at country level. We list the main challenges and issues below:

- The private sector is highly fragmented, and the different actors are not well organised, making them a difficult partner to work with for the public sector.
- The level of development of the private sector in medicines and health commodities provision varies considerably among countries, and in some countries, the capacity of the formal private sector remains limited. Reasons include challenging commercial environment (e.g. high taxes), and low purchasing capacity of the population.
- The private sector is not sufficiently involved in the national or local health systems, which provides challenges in two ways. First, private sector actors do not know what is expected from them, and how they can play their role, and second, the public sector does not have access to crucial data from the private sector (e.g., on users, consumption, demand). At the same time, many governments have a certain bias for the public sector; they feel they lack control and visibility of the private sector.
- Clear and easily implementable regulations for private sector providers are often lacking, and the legislative framework has been unpredictable in some countries making long term investments unattractive. For example, as soon as sufficient stocks were available in the public sector, the government of Burundi decided not to approve import authorisations for oral contraceptives anymore which negatively affected the private sector having made investments for these commodities.¹⁶³

¹⁶⁰ Pharos Global Health Advisors. Transitions in Family Planning: Challenges, Risks, and Opportunities Associated with Upcoming Declines in Donor Health Aid to Middle-Income Countries. 2019

¹⁶¹ Share-Net International. Getting to know each-other Private sector engagement in improving Sexual and Reproductive Health and Rights in developing countries

¹⁶² This information is based on the study team's own experience and information gathered through previous studies, but could not be supported by literature under the scope of this study.

¹⁶³ Vreeke, E. Sexual and reproductive health: a market scan in Burundi. October 2019

- Negotiated or reduced prices with big international suppliers make the market unattractive for small(er) suppliers, thereby limiting competition and thus opportunities to create a healthy market.
- Obtaining registration with the national medicines regulatory authorities is a hurdle; procedures are expensive, complex and time consuming, and vary per country. Several stakeholders support the harmonisation of regulatory requirements and procedures among countries in the same region, and while initial results are being achieved, full harmonisation is a lengthy process. Long-term joint efforts to strengthen regulatory bodies in LMIC start to pay off, and it is noted that these bodies are becoming stricter. In the initial phases of the strengthening process, processing times for registration applications may be longer than in the past.
- In some countries, in addition to national registration, the product needs to be included in the National Essential Medicines List (NEML) to make it available on the national market. Committees exist within the MOH to establish and review the NEML. Its content is generally guided by the WHO Model Essential Medicines List.¹⁶⁴
- Private sector providers lack information on pricing, and their volumes are often too small to allow for strong negotiation with their suppliers.¹⁶⁵
- Private sector wholesalers or distributors often have limited access to foreign currency, limiting their possibilities to procure abroad.¹⁶⁶
- The small size markets of many LMICs and the related limited volumes are not attractive to local distributors, yet most manufactures want or have to work with them. Distributors or wholesalers in small markets often lack the supportive marketing and educational materials to attract customers and achieve sales targets.
- Procurement procedures from national procuring entities, central medical stores or similar, are lengthy and complicated and involve financial risks for manufacturers or other suppliers interested in doing business directly with countries. National suppliers are most likely acquainted with these procedures and have aligned their own processes to meet the criteria imposed by the procuring entities. With increasing domestic financing, it is expected that more countries will conduct procurement through government entities. Considering the challenging procurement procedures, commodity costs might increase because of higher margins applied by manufacturers to compensate for order handling and financial risks. For manufacturers it is easier and more attractive to trade with UNFPA Supplies, USAID or the large INGOs.

Involvement of the private sector in in-country public health supply chain management is a longstanding discussion. Collaboration between the private and public sector has shown positive effects on the efficiency and overall performance in some countries (e.g., Senegal, Zambia), but stakeholders remain reluctant. Criticism includes that through private sector involvement governments miss opportunities to strengthen the public systems, and that governments often mistrust private sector and are not willing to give up control. Private sector actors on the other hand would not find governments reliable partners.¹⁶⁷ For adequate collaboration between public and private sector actors, strong national stewardship to oversee the supply chain is indispensable.¹⁶⁸

¹⁶⁴ Briggs J, Embrey M, Hedman L, Requejo J, Maliqi B. How to assure access of essential RMNCH medicines by looking at policy and systems factors: an analysis of countdown to 2015 countries. *BMC Health Serv Res.* 2018;18(1):1–12.

¹⁶⁵ Vreeke, E. Sexual and reproductive health: a market scan in Burundi. October 2019

¹⁶⁶ Vreeke, E. Sexual and reproductive health: a market scan in Burundi. October 2019

¹⁶⁷ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁶⁸ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

It should also be taken into consideration that in relation to commodity security the private sector has a different role to play than the public sector; the public sector has an obligation to ensure availability of essential medicines and health commodities for its population (value-oriented), wherever this population lives. The private sector however usually provides medicines and commodities where sales opportunities are presented (profit-oriented); as a consequence, the private sector will be active in those regions where profit can be made, and will offer those products that will generate profit.¹⁶⁹

2.5.3.2 Sub question 4a – Possible support to the development of private market for RHCs

Sub question 4a:

How can the Netherlands support the development of a sound private market for RHCs considering the present vulnerabilities, risks and barriers?

Despite some criticism and doubts, there is consensus that in order to improve availability of RHCs the collaboration between the public and the private sector has to be intensified. This can be achieved in different ways.

The literature reviewed describes several activities that have the potential to contribute to the development of a more robust private market, mainly at country level. KIIs provided valuable views from stakeholders on what they consider useful interventions to increase RHC availability. We list the most promising and feasible ones that are in line with Dutch policies (e.g., promoting equal access). Many of the interventions listed below cannot be implemented by the Netherlands alone and should be placed in the existing collaboration framework, e.g. membership of RHSC or UNFPA Supplies. In section 4 we provide policy options with relevant reasoning.

Global level

- Support the WHO prequalification mechanism to review current processes that are perceived as being cumbersome and expensive.
- Support manufacturers financially to obtain WHO prequalification.
- Contribute to a healthy price competition, and avoid that reduced/negotiated price arrangements by big projects or procurement agencies make it impossible for competitors to compete.¹⁷⁰ This intervention can be linked to the Fair Pricing Forums conducted in 2017 in the Netherlands and in 2019 in South Africa that have as objectives *to share experiences on regulatory and non-regulatory measures to achieve 'fair' prices for medicines and health commodities; explore tools and approaches that could support affordable and sustainable pricing; and identify areas of actions to support countries to achieve fairer pricing.* The next forum is scheduled for 2021, and different working groups will be established to prepare for this forum.¹⁷¹¹⁷²
- Support current efforts to harmonise registration procedures through existing initiatives such as the WHO Collaborative Procedure for Accelerated Registration, and the SRA Collaborative Procedure. The WHO Collaborative Procedure is a collaboration between WHO and national regulatory authorities to facilitate accelerated national registration of WHO prequalified pharmaceutical

"... this wide range of market problems is something that we can try to address comprehensively, rather than through a lot of individual and fragmented investments.... "

Key informant

¹⁶⁹ This information is based on the study team's own experience and information gathered through previous studies, but could not be supported by literature under the scope of this study.

¹⁷⁰ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁷¹ https://www.who.int/medicines/access/fair_pricing/en/

¹⁷² Fair Pricing Forum 2019 Meeting Report. Geneva: World Health Organisation; 2019. WHO/MVP/EMP/IAU/2019.09 Licence: CC BY-NC-SA 3.0 IGO.

products. The pilot started in 2012, and at the end of 2017 national medicines regulatory authorities of almost 30 countries participated; 257 products were registered of which 26 RHCs (e.g. Sayana Press).¹⁷³¹⁷⁴

- Review quality assurance strategies and protocols so that quality of the commodities is safeguarded without discouraging manufactures and importers because of heavy and costly procedures and unreasonable requirements.¹⁷⁵ This intervention can be implemented at country level, and at global level with the objective to develop a common quality framework.

Country level

- Reduce barriers related to regulation and policy for private sector actors (e.g., facilitate registration processes, lift procurement restrictions that prohibit procurement of abortion supplies by government institutions, reduce taxes and tariffs, conduct price control).¹⁷⁶¹⁷⁷ In Jordan for example, The Jordanian Association for Family Planning and Protection successfully lobbied to ease regulation for the family planning market and decrease fees for contraceptives provided by the private sector. This resulted in removal of all taxes, duties and tariffs on imported contraceptive commodities, except for intrauterine devices.¹⁷⁸¹⁷⁹
- Subsidise private sector distributors and service providers that reach particular populations and/or populations that are not reached through the regular channels of the public sector.¹⁸⁰
- Support country governments in their role of stewardship. Strong public stewardship is required to regulate involvement of private sector actors in different areas of RHCs. This will eventually facilitate inclusion in the national and local health system for particular interventions such as provision of family planning services in areas or for populations that are not easily reached by regular public health services.¹⁸¹
- Support private sector service providers to organise themselves better and become a reliable partner in the national and/or local health system. Organisations such as national federations, associations of private practitioners, and associations of pharmacists could be potential institutions to act as umbrella for this sector. Several examples exist of collaboration between public sector and private sector organisations (e.g., councils, associations):
 - In Malawi, the National Private Paramedical Practitioners Association of Malawi (NAPPPAM), collaborates with the Medical Council who is responsible for registration and licensing of private (service) providers for training of private sector providers, verification of credits reported by these providers and required for registration, and development of quality standards of social marketing and social franchising networks.
 - In Malaysia, the Association of Private Hospitals and the Malaysian Medical Association, through the Malaysian Society for Quality in Health, are mandated by the MOH to accredit

¹⁷³ WHO. WHO PQ Collaborative Registration Procedure and SRA Collaborative Procedure. Orientation for Assessment Session. November 2017

¹⁷⁴ <https://www.tmda.go.tz/programs/hamornization-and-international-collaboration>

¹⁷⁵ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁷⁶ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁷⁷ USAID/SHOPS Plus. Stewarding the Private Sector for Family Planning. January 2019

¹⁷⁸ USAID/SHOPS Plus. Stewarding the Private Sector for Family Planning. January 2019

¹⁷⁹ Intrauterine devices were excluded based on their categorization as a non-pharmaceutical product

¹⁸⁰ Riley C, Garfinkel D, Thanel K, Esch K, Workalemahu E, Anyanti J, et al. Getting to FP2020: Harnessing the private sector to increase modern contraceptive access and choice in Ethiopia, Nigeria, and DRC. *PLoS One*. 2018;13(2): e92522.

¹⁸¹ USAID/SHOPS Plus. Stewarding the Private Sector for Family Planning. January 2019

public and private health facilities. The Society also supports facilities to comply with the quality standards.¹⁸²

- Generate knowledge about the reasons why people prefer to use the private sector to obtain their supplies in order to adapt strategies and policies accordingly. Private sector actors have access to market data and information that can be useful to the public sector decision makers (e.g., understanding the role of pharmacies or drug stores, the type of clients they serve, supply preferences of their clients). Current knowledge indicates that reasons differ between and even within countries, and therefore studies have to be conducted at country level.¹⁸³ The ultimate goal should be to understand how the private sector can contribute in the best possible way to increase availability of RHCs for all different population groups, and how to create synergies between the different providers.
- Support total market approaches (TMA). Different definitions and methodologies exist for TMA which is a tool used by a variety of organisations working on health in general, and RHCs in particular. The tool allows for exploring options for involvement of all sectors to provide health services to the population. For RHCs this generally means governments and donors meet the needs of those with few financial resources, while the private sector provides products and services to more prosperous segments of the population. The process involves an analysis to better understand the contraceptive market (e.g., use, unmet needs by age, gender), who are the groups not reached through the common channels, and how contraceptives can be made available to these groups. Various tools exist to guide government, nongovernmental, and private-sector actors through the development of national TMA plans.

2.5.4 SUMMARY STUDY QUESTION 4

The RHC market is a challenging market with few manufacturers and few buyers. Main challenges for manufacturers include difficulties to comply with the buyers' quality standards (WHO prequalification requirement) and mandatory registration in most countries, processes that are cost and labour intensive.

In recent years several market shaping interventions (e.g. volume guarantees) have been implemented by key actors in an attempt to create a healthier market that supports the availability of RHCs. As a result, the family planning supplies method mix increased in many countries, but there has also been criticism of this approach and some even say that it has made the market more vulnerable. Manufacturers lost appetite to enter the market because of the low prices paid and because existing agreements limited their business opportunities.

At country level, the private sector is not well organised and its participation in the national or local health system remains limited for different reasons (e.g., lack of market information, unclear requirements). Nevertheless, consensus exists that the private sector should be more involved to ensure all future needs can be met.

The following interventions to strengthen the private market at country level could be considered:

- Improve public stewardship required to involve the private sector in health systems in an efficient and sensible way
- Support the TMA to obtain an in-depth understanding of the market and identify opportunities to make use of the different sectors to reach different users

¹⁸² USAID/SHOPS Plus. Stewarding the Private Sector for Family Planning. January 2019

¹⁸³ USAID/SHOPS Plus. Stewarding the Private Sector for Family Planning. January 2019

- Explore collaboration with relevant private sector institutions such as national federations, associations of private practitioners, and associations of pharmacists; these, when well organised, can act as focal point for the private sector and in that role facilitate collaboration with the public sector

Limited written information is however available on the results of such interventions.

2.5.5 STUDY QUESTION 5 - MAIN PLAYERS IN RHCS PROCUREMENT AND TECHNICAL ASSISTANCE

2.5.5.1 Overarching question 5 – Main players in procurement and technical assistance

Study question 5 – overarching question:

Who are the main players in RHCs procurement and technical assistance in public and private sector?

Main players in procurement

In the public sector, there are 2 main buyers of RHCs: USAID and UNFPA Supplies. Together they procure 97% of donor funded supplies, and because of the large volumes they procure, they managed to negotiate low prices.¹⁸⁴¹⁸⁵

Procurement by UNFPA Supplies is conducted by the UNFPA Procurement Services Branch (PSB). Procurement conducted by UNFPA Supplies for domestic governments or organisations in the not-for-profit sector such as PSI, DKT International, or MSI is referred to as TPP.¹⁸⁶ All procurement departments have to adhere to the UNFPA Procurement Procedures. These procedures, available online, describe in detail the policies and processes for procurement conducted by UNFPA. The guiding principles include maximisation of economy and efficiency, encouragement to broadly share requests for proposal to promote competition, to procure from sources from developing countries, and promotion of integrity and fairness, as well as maintenance of transparency throughout the procurement process.¹⁸⁷

UNFPA Supplies is allowed to procure commodities that are prequalified by WHO, approved by SRA or by the External Review Panel (ERP). For procurement two types of competition are used (open international competition and limited competition), and for contracting of suppliers mainly long-term agreements are used. UNFPA sales prices are available through the UNFPA Supplies price indicator and have decreased or changed only slightly for five of the eight key contraceptives in the period 2013-2016.¹⁸⁸

The Mid-Term Evaluation conducted in 2018 reports that one of the main challenges for the PSB is financing of rapid procurement in case of emergencies; orders can only be placed with the supplier when the funds are on the account of the PSB. More generally, unpredictable funding flows caused several procurement issues in the past, but this challenge has been largely overcome by the establishment of the Bridge Funding Mechanism.

The USAID supply program (Global Health Supply Chain Program/Procurement and Supply Management, GHSC-PSM), currently managed by Chemonics, conducts central procurement for all USAID supported programmes, including for RHCs. All procurement has to comply with contract terms and US government regulations. Chemonics uses open competitive tender procedures. Oral contraceptives, injectables and

¹⁸⁴ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁸⁵ Countdown 2030 Europe. Contraceptive supplies financing: what role for donors? A brief guide. September 2018

¹⁸⁶ In this context, local procurement does not refer to procurement from local suppliers.

¹⁸⁷ <https://www.unfpa.org/resources/procurement-procedures>

¹⁸⁸ UNFPA Evaluation Office. Mid-Term Evaluation of the UNFPA Supplies Programme (2013-2020). 2018

implants have to comply with standards from the US Food and Drug Administration New Drug Application (USFDA NDA) or the Abbreviated New Drug Application (ANDA), be approved by a USAID recognised SRA, or have a WHO prequalification.¹⁸⁹

Since the beginning of the multibillion contract with USAID (April 2015), Chemonics has had various problems in implementing this contract, including decreasing on-time delivery rates¹⁹⁰ and stock-outs in several countries. Mid 2019 the issues were discussed by the USAID inspector general during a House Appropriations State and Foreign Operations subcommittee hearing. The inspector found several risks related to the delivery, but also to storage and record keeping of health commodities, and he confirmed auditing of the current contract will continue.¹⁹¹¹⁹²¹⁹³

The Global Fund is an important donor for condoms. Condoms are procured by the principle recipients of the Global Fund grants who can make use of the Pooled Procurement Mechanism (PPM) which is established by the Global Fund to decrease prices and improve efficiency. Those principal recipients that procure through PPM have access to wambo.org, an online platform that has been established to facilitate procurement processes, to offer quality-assured medicines and health commodities at affordable prices, and to increase visibility. A 2017 audit on the wambo.org platform reports the platform increased transparency for PPM ordering processes and was well received by the users/clients of the platform, but noted improvement is required to meet the project's key objectives.¹⁹⁴ The Global Fund board requested consultations regarding the wambo.org pilot in early 2020, and an evaluation in 2022.¹⁹⁵

Furthermore, IPPF is mentioned as procuring entity.¹⁹⁶¹⁹⁷ Some (national and decentralised) governments and NGOs also procure directly from manufacturers.¹⁹⁸ Countries supported by the GFF are responsible for procurement of RHCs with GFF funding, in line with the WB standards and guidelines, and use different options available to them (e.g., DRC made use of the procurement services from UNFPA, Kenya procured through its central medical stores KEMSA)

In the private sector, the main players are commercial procurement agencies and local distributors and sales agents or representatives of manufacturers.¹⁹⁹

Main players in technical assistance

UNFPA Supplies provides technical assistance for countries to strengthen their procurement systems and supply chains with a focus on the different elements of RHCs procurement and supply management. The UNFPA Supplies 2018 report notes the demand for technical assistance is increasing; the growing use of domestic resources for procurement of RHCs implies that countries have to rely on the national procurement and supply systems which often need to be strengthened or upgraded to absorb the RHCs.²⁰⁰ UNFPA Supplies

¹⁸⁹ <https://www.ghsupplychain.org/for-suppliers/how-to-work-with-us>

¹⁹⁰ On time delivery is an indicator to assess the ability of a business/central medical store in fulfilling the shipment order within the period of promised delivery date.

¹⁹¹ <https://www.devex.com/news/exclusive-chemonics-battles-wave-of-challenges-with-9-5b-health-supply-chain-project-91150>

¹⁹² <https://www.devex.com/news/significant-mistakes-in-usaid-global-health-supply-chain-house-says-93674>

¹⁹³ <https://www.devex.com/news/usaid-should-rethink-its-culture-of-partnership-with-implementers-inspector-general-says-95273>

¹⁹⁴ The Global Fund Office of the Inspector General. Audit report. The wambo.org platform. Progress against business case, key risks and current implementation arrangements. November 2017

¹⁹⁵ <https://www.theglobalfund.org/board-decisions/b42-dp05/>

¹⁹⁶ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

¹⁹⁷ Babazadeh S, Lea S, Kayembe P, Akilimali P, Eitmann L, Anglewicz P, et al. Assessing the contraceptive supply environment in Kinshasa, DRC: trend data from PMA2020. Health Policy Plan [Internet]. 2018 Mar 1;33(2):155–62.

¹⁹⁸ Briggs J, Embrey M, Maliqi B, Hedman L, Requejo J. How to assure access of essential RMNCH medicines by looking at policy and systems factors: an analysis of countdown to 2015 countries. BMC Health Serv Res [Internet]. 2018 Dec 7;18(1):952.

¹⁹⁹ Braddock M., Skibiak J. Creating an effective & sustainable ecosystem for reproductive health supplies by 2030. October 2019

²⁰⁰ UNFPA Supplies. Annual report 2018

does not have sufficient technical capacity in house to provide technical assistance to countries, instead it uses contracting and consultants.

An entity providing technical assistance specifically in RHC procurement and supply chain is the RHSC with its regional partners, such as the ForoLAC in Latin America who supported national procurement officers to obtain relevant and up to date knowledge on prices and procurement strategies.

The study team is aware that there is a range of other organisations that provide support to countries' national procurement and supply chain management systems, including on RHCs, yet no particular organisations were mentioned in the literature and in KIIs. Well-known organisations working in this field are USAID through its different implementing partners (e.g. Chemonics/GHSC-PSM, JSI, MSH), UNICEF, CHAI, and Village Reach who focuses on last mile distribution. Annex 4 (Volume II) provides more information about these organisations.

2.5.5.2 Sub question 5a – Organisations best positioned to align interests of the private sector

Sub question 5a:

Which of these organisations are best positioned to align interests of the private sector (this concerns global manufacturers, local wholesalers and importers of RHCs)?

All the organisations mentioned above involve private sector actors in their work. The literature review and the KIIs did however not provide sufficient information to identify which organisations are best positioned to align interests of the private sector.

Organisations involved in RHCs with longstanding experience in engaging with the private sector are the organisations working on social marketing, of which PSI and DKT International are the main ones. These organisations do however not focus, to our knowledge, on provision of broader technical assistance but on specific assistance related to implementation of their projects.

Several organisations provide technical support to the private sector with regards to WHO prequalification and/or registration at country level. Below we list the organisations referred to us in the KIIs:

- **The Concept Foundation** – The Concept Foundation, an INGO based in Bangkok/Thailand and Geneva/Switzerland, *assists partners with manufacturing, quality certification, registration and market introduction of pharmaceutical products.*²⁰¹ It supported Shanghai Dahua Pharmaceutical Co. Ltd for the prequalification of Levoplant, a long-acting, reversible contraceptive implant also known as Sino-implant (II).
- **WCG** – WCG is an international not for profit organisation supporting women and girls to make informed decisions about their reproductive and sexual health. WCG provides support to manufacturers to register their products through their Global Regulatory Affairs Department. Since 2010, this Department supported registrations for 16 medicines and medical devices in more than 90 countries, and the prequalification program from the WHO. The support focuses on ensuring compliance with changing and diverse regulatory requirements throughout the registration process. WCG collaborates with a variety of actors in the RHCs landscape including USAID, Shanghai Dahua Medical Apparatus Company (China – Woman's Condom), DKT International, and PATH.²⁰²

Another organisation mentioned in an interview is CONRAD. CONRAD, established in 1995, focuses on development of new, safe and effective microbicides, contraceptives, and multipurpose prevention

²⁰¹ <https://www.conceptfoundation.org>

²⁰² <http://wcgcares.org>

technologies. It is active in HIV prevention as well as contraceptives. Regulatory submission is among the capabilities of CONRAD, but this does not seem to be their core business.²⁰³

2.5.5.3 Sub question 5b

Sub question 5b:

Which organisations can facilitate increased availability of RHCs, quality assurance, including registration processes globally and in the Netherlands priority countries?

Organisations that can facilitate increased availability of RHCs

At global level

There is a variety of organisations that work on topics related to increase availability of RHCs at global level (see Annex 4, Volume II), but results from the literature review did not provide us with a clear view on which of these organisations are best positioned to facilitate the increase of RHCs in line with the Netherlands policy.

KII provided some more insights, but none of the interviewees mentioned specific organisations that could provide added value, or organisations that they recommend collaborating with. We think the question might have been too broad; availability has many facets, and the number of players involved may be too large.

Organisations most mentioned both in literature and in KII are the best-known organisations working on mainly operational supply chain management issues as listed in the answer to sub question 5a in section 2.5.3.2 above and in Annex 4 (Volume II).

Several interviewees referred to the RHSC as the platform with most visibility and experience. This platform brings all stakeholders together, and thus also a wealth of knowledge, expertise and skills. Members, whether or not brought together in working groups, can be mobilised for specific topics or questions from other members.

Apart from organisations mentioned thus far that mainly focus on technical assistance or implementation of interventions, the Centre for Global Development (CGD) was identified as an important organisation that focuses on research. CGD aims *to reduce poverty and improve lives through innovative economic research that drives better policy and practice by the world's top decision makers*.²⁰⁴ Several working groups exist of which the following might be of interest for DSO:

- **The Future of Global Health Procurement** – This group explores the future of global health procurement in the changing environment where more countries will become less donor dependent and conduct procurement through national procurement mechanisms. Mid 2019, the report titled ‘Tackling the Triple Transition in Global Health Procurement’ was published. It provides insights in what the working group calls the triple transition (transition from donor aid, epidemiological transformation, and transition in health system organisation) and provides recommendations for reform for more strategic procurement policy and practice.²⁰⁵
- **Alignment in Family Planning** – This group works on themes related to allocation strategies and coordination mechanisms in family planning investments. A recent publication of this working group is the report ‘From Vision to Architecture: Three Questions to Guide the Global Family Planning

²⁰³ <https://www.conrad.org>

²⁰⁴ <https://www.cgdev.org>

²⁰⁵ <https://www.cgdev.org/better-health-procurement>

Movement Towards 2030'. The three main questions addressed are: will new players join the current main partners (BMGF, DFID, UNFPA and USAID), how will resources be mobilised and sustained, and how will mutual accountability become imbedded in family planning interventions?²⁰⁶

An entity that cannot be go unmentioned in a study on RHCs is the Human Reproductive Programme (HRP), the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. HRP, based at the WHO headquarters, plays a key role at global level by conducting research, disseminating results through different channels and supporting LMIC to conduct high quality research. They cover a broad range of topics (e.g., abortion, health systems, maternal and perinatal health). None of the recent and current research addresses topics directly related to RHCs.

In the Netherlands priority countries

Based on the results from the literature review and KIs, we are not in a position to identify names of organisations that could potentially facilitate increased availability of RHCs in priority countries; in-depth knowledge of key players in the different countries is required which is difficult to obtain through literature review and interviews with a selection of mainly global)key informants. We however provide an overview of the type of organisations that could potentially support improved availability of RHCs in their respective countries.

Considering the interest of DSO to explore opportunities to support the last mile distribution, collaboration with or support to civil society organisations (CSO) is considered useful. Such organisations are strong at the lower levels of the health system, where most of the supply chain challenges occur, and have good understanding of the context of the communities they support. Through this knowledge and connections, they can, for example, support community health posts or health facilities with stock management.²⁰⁷

At all levels of the supply chain involvement of youth organisations seems useful; youth represent a large user group and through their understanding of and experience with modern technologies and social media, they can for example facilitate data collection, and increase accountability of public and private service providers.²⁰⁸

Organisations that focus on advocacy can play an important role in the discussion on domestic funding.²⁰⁹ Strong partnership between UNFPA Supplies and the European Parliamentary Forum for Population and Development continued to fuel engagement with parliamentarians from both program country and donor governments on increasing resources for reproductive health, especially commodities, as well as advancing policies for voluntary, rights-based family planning.²¹⁰ Other entities involved in the debate include WAHO, and HRP.

Currently PSI provides some technical assistance to governments, at special request, on topics related to social marketing or the TMA (e.g., branding, development of a consumer profile). PSI however does not provide technical assistance related to distribution of commodities through the regular public health supply chains.

The African Association of Procurement Centres (Association Africaine des Centrales d'Achats de Médicaments Essentiels/ACAME), a membership organisation operating from Burkina Faso with 10 partners, 22 member countries and serving 350 million inhabitants in the region, is a potential partner for DSO for procurement and supply chain related aspects in most countries in West Africa. Its mission is to contribute to better performance of its members' central medical stores in order to improve the availability of

²⁰⁶ <https://www.cgdev.org/blog/vision-architecture-three-questions-guide-global-family-planning-movement-towards-2030>

²⁰⁷ Advance Family Planning. Advocacy in Zanzibar Leads to Reduction in Family Planning Commodity Stock-outs- Case study. November 2015

²⁰⁸ Castle S. Intersections between Youth and Reproductive Health Supplies A Report to the Reproductive Health Supplies Coalition. May 2016

²⁰⁹ FP2020. Women at the centre – A call to action from FP 2020's 2018-2019 annual progress report

²¹⁰ UNFPA Supplies. Annual report 2018

affordable, quality assured medicines and health commodities.²¹¹ Two current projects managed by ACAME can be of interest for DSO, PERF-APPRO (an initiative for an integrated quality system among the central medical stores members of ACAME), and CEDAG (a pooled procurement initiative). Information on these projects is provided in Annex 6 (Volume II). WAHO, actively supporting countries in procurement and distribution of RHCs in the West African region, is considering collaboration with ACAME for pooled procurement but this collaboration is not yet explored in detail.

Organisations that can facilitate quality assurance related topics

At global level

WHO is the main body with regards to quality related aspects, and provides, on request, technical and scientific advice to manufacturers with their application for prequalification. This advice focuses on the explanation of the international pharmaceutical norms and standards, and how to meet those.²¹²

Through interviews we were informed that FHI360 plays an important role in quality assurance related topics mainly for USAID. FHI360's product quality and compliance department, established in 1995, initially focused on quality assurance and technical assistance for procurement of contraceptives for USAID funded programmes. Nowadays, the department works with a wide range of products and partners. USAID continues to rely on FHI360 in particular because USAID does not use the WHO prequalification as a standard.²¹³

For quality related topics, we also want to draw attention to QUAMED. QUAMED is a non-profit membership organisation dedicated to improve access to quality medicines. Its members are organisations involved in the supply of medicines and health commodities, comprising NGOs, international organisations and purchasing centres including a number of the central medical stores in West Africa. The organisation provides a range of services of which several could be of interest to DSO (e.g., audits of suppliers, assessments of local markets, technical assistance, development of quality assurance systems, review of product files, evaluation of supply sources, and training). QUAMED does not particularly focus on RHCs but these commodities certainly are within the scope of the organisation.

More information is provided in the section above where we elaborate on which organisations are best positioned to align interests of the private sector.

In the Netherlands priority countries

At regional level, the African Medicines Regulatory Harmonisation (AMRH) initiative, a program of the African Union's New Partnership for Africa's Development (NEPAD), focuses on the improvement of access to good quality medicines through an enabling regulatory environment. The AMRH project for the West-African region aims to *improve the availability of quality, safe and effective medicines and vaccines in the Economic Community of West African States (ECOWAS) region*.²¹⁴ WAHO is the main coordinator of the West-Africa Medicines Harmonisation project.²¹⁵ The project started in July 2017, and will end in May 2020. Mid 2019, a call for Expression of Interest (EOI) for regional joint medical products evaluation for reproductive health was published, that included RHCs from different categories e.g., oral hormonal contraceptives, injectable hormonal contraceptives, implantable contraceptives, hormonal IUD, intravaginal

²¹¹ <http://www.acame.net/en/#>

²¹² <https://extranet.who.int/prequal/content/technical-advice>

²¹³ <https://www.fhi360.org/expertise/product-quality-and-compliance>

²¹⁴ ECOWAS member states are: Benin, Burkina Faso, Cabo Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo

²¹⁵ <https://www.wahooas.org/web-ooas/en/projets/wa-mrh-west-africa-medicines-regulatory-harmonization-project>

contraceptives and utero-tonic drugs. The status of this EOI did not become clear. Collaboration with AMRH and/or WAHO for quality assurance related topics could be an opportunity but should be further explored.²¹⁶

The East African Community Medicines Regulatory (EAC – MRH) program was launched in 2012 to start the implementation of the AMRH in the East African Community. Under the programme, several joint Good Manufacturing Practices (GMP) inspections have been performed, as well as joint assessment procedures. The latter involve the simultaneous submission of one application in all EAC Member States national medicines regulatory authorities, followed by a joint assessment whose results are binding for all Member States.²¹⁷

In 2019, the African Medicines Agency (AMA) Treaty was established in the African Union.²¹⁸ This Agency has as the main objective to *regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent*. This includes regulatory strengthening and harmonisation within the African Union, but details are not yet available due to the recent establishment of the AMA.²¹⁹

At country level, stronger National Regulatory Authorities (NRA) and robust regulatory strategies and procedures are required to assure the quality of RHCs throughout the supply chain up to the end user. This becomes a priority with the increase of domestic resources used to procure RHCs, and decentralised (procurement) systems. Organisations such as the WHO, through their country offices, could provide adequate technical support to NRAs to develop and/or revise quality assurance policies. Similarly, AMA and NEDAP could provide (technical) support at regional level, yet it is not fully clear what their capacity at country level is.

Organisations such as Management Sciences for Health (MSH) could support NRAs with operational elements of quality assurance, e.g. post marketing surveillance. MSH currently implements the USAID funded Medicines technologies, and pharmaceutical services program (MTAPS) that has as main objectives to strengthen pharmaceutical sector governance and increase institutional and human resource capacity for pharmaceutical management including regulation of medical products.²²⁰

2.5.6 SUMMARY STUDY QUESTION 5

There are only 2 main actors in procurement of RHCs, UNFPA Supplies and USAID. These organisations apply different procurement procedures, including different quality standards. One of the main challenges of UNFPA Supplies is the unpredictability of funding combined with the fact that the funds have to be on UNFPA's account before orders can be placed. Since 2015, USAID's supply program has been facing numerous challenges including decreasing on-time delivery rates and increasing stock-outs in the supported countries. Smaller buyers include NGOs (e.g., MSI, IPPF). For condoms, the Global Fund is an important buyer who provides the online platform wambo.org for procurement by its principle recipients.

A variety of organisations provide technical assistance in aspects related to RHC availability with a focus on general aspects of supply chain management (e.g., Chemonics, JSI, Village Reach, MSH). ACAME is a regional organisation with 22 member countries in West Africa with the objective to contribute to better performance of its members' central medical stores in order to improve the availability of affordable quality assured medicines and health commodities. Their involvement can be interesting for interventions related to strengthening of public health supply chains.

²¹⁶ <https://www.nepad.org/programme-details/998>

²¹⁷ <https://www.tmda.go.tz/programs/hamornization-and-international-collaboration>

²¹⁸ The African Union consists of 55 states located throughout the African continent.

²¹⁹ <https://au.int/en/pressreleases/20200205/african-medicine-agency-ama-treaty>

²²⁰ https://www.msh.org/sites/default/files/factsheets_mtaps_pharmaceutical_regulatory_systems_042319.pdf

Through literature review and KII we identified two organisations that support manufacturers with WHO prequalification and registration at country level, namely the Concept Foundation and WCG.

Other organisations active in quality assurance are FHI360 and QUAMED. The development agency of the African Union (NEDAP) supports AMRH, a program working on regulatory issues including harmonisation of registration in regional economic communities of the African Union.

CGD is a research organisation working on, among other things, global health, and recently published, through its working groups, articles on the future of procurement and funding for family planning that provide interesting insights from a scientific perspective. Other research institution involved in RHC related topics include HRP, the Guttmacher Institute and the William Davidson Institute.

3 CONCLUSION

3.1 MANY INTERVENTIONS, LIMITED EVIDENCE

The literature identified through the systematic approach provided the necessary information to draw an overall picture of the current RHCs landscape in the focus areas identified by DSO. KIIs provided additional information and allowed for further deepening of certain issues. Information obtained through both methods did however not allow to answer all the specific study questions in detail. Therefore, some additional targeted searches for peer reviewed and grey literature were conducted, which clarified some of the remaining questions.

Nevertheless, for some study questions it proved difficult to formulate an unambiguous answer. The community consists of a large variety of actors, each with their own interests which at times are conflicting. Diverging views exist in the RHC community on a number of issues (e.g., role of private sector in supply chain management, volume guarantees, impact and future of social marketing).

The in general limited body of evidence on interventions to improve availability of RHCs made it challenging to understand and assess which of the many interventions have impact. However, the information obtained through literature review, KIIs and additional literature searches allowed to identify a number of policy options for DSO in line with the Dutch priority areas.

3.2 RECENT DEVELOPMENTS

The overall increasing global population leads to a growing demand for RHCs in the coming years and puts equitable availability of quality assured RHCs to everyone who needs them, under pressure.

At the same time, a decreasing trend in donor funding is expected although exact figures are not readily available in the public domain. In many countries, particularly in LMIC, external funding for RHCs continues to play a substantial role. Most information published focuses on funding for family planning. In general, information about other RHCs product categories (e.g., maternal health commodities, abortion commodities) was less available, which might be linked to (global) priorities within the RHC community.

The current context is complex: a growing demand for RHCs, a decreasing trend in donor funding, key stakeholders that are in the process of (re-)strategizing and re-structuring their organisation, and the COVID-19 pandemic are creating important and not always expected effects at global level. This situation confirms the importance of a strong policy to improve availability of RHCs while at the same time maintaining sufficient flexibility to make necessary adjustments in a changing context.

The COVID-19 pandemic that broke out early 2020, is likely to have a large impact on the availability of RHCs. At short term, potential scarcity of raw materials and workplace restrictions in manufacturing countries may influence the overall manufacturing capacity. Transportation from manufacturer to the end user may be hindered by the strict measures taken by most governments, limiting transport capacity, increasing lead times, and increasing transport related costs. Moreover, funding is likely to decrease in the longer term, both from donors and from receiving countries due to shrinking economies globally. The actual impact of the pandemic on RHC availability is still difficult to assess but increasing prices and long(er) lead times are reported.

3.3 KEY AREAS IDENTIFIED PROVIDE OPPORTUNITIES FOR SUPPORT

The focus areas as identified by the Netherlands (last-mile distribution, domestic resource mobilisation, private sector) are well in line with the global trends and priorities. West Africa is a geographical focus.

3.3.1 LAST MILE DISTRIBUTION

The study findings show that the main supply chain management issue for RHCs is related to last mile distribution. The fact that most RHCs are dispensed for free to the population plays an important role in this matter, particularly in countries with cost-sharing/-recovery policies. In such systems, health facilities sell medicines and health commodities with a small margin to the population which allows for adequate handling including transport from the higher level of the supply chain to the health facility of these medicines and commodities. When it is decided to dispense commodities for free to the population, other funds need to be made available to cover the costs involved in handling, either from government or donor agencies. In the absence of such funds, the last mile distribution becomes a challenge. Over time, many interventions to improve last mile distribution have been designed and implemented (including with the support from the Netherlands) yet the body of evidence on what works and what not, and particularly why or why not, remains limited. Most of the interventions piloted are small scale interventions with considerable donor support, and do not provide sufficient information and knowledge on whether such interventions are scalable, under which circumstances, in which context, and at what cost.

3.3.2 DOMESTIC RESOURCE MOBILISATION

Domestic resource mobilisation is an emerging topic in the RHCs space. Overall donor funding is decreasing, and the reduced funds are mainly deployed in the LICs, leaving the L-MIC with less donor funding and an increased responsibility to allocate domestic funding for RHCs. Several interventions to support countries with this process are being implemented, yet clear results of the effective increase of domestic funding attributable to these interventions are lacking. Several elements related to domestic funding remain unclear; e.g., which RHCs related expenses are considered, and what and how expenses are tracked. A common approach from the donor community on financial contribution from the receiving countries (e.g., the amounts or percentages of commodities funded by donor agencies, gradual contribution, timelines) is also not yet agreed upon. The donor community is concerned that increasing use of domestic funding may for different reasons (e.g., competing priorities, national procurement capacity) compromise equitable availability of quality RHCs. Contribution from the Netherlands to support countries through the gradual transition from donor dependence to independence is therefore relevant.

The importance of including all SRHR interventions and the medicines and health commodities required for these interventions in the national UHC strategies and national health insurance schemes is acknowledged by all key RHCs stakeholders. Some successful examples exist in Latin America, yet in West Africa successful inclusion and implementation remains limited.

The expected increased use of domestic funding for procurement and management of RHCs, coupled with decreasing donor funding, will lead to more requests for support to strengthen all components of the national health systems.

3.3.3 PRIVATE SECTOR

There is consensus in the global RHCs community that the private sector will have to be more involved in order to meet the growing demand for RHCs. This sector comprises a large range of actors with diverse roles, expertise, and key activities (e.g., manufacturers, service providers, pharmacists), both at global and country level. Lack of adequate regulation of the private sector continues to be a challenge in many LMIC. Initiatives to involve the private sector in efforts to increase RHCs availability are emerging (e.g., support to market introduction, volume agreements, public stewardship), yet the effects are still difficult to measure, mainly due to the relatively short period of implementation. Common approaches for effective cooperation have therefore not yet been fully developed.

Among the interesting public private initiatives are the informed push model and the prime vendor model. Both models combine expertise and services from the private and public sector to ensure non-interrupted

supplies to the population. In countries with increasing incomes, several initiatives for online sales of RHCs and other health related products show promising results. Nevertheless, most of these initiatives are implemented at small scale and received continuous technical and financial support from donors. As most initiatives are relatively new, detailed information on scalability and sustainability is not yet available in the public space.

In reaction to decreasing donor funding and increasing purchasing power in L-MIC, social marketing organisations are slowly but successfully shifting their set up from charity towards social enterprises. In less developed countries (e.g., several countries in West Africa) however, subsidies are still required for social marketing organisations to be able to operate and serve the specific population groups that may otherwise not have access to RHCs in the public and private sector.

3.4 SUPPORT OF THE NETHERLANDS REMAINS RELEVANT

The Netherlands is a long-standing and overall appreciated partner in the global RHCs space. Its support has been a mix of improving RHCs availability by funding their procurement, and advocacy for better availability, access for all, and leaving no one behind (e.g., demand creation, improved method mix).

The focus of the Netherlands' support to West Africa including the Sahel is considered relevant. The region's key SRHR indicators are the lowest in the world: unmet need for family planning (modern methods) among women aged 15-49 is 24% versus 12% worldwide, the contraceptive prevalence rate among women aged 15-49 is 18% compared to 58% globally, and the maternal mortality rate is 676 per 100,000 live births versus 216 worldwide.²²¹ The context is complex with high levels of insecurity and related humanitarian crises. Innovative solutions that successfully improved RHC availability in other regions may not work in this particular context or may require important adaptations. With the long term presence of health experts in several countries in this region and a proven fairly flexible approach, the Netherlands is well placed to play an important (coordinating) role in RHCs provision and broader supply chain management issues in selected countries

²²¹ UNFPA State of World Population 2019. Unfinished business- the pursuit of rights and choices for all. 2019
hera / DSO – Study report - Final version Volume I / June 2020

4 POLICY OPTIONS

4.1 INTRODUCTION

Table 4 below provides options for interventions that are expected to contribute to increased availability of RHCs. These options were established based on results from the literature review and KIIs; additional background information that was particularly searched for to cover certain topics; feedback received from DSO; and exchanges with experts from our own network.

Table 4. Policy options

Category	Option
Strategic support at global, regional, and country level	Option 1 - Continue support to UNFPA Supplies, at least during the period of the transition of the organisation: funding for procurement of RHCs and technical and financial support for the transition
	Option 2 - Support the RHSC
	Option 3 - Continue support to the Regional Financing Mechanism Fund coordinated by WAHO
	Option 4 - Support specific product categories that globally have less attention and funding, e.g., supplies for menstrual health and hygiene, and safe abortion
RHCs research	Option 5 - Fund independent (operational) research to add to the limited body of evidence on interventions that can contribute to increased availability of RHCs
	Option 6 - Conduct studies to better understand existing national RHC markets (supply and demand) and identify possible roles for actors of all sectors for increasing availability of RHCs
	Option 7 - Support (independent) evaluations and impact assessments of promising models and interventions to ensure availability of RHCs at the last mile
	Option 8 - Support a feasibility study for the development and implementation of a co-financing strategy to facilitate agreement among donors
Last mile distribution	Option 9 - Support models and interventions involving entrepreneurial approaches that have proven successful to ensure availability of RHCs at the last mile in Sub-Saharan Africa (particularly anglophone countries in Southern and Eastern Africa)
	Option 10 - Consider, based on results of recent assessments, to provide general financial and technical support to the national public health procurement and supply chain system, including last mile distribution
Domestic resource mobilisation	Option 11 - Support countries to develop resource mobilisation plans or transition plans with a focus on increasing domestic resources and decreasing dependency on external funding
Private sector	Option 12 - Support initiatives to harmonise medicines registration processes
	Option 13 - Support social marketing organisations (SMO) to set up a sustainable supply chain that is independent from external support
	Option 14 - Assess barriers related to regulation and policy for private sector actors to participate in the RHC market, and advocate for lifting unreasonable restrictions

The table groups the options based on each of the DSO focus areas as defined in the TOR, except for the focus area West Africa. We listed for each of the options whether it concerns an option for global, regional and/or county level, and country level then refers primarily to focus countries in West Africa. Several interventions cover more than one of the focus areas (e.g. Option 9 addresses last-mile distribution as well as private sector engagement).

The sections below provide the rationale for the options, list possible risks and disadvantages, identify added value of the Netherlands for the particular intervention, and suggest the type of organisations to collaborate with for implementation. The list of organisations provided in the table is however not exhaustive. For options at country level, these organisations could only be specified to a minimum extent.²²² For additional information on potential organisations for collaboration we refer to section 2.5.5.2 and Annex 4 (Volume II).

For each of the options, a priority ranking (low, medium, high) is included, based on the following indicators:

- To what extent does the proposed option contribute to the main objectives of the Dutch Policy for Foreign Trade and Development Cooperation related to SRHR²²³²²⁴ (better information and greater freedom of choice for young people about their sexuality, improved access to contraceptives and medicines, better public and private SRHR services, including safe abortions, and more respect for SRHR of groups whose rights are often violated)?
- Within which period can the proposed option show attributable results/impact (short, medium, or long term), thereby assuming a preference for short to medium term results/impact?
- How do the costs of this option relate to its potential (short, medium, or long term) benefits?
- To what extent is the existing context favourable to implement the proposed option? Can interventions be added on existing interventions with existing infrastructure? Do new structures/infrastructures have to be established, requiring additional investment?
- Does the proposed intervention cover more than one of the focus areas identified by DSO in the study's TOR (last mile distribution, domestic resource mobilisation, private sector West Africa)

The listed options provide a balanced mix of interventions at the different levels that allows the Netherlands to maintain the opportunity to be involved in policy making at global (and regional) level, and at the same time to understand what the effects of global level input are on the availability of RHCs at country level. Lessons learned at country level are essential for informed decision making at global level, while with insights from global level policy making, the Netherlands has a good position to contribute to the RHC dialogue in the supported countries. Furthermore, the mix is developed in such a way that the various options can work on their own but reinforce each other when more or all are implemented. For each of the proposed options the link with other options is mentioned. We recommend linking the options for research directly to options for implementation of specific interventions, e.g. the implementation of Option 13 (Support social marketing organisations (SMO) to set up a sustainable supply chain that is independent from external support) can be accompanied by operational research in order to objectively document lessons learned.

The following should be taken into consideration when reviewing the suggested options:

- As strengthening health systems is a requirement to support SRH interventions, the overall strategy of the Netherlands' support to achieve increased availability of RHCs should be to strengthen national procurement and supply chain systems and avoid, to the maximum extent, the establishment and use of vertical or parallel systems. The options provided below are consistent with this strategy and should be adapted to the context of each of the focus countries where interventions will be implemented. The use of private sector (for profit and not for profit) supply chains actors should not be excluded; these are considered as part of the national system.

²²² For identification of local organisations more in-depth knowledge of these countries is required. As per the TOR, the list of countries to be supported in the focus region is not yet defined.

²²³ Investing in Global Prospects, For the World, For the Netherlands, Policy Document on Foreign Trade and Development Cooperation. May 2018

²²⁴ Theory of Change Sexual and Reproductive Health and Rights. Ministry of Foreign Affairs Directorate-General for International Cooperation (DGIS), Department of Social development (DSO). October 2018

- In West Africa, one of the focus regions of the Netherlands, today several countries are unstable, mainly caused by increasing armed conflicts by extremist and/or terrorist groups, and tension between ethnic groups. Through weak governance and climate change, and more recently the COVID-19 pandemic these countries risk to destabilise further. The evolution of the situation in specific countries in the region is hard to predict and is expected to be different in each country. The options for support to increase availability of RHCs in this region will therefore have to remain, to a certain extent, flexible, ensuring adaptive interventions that can be implemented by different organisations; interventions and implementing organisations in emergencies are often different from those for development support. These differences, however, are becoming smaller as a result of emerging debates and attention to the humanitarian-development nexus. Providing support to build resilient health systems (of which the supply chain is part and parcel) is therefore also becoming the norm in humanitarian settings.
- In several countries in the focus region West Africa, financial and technical support for additional interventions to facilitate access to RHCs, particularly for adolescents, hard to reach and other vulnerable populations, are required; increased availability of RHCs will, in these contexts, not per se lead to improved access and increased use as the demand is still weak. Examples for such interventions include provision of adequate information on RHCs, advocacy to increase access, demand generation, awareness creation, and youth friendly services. These interventions are not directly linked to RHCs availability but rather components of the broader SRHR support and therefore not further elaborated.
- The options for research can be directly linked to options for implementation of specific interventions.
- Most interventions, particularly those at country level, need to be further elaborated considering the specific context in which they will be implemented.

4.2 POLICY OPTIONS TO INCREASE AVAILABILITY OF RHCS

4.2.1 STRATEGIC SUPPORT AT GLOBAL, REGIONAL AND COUNTRY LEVEL

Option 1 - Continue support to UNFPA Supplies, at least during the period of the transition of the organisation: funding for procurement of RHCs and technical and financial support for the transition

Level	Global
Rationale	<ul style="list-style-type: none"> • Particularly important given the current transition in which the Netherlands plays an important role: this transition focuses on country support to strengthen national systems including interventions related to the increase of domestic funding • Provides opportunities to remain involved in development of global strategies, influence policy making, and monitoring of implementation of these strategies (e.g. co-financing) • Allows for strategic lobbying to keep sensitive issues on the RHC agenda (e.g., safe abortion, adolescents) • Allows for strategic lobbying to ensure RHCs for humanitarian settings are being procured • At global level, few/no alternatives exist for similar support
Risks/Disadvantages	<ul style="list-style-type: none"> • Potential reputational damage in the event of unsuccessful transition. Close monitoring of implementation of the transition plan will be required, in collaboration with other donors. • Limited sustainability at long term

Option 1 - Continue support to UNFPA Supplies, at least during the period of the transition of the organisation: funding for procurement of RHCs and technical and financial support for the transition	
Added value of the Netherlands	The Netherlands actively contribute to the strategic direction of UNFPA Supplies and to monitoring of the implemented activities. This contribution is valued by the main stakeholders.
Organisation	UNFPA Supplies
Priority ranking	High Contributes to main objectives of the Dutch SRHR policy, impacts directly on availability of RHCs, context is favourable to implement this option without additional investment – longstanding relationship between the Netherlands and UNFPA Supplies
Additional remarks	<ul style="list-style-type: none"> • This is an important strategic intervention, which has proven to be effective in the past • This option is also related to last mile distribution and domestic resource mobilisation • Linked to Options 3 and 4

Option 2 - Support the RHSC	
Level	Global
Rationale	<ul style="list-style-type: none"> • Important source of information; RHSC provides high quality relevant information on a broad range of topics related to RHCs • Includes all important RHCs stakeholders (from global and country level), and provides a venue to publicly promote the role of the Netherlands in the field • Allows for strategic lobbying to keep sensitive issues on the RHC agenda (e.g., safe abortion, adolescents) • Allows to participate in the design and creation of a possible future 'market manager' (an entity that should have full and up to date information and that can take timely action in the case of anticipated changes or problems) • Allows for advocacy at global level for inclusion of all medicines and health commodities needed for the implementation of the essential package of SRH interventions in the national UHC schemes (the essential package of SRH interventions defined in the Guttmacher/Lancet report from 2018 can serve as a starting point²²⁵) • Working groups and funds from the RHSC focus on topics important for the Netherlands policy (e.g., Systems Strengthening and Market Development Approaches Working Groups, RHSC Manufacturers Group, Youth Caucus, Innovation Fund, Safe Abortion Supplies)
Risks/Disadvantages	Possible impact will only be measurable in the medium to long term.

²²⁵ Comprehensive sexuality education; Counselling and services for a range of modern contraceptives, with a defined minimum number and types of methods; Antenatal, childbirth, and postnatal care, including emergency obstetric and newborn care; Safe abortion services and treatment of complications of unsafe abortion; Prevention and treatment of HIV and other sexually transmitted infections; Prevention, detection, immediate services, and referrals for cases of sexual and gender-based violence; Prevention, detection, and management of reproductive cancers, especially cervical cancer; Information, counselling, and services for subfertility and infertility •; Information, counselling, and services for sexual health and wellbeing (Source: 2018 Stars A et al. Accelerate progress in SRHR : report of the Lancet Guttmacher commission [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(18\)30293-9.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(18)30293-9.pdf))

Option 2 - Support the RHSC	
Added value of the Netherlands	The Netherlands is a reliable and stable donor supporting RHCs with relevant knowledge and experience in the domain across various sectors.
Organisation	RHSC
Priority ranking	Medium Contributes to main objectives of the Dutch SRHR policy, attributable results/impact may be measurable at medium to long term only, covers focus areas (last mile distribution, domestic resource mobilisation, private sector)
Additional remarks	<ul style="list-style-type: none"> Consider active involvement in relevant RHSC working groups Allows, through working groups, to support platforms/ organisations that promote and/or contribute to a healthy price competition in the RHC market (e.g., The Fair Pricing Forums, HAI, Access to Medicines Foundation) Linked to all options of the different focus areas

Option 3 - Continue support to the Regional Financing Mechanism Fund coordinated by WAHO	
Level	Regional
Rationale	<ul style="list-style-type: none"> Works in the focus region of the Netherlands policy (West Africa) Focuses on strengthening of national procurement system for RHCs Provides opportunity to be involved in regional policy development Established relationship At regional level, few/no alternatives exist for similar support with similar focus and impact
Risks/Disadvantages	<ul style="list-style-type: none"> Technical assistance component is not sufficiently well implemented due to lack of capacity at WAHO. Concrete output has to be well formulated, and regular assessment/evaluation, in collaboration with other donors, should focus on weaknesses of this component, and provide recommendations for further improvement. Limited sustainability at the long term
Added value of the Netherlands	The Netherlands has experience and strong relations in several of the countries in the region supported by the Fund
Organisation	WAHO, possibly in collaboration with ACAM)
Priority ranking	Low/Medium Contributes to main objectives of the Dutch SRHR policy, impacts directly on availability of RHCs, context is favourable to implement this option– existing relationship between the Netherlands and WAHO, cost related to potential benefit seem high
Additional remarks	<ul style="list-style-type: none"> Requires adequate consultation/coordination in relation to Option 1 to avoid overlap and gaps Linked to Options 1, 2 and, to a certain extent, Option 12 Consider direct support to ACAME as an alternative: <ul style="list-style-type: none"> Rationale – <ul style="list-style-type: none"> Works in all countries of the focus region of the Netherlands policy (West Africa) focuses on strengthening of national procurement and supply systems in general

Option 3 - Continue support to the Regional Financing Mechanism Fund coordinated by WAHO

	<ul style="list-style-type: none"> ▪ ACAME has in-house technical expertise on procurement and supply chain management ▪ ACAME is exploring options for pooled procurement ▪ seems sustainable option for the future ○ Risk/Disadvantages - New relationship that needs to be built (and/or linking WAHO and ACAME to facilitate this process)
--	--

Option 4 - Support specific product categories that globally have less attention and funding, e.g., supplies for menstrual health and hygiene, and safe abortion

Option 4a - Support specific supplies for menstrual health and hygiene

Level	Global and country
Rationale	<ul style="list-style-type: none"> • Global RHC community focusses primarily on family planning • Provides opportunity for private sector engagement • Supplies particularly important for youth which is a focus population group of the Netherlands policy • Creates synergies between sections: strong linkages with WASH, a focus area of the Netherlands policy
Risks/Disadvantages	There is no consensus yet whether menstrual health and hygiene supplies are considered RHCs
Added value of the Netherlands	The Netherlands has extensive experience in WASH which might provide useful links and connections to support availability of menstrual health and hygiene supplies
Organisation	International NGOs, local NGOs/CSOs, MOH, Ministry of Finance (MOF), National Medicines Regulatory Authority (NMRA)
Priority ranking	Low Costs related to potential benefits may be high, existing context rather unknown (new relationships/infrastructure have to be built)
Additional remarks	<ul style="list-style-type: none"> • Start with an assessment to identify key issues and specific needs related to increasing availability of these product categories (e.g., product development, quality guidelines) • Linked to Options 1, 2, 9, 13

Option 4b - Support specific supplies for safe abortion

Level	Global and country
Rationale	<ul style="list-style-type: none"> • Global RHC community focusses primarily on family planning • Provides opportunities to have influence/can generate impact • Supplies are particularly important for youth which is a focus population group of the Netherlands policy • Safe abortion services and treatment of complications of unsafe abortion are included in the essential package of SRH interventions as recommended by the Lancet Commission (Lancet series)
Risks/Disadvantages	Complexity and sensitivities of the topic can make it difficult to achieve results (at short term)
Added value of the Netherlands	The Netherlands is known as a strong supporter of safe abortion, and has diplomatic skills and experience required for supporting safe abortion

Option 4 - Support specific product categories that globally have less attention and funding, e.g., supplies for menstrual health and hygiene, and safe abortion

Organisation	International NGOs (e.g., Marie Stopes International (MSI)), national NGOs, multilateral and regional organisations (e.g., UNFPA Supplies, ACAME, WAHO), MOH, MOF, NMRA
Priority ranking	Medium/High Fully in line with main objectives of Dutch policy, existing context known yet challenging (sensitive issue, legal barriers)
Additional remarks	<ul style="list-style-type: none"> • Strong barriers to safe abortion continue to exist (e.g., legal, political, religious, cultural); therefore, continuous advocacy will be required • Linked to Options 1, 2, 14

4.2.2 RHCS RESEARCH

Option 5 - Fund independent (operational) research to add to the limited body of evidence on interventions that can contribute to increased availability of RHCs

Level	Global and country
Rationale	<ul style="list-style-type: none"> • Paucity of independent research and peer reviewed literature on availability of RHCs; evidence on why and in what circumstances interventions have impact on the availability of RHCs is limited • Facilitates informed decision making on funding and support by the Netherlands and donor community • Provides recipient countries with valuable information for the development of national strategies including definition of priority interventions thereby ensuring to make best use of limited resources; facilitates decision on whether and how successful (pilot) interventions can be brought to a large(r) scale; supports the gradual transition from predominantly external funding to domestic funding • Provides opportunity to answer specific questions on projects and/or interventions, e.g., <ul style="list-style-type: none"> ○ Has GFF been able to make a difference at country level and to increase domestic funding for SRHR including RHCs? ○ What is the impact of free dispensing of RHCs in the public sector for handling and last mile distribution, and in the private sector? (current evidence is non-conclusive) ○ What role can blockchain play in supply chain management of RHC? • Involvement of institutions and universities from both north and south creates synergies and learning
Risks/Disadvantages	Possible impact will only be measurable in the medium to long term.
Added value of the Netherlands	The Netherlands is a flexible donor able to offer broader support rather than on a defined topic
Organisation	Independent international and national research institutions (e.g., CGD, HRP, Guttmacher Institute, William Davidson Institute), (local) universities
Priority ranking	Medium Attributable results/impact may be measurable at medium to long term only, new infrastructure/relationships to be built, addresses the paucity of independent research on RHCs

Option 5 - Fund independent (operational) research to add to the limited body of evidence on interventions that can contribute to increased availability of RHCs

Additional remarks

- Recommended to carefully select (operational) research and link with option provided for last mile distribution, domestic resource mobilisation and West Africa
- Linked to Options 3, 6, 7, 8, 9

Option 6 - Conduct studies to better understand existing national RHC markets (supply and demand) and identify possible roles for actors of all sectors for increasing availability of RHCs

Level

Country

Rationale

- Supports the Total Market Approach
- Allows for inclusion/collaboration with private sector
- Provides information on which sector/organisation and which interventions can best be supported in order to optimise investments (e.g., Is it worth to subsidise private sector distributors? Which (service) providers/sectors reach particular populations?)
- Allows to obtain disaggregated information to enable identification of specific interventions required to increase availability of RHCs for vulnerable groups

Risks/Disadvantages

Possible impact will only be measurable in the medium to long term

Added value of the Netherlands

The Netherlands promotes evidence-based interventions and supports involvement of research institutions

Organisation

Independent international and national research institutions (e.g., CGD, HRP), (local) universities, national NGOs, CSO

Priority ranking

Medium
Attributable results/impact may be measurable at medium to long term only, new infrastructure/relationships to be built, covers focus area (West Africa)

Additional remarks

- Involve youth organisations when data are required on availability of commodities and selling points or related topics
- Recommended to carefully select (operational) research and link with option provided for last mile distribution, domestic resource mobilisation and West Africa
- Linked to Options 1, 4, 5, 7, 9, 10, 14

Option 7 - Support (independent) evaluations and impact assessments of promising models and interventions to ensure availability of RHCs at the last mile

Level

Country

Rationale

- Currently body of evidence is limited
- Allows for inclusion/collaboration with private sector
- Provides recipient countries and global RHC community with valuable information for the development of national strategies including definition of priority interventions thereby ensuring to make best use of limited resources; facilitates decision on whether and how successful (pilot) interventions can be brought to a large(r) scale; supports the gradual transition from predominantly external funding to domestic funding

Option 7 - Support (independent) evaluations and impact assessments of promising models and interventions to ensure availability of RHCs at the last mile	
	<ul style="list-style-type: none"> Involvement of institutions and universities from both north and south creates synergies and learning
Risks/Disadvantages	Possible impact will only be measurable in the medium to long term
Added value of the Netherlands	The Netherlands promotes evidence-based interventions and supports involvement of research institutions
Organisation	Independent international and national research institutions (e.g., CGD, HRP, Guttmacher Institute, William Davidson Institute), (local) universities, RHSC, CHAI
Priority ranking	<p>Medium</p> <p>Attributable results/impact may be measurable at medium to long term only, new infrastructure/relationships to be built, covers focus areas (last mile distribution, West Africa), addresses the paucity of independent research on RHCs</p>
Additional remarks	<ul style="list-style-type: none"> Evaluations and impact assessments should focus on scalability of models Linked to Options 1, 3, 4, 5, 6, 7, 8, 10, 13, 14

Option 8 - Support a feasibility study for the development and implementation of a co-financing strategy to facilitate agreement among donors	
Level	Global
Rationale	<ul style="list-style-type: none"> Overall donor funding is expected to decrease while demand is increasing Growing pressure from donor community to increase domestic funding (and allow for gradual decrease of donor funding) Allows participation and influence in the debate The Netherlands has a strong position due to large involvement in UNFPA Supplies (in general and for transition period)
Risks/Disadvantages	Possible impact will only be measurable in the medium to long term
Added value of the Netherlands	In line with the Netherlands' support to the transition of UNFPA Supplies that focuses on increased use of domestic funding for RHCs
Organisation	Independent international and national research institutions (e.g., CGD), consultancy firms
Priority ranking	<p>Low</p> <p>Attributable results/impact may be measurable at medium to long term only, new infrastructure/relationships to be built, covers focus area (West Africa, domestic resource mobilisation), addresses the paucity of independent research on RHCs</p>
Additional remarks	<ul style="list-style-type: none"> Focus on the transition period where external funds are decreasing and domestic resources increasing To be conducted in collaboration with main stakeholders in RHCs Gradual increase / differentiated approaches for different countries are important (depending on level of development) Lessons learned from other organisations (for other product categories) are available UNFPA and UNFPA Supplies to play main role for implementation Recommended to include mechanism for tracking domestic funding for SRH

Option 8 - Support a feasibility study for the development and implementation of a co-financing strategy to facilitate agreement among donors

- Linked to Option 11

4.2.3 LAST MILE DISTRIBUTION

Option 9 - Support models and interventions involving entrepreneurial approaches that have proven successful to ensure availability of RHCs at the last mile in Sub-Saharan Africa (particularly anglophone countries in Southern and Eastern Africa)

Notes:

- *These models should work together with or complement the public sector in order to contribute to the building of resilient national systems*
- *Examples of models: Healthy Entrepreneurs (e.g., Uganda, Kenya, Ghana), Community Health Promoters (Uganda), community-based distributors (Ghana), online sales/distribution (KASHA (Rwanda, Kenya), MYDAWA (Kenya))*

Level	Global, regional, country
Rationale	<ul style="list-style-type: none"> • Supports entrepreneurship, local organisations and sustainability • Allows models to further mature, and explore scalability • Promotes innovation, particularly for e-commerce/ pharmacies • Focuses on local solutions (increases sustainability) • Allows for inclusion/collaboration with private sector • Creates synergies with WASH: many entrepreneurial models include sales of WASH related commodities
Risks/Disadvantages	<ul style="list-style-type: none"> • Investment in e-commerce / distribution might involve risks as these models are in early stages • Quality assurance systems in place may not be adequate to assure quality of commodities sold online • For e-commerce broad coverage of reliable internet and well-functioning postal services or other delivery services have to be available • Limited information available from interventions in (francophone) West Africa
Added value of the Netherlands	The Netherlands supports strengthening of local organisations
Organisation	<ul style="list-style-type: none"> • Research for the present study has not yielded information on organisations in the focus region, although these might exist. • Examples of organisations focusing on 'physical' distribution models: BRAC (e.g., Liberia, Sierra Leone, Rwanda, Uganda), Living Goods (e.g., Kenya, Uganda), Healthy Entrepreneurs (e.g., Uganda, Kenya, Ghana), HealthKeepers Network (Ghana) • Examples of organisations focusing on e-sales and distribution models: KASHA (Rwanda, Kenya), MYDAWA (Kenya) • Central medical stores, NMRA
Priority ranking	<p>High</p> <p>In line with objectives from the Dutch policy, attributable results/impact may be measurable at short term, new infrastructure/relationships to be built, costs related to benefits may be high (particularly at short- to medium-term), covers several focus areas (last mile distribution, private sector, West Africa)</p>

Option 9 - Support models and interventions involving entrepreneurial approaches that have proven successful to ensure availability of RHCs at the last mile in Sub-Saharan Africa (particularly anglophone countries in Southern and Eastern Africa)

Notes:

- *These models should work together with or complement the public sector in order to contribute to the building of resilient national systems*
- *Examples of models: Healthy Entrepreneurs (e.g., Uganda, Kenya, Ghana), Community Health Promoters (Uganda), community-based distributors (Ghana), online sales/distribution (KASHA (Rwanda, Kenya), MYDAWA (Kenya))*

Additional remarks

- Focus on scalability of existing models (e.g., under which circumstances, barriers, facilitators)
- Examples for ‘physical’ distribution models: Healthy Entrepreneurs (e.g., Uganda, Kenya, Ghana), Community Health Promoters (Uganda), community-based distributors (Ghana)
- Examples for e-sales and distribution models: e-retail pharmacy or e-commerce platform and distribution systems (Rwanda, Kenya)
- See option 13 below for possible options related to social marketing
- Linked to Option 4, 5, 6, 7, 13

Option 10 - Consider, based on results of recent assessments, to provide general financial and technical support to the national public health procurement and supply chain system, including last mile distribution

Level	Country
Rationale	<ul style="list-style-type: none"> • Strong national systems are the most sustainable option to ensure non-interrupted supplies for RHCs (and medicines and health commodities in general) • Also improves availability of other medicines and health commodities • Provides opportunity to be involved in the national policy dialogue • Provides opportunity to obtain in-depth understanding of functioning of supply chains, and of effects of global level initiatives • Allows for further piloting and/or documenting the implementation of Informed Push Model and Prime Vendor system
Risks/Disadvantages	<ul style="list-style-type: none"> • Not only focusing on RHCs availability • Strong dependency on national actors
Added value of the Netherlands	The Netherlands has extensive experience in strengthening national systems and a valued Dutch partner working on supply chain systems is available
Organisation	<ul style="list-style-type: none"> • International NGOs providing technical support on procurement and supply chain management systems (including i+ solutions as a Netherlands based organisation). • Other examples are MSH (francophone countries in West Africa), Village Reach (francophone countries in West Africa), CHAI (West Africa, mainly anglophone countries) • MOH, MOF, NMRA, central medical stores
Priority ranking	<p>Medium</p> <p>In line with objectives from the Dutch policy, attributable results/impact may be measurable at short term, structures/infrastructures exist but may need funds for upgrading, covers different focus areas (last mile distribution, West Africa)</p>

Option 10 - Consider, based on results of recent assessments, to provide general financial and technical support to the national public health procurement and supply chain system, including last mile distribution

Additional remarks

- In most countries the main issues related to the public health supply chain are well documented; however, if no recent assessments are available these should be conducted before the start of the intervention to allow for adequate project design
- Needs to be directly linked to main national policies and strategies (e.g., national health sector plans and budgets, costed implementation plan)
- Two options:
 1. Project managed by the Netherlands. This involves tendering, contracting, monitoring, etc, and requires experienced staff at country level to oversee such project.
 2. Support existing project(s) strengthening the national public health procurement and supply chain systems that are in line with the Netherlands' policy and that can be complemented. This requires a strong partner and adequate coordination.
- The support should be comprehensive; isolated support to one or several components of the supply chain should be avoided (unless as a complement to other projects). The focus should be on the system, not on RHCs specifically.
- Consider a review of current approaches to ensure sufficient funding for handling and distribution for medicines and health commodities that are dispensed to the population for free. This is particularly important for countries that apply a cost recovery system. Advocacy may be needed to ensure that either donors or the government make additional contributions for this purpose.
- Linked to Options 1, 3, 4, 12

4.2.4 DOMESTIC RESOURCE MOBILISATION

Option 11 - Support countries to develop resource mobilisation plans or transition plans with a focus on increasing domestic resources and decreasing dependency on external funding

Level	Country
Rationale	See above for option 8
Risks/Disadvantages	See above for option 8
Added value of the Netherlands	See above for option 8
Organisation	International or national NGOs, consultancy firms, international organisations with country presence involved in RHCs (e.g., UNFPA Supplies), MOH, MOF
Priority ranking	Low Attributable results/impact may be measurable at medium to long term only, new infrastructure/relationships to be built, covers several focus areas (West Africa, domestic resource mobilisation)
Additional remarks	<ul style="list-style-type: none"> • Lessons learned from other organisations are available • Linked to Option 8

4.2.5 PRIVATE SECTOR

Option 12 - Support initiatives to harmonise medicines registration processes	
Level	Regional
Rationale	<ul style="list-style-type: none"> Manufacturers are discouraged to enter markets because of cumbersome and time-consuming registration processes that are different in each country Strengthens overall health system, improves availability of quality assured medicines and commodities in general Structures/initiatives exist and can be built upon/strengthened Requires long time support but results can be sustainable Includes political component (and several countries involved)
Risks/Disadvantages	Experiences from regional initiatives are not yet very encouraging
Added value of the Netherlands	The Netherlands promotes access to high quality medicines and health commodities, and supports private sector involvement in the RHC market
Organisation	Regional initiatives (e.g., African Medicines Regulatory Harmonisation Initiative, WAHO, AU/NEPAD), MOH, NMRA
Priority ranking	Low/Medium Attributable results/impact may be measurable at medium to long term only, potential high costs for potential long-term benefits, new infrastructure/relationships to be built, covers several focus areas (private sector, West Africa)
Additional remarks	<ul style="list-style-type: none"> Similar regional initiative works in East Africa (Joint Assessment Procedure from EAC-MRH: East African Community Medicines Regulatory Harmonisation Programme) Linked to Option 1, 3, 6, 14

Option 13 - Support social marketing organisations (SMO) to set up a sustainable supply chain that is independent from external support	
Level	Country
Rationale	<ul style="list-style-type: none"> SMOs are generally important and appreciated providers of (a limited range) of RHCs In the context of decreasing donor funding this assists to prepare countries to be more self-sustaining for supply of RHCs Supports local organisations, improves last mile distribution, and increases choice of providers for users
Risks/Disadvantages	<ul style="list-style-type: none"> Possible impact will only be measurable in the medium to long term. Particularly for some focus countries in West Africa with limited economic growth, the populations' purchasing power might not (yet) be sufficient to generate the necessary revenue to cover supply chain costs for SMOs.
Added value of the Netherlands	The Netherlands has long standing relation with SMOs and supports the Total Market Approach.
Organisation	International NGOs (e.g., DKT, PSI), local NGOs, local SMOs, MOH
Priority ranking	Medium/High In line with objectives of Dutch policies attributable results/impact may be measurable at medium to long term only, long term benefits, existing

Option 13 - Support social marketing organisations (SMO) to set up a sustainable supply chain that is independent from external support

	infrastructure/relationships, covers focus several areas (last mile distribution, private sector, West Africa)
Additional remarks	<ul style="list-style-type: none"> Evidence exists on transitioning financially dependent SMO to independent social enterprises (e.g. DKT) Focus on local social marketing organisations Linked to Option 6, 7, 8, 9

Option 14 - Assess barriers related to regulation and policy for private sector actors to participate in the RHC market, and advocate for lifting unreasonable restrictions

Level	Country
Rationale	<ul style="list-style-type: none"> Contributes to the motivation of new private sector actors to enter the market, and to the creation of a healthier market Improves the enabling environment Provides the opportunity to improve conditions for the private sector for other medicines and commodities as well, creating a stronger and healthier pharmaceutical market
Risks/Disadvantages	Quality may be compromised if interventions are not adequately implemented
Added value of the Netherlands	The Netherlands has good experience in advocacy and have proven their commitment to advocate for improvement of issues that may be delicate.
Organisation	International NGOs (e.g., MSH, Concept Foundation and WCG), national NGOs, CSOs, regional initiatives (e.g., AMRH), MOH, NMRA
Priority ranking	Medium/High Attributable results/impact may be measurable at medium to long term only, potential high costs for long-term benefits, new infrastructure/relationships to be built, covers several focus areas (private sector, West Africa)
Additional remarks	<ul style="list-style-type: none"> Examples of possible barriers: procurement restrictions that prohibit procurement of abortion supplies by government institutions, taxes and tariffs, lack of price control Regional initiatives might be possible Explore collaboration with relevant private sector institutions such as national federations, associations of private practitioners, associations of pharmacists Linked to Option 4, 6, 12