

## **Complete set of regulations for securing the affordability and accessibility of expensive medicines**

**December 2015**

Compiled by the following:

- Dutch Association of Medical Specialists (FMS)
- The Netherlands Federation of University Medical Centres (NFU)
- Dutch Hospital Association (NVZ)
- The Dutch Healthcare Authority (NZa)
- The Federation of Patients and Consumer Organizations in the Netherlands (NPCF)
- The Dutch Nurses Association (V&VN)
- The Dutch Association of Independent Healthcare Clinics (ZKN)
- The National Health Care Institute (ZiNL)
- Dutch Associated Health Insurance Companies (ZN)
- Ministry of Health, Welfare and Sport (VWS)

### **I. Preamble**

- a. The Dutch Cancer Society (KWF) report 'Effective new anti-cancer drugs, but the financing system is creaking at the seams', together with the Dutch Healthcare Authority (NZa) report 'Investigation of the accessibility and affordability of medicines in specialist medical care', reveal signs of financial bottlenecks in the accessibility of expensive medications. The reports make various recommendations in this area. In a joint letter to the minister, dated 25 June 2015, the Dutch Associated Health Insurance Companies (ZN), The Netherlands Federation of University Medical Centres (NFU) and the Dutch Hospital Association (NVZ) express their grave concern regarding the accessibility and affordability of expensive medicinal care due rapidly increasing costs. They also express concern in relation to the macro level growth agreed to in the Framework Agreement Specialist Medical Care. These organizations say multiple, simultaneous measures are needed.
- b. As a result of the reports and the letter, the parties began discussions aimed at formulating wide-ranging set of regulations for 2016 and beyond. This integrated set of measures is in line with the Medicines Policy Plan which the minister of Health, Welfare and Sport (VWS) has agreed to in a letter to parliament ('Medicines Policy Plan', 29 January 2016, reference no. 899467-145972-GMT). Where the KWF and NZa reports recommended further study, this was not included in the integrated set of measures, but proceeds under the rubric of the Medicines Policy Plan.
- c. With this wide-ranging set of regulations, the parties intend to safeguard the affordability and accessibility of expensive medicines as well as support parties in carrying out their roles and responsibilities.
- d. As part of their legal duty in the healthcare system, insurers are responsible that no patients are denied access to expensive medicines for budgetary reasons. The Dutch Healthcare Authority (NZa) oversees the insurance industry's responsibility to provide healthcare.
- e. Healthcare providers operate according to guidelines and therefore, when it is necessary for medical reasons, prescribe expensive medicines for patients. The quality and safety of care, as well as appropriate use, are starting points for establishing and amending guidelines.
- f. Healthcare providers and insurers take expensive medicines into account when making contracts for the delivery of healthcare. If a provider runs into difficulty in a particular situation regarding the supply of an expensive drug due to financial obstacles and/or because

supplying the drug falls outside the contract, then the provider will consult the relevant insurer.

- g. The Health Care Inspectorate (IGZ) oversees the provision of responsible care by the healthcare providers.
- h. The Ministry of Health, Welfare and Sport (VWS) is responsible for the prerequisites under which this care is provided, such as earlier and better insight into developments in the drugs market and making available a sufficient macro-economic framework in which the specialist medical care authorized for the basic insurance package can be budgeted. In doing so the ministry bases its criteria on the agreements in the Framework Agreement Specialist Medical Care (MSZ) 2014-2017.
- i. Recently the minister decided that health insurance companies will carry the full financial risk for all add-on medicines, including oncolytics. The ministry intends this as an impetus for insurers toward more efficient procurement. A temporary exception has been granted when it comes to the financial risk associated with new expensive medicines which are allowed into the basic insurance package through the so-called sluice.
- j. Even with more prior information, it will remain important in the next few years to be vigilant. Parties will monitor current developments and consult in a timely fashion, both locally and nationally.
- k. Our objective is socially acceptable prices for drugs. The pharmaceutical industry bears a major responsibility in achieving this. Healthcare costs should be sustainable, even in the long term.

## **II. Set of measures**

In order to ensure the affordability and accessibility of expensive drugs, measures are needed in six different areas.

- 1. Information flow to and from healthcare providers, insurers and the Ministry of Health, Welfare and Sport (VWS)
- 2. Drugs procurement by the pharmaceutical industry
- 3. Allocation of funds between healthcare providers and within healthcare organizations
- 4. Responsible use of medicines
- 5. Systemic
- 6. Finances

### **1. Information flow to and from healthcare providers, insurers and the Ministry of Health, Welfare and Sport (VWS)**

- a. Earlier awareness of new expensive drugs, indication expansion and duration of patents

More information is available for healthcare providers, insurers, professional associations and the government regarding which expensive drugs are coming on the market and when, when indication expansion for expensive drugs can be expected, and which expensive drugs in the basic insurance package are losing their patent. This summary gives an initial estimate of associated costs (on the basis of the list price from the manufacturer, hence prior to any price negotiations). This summary is kept up to date and updates are periodically sent to healthcare providers, insurers and the Ministry of Health, Welfare and Sport (VWS).

This summary is generated under the responsibility of the VWS, meaning among others that the VWS's horizon scan can be used. VWS involves other relevant parties, including professional associations, healthcare providers, insurers and patient associations.

b. Monitoring the implementation

The Dutch Healthcare Authority (NZa) will discuss with The National Health Care Institute (ZiNL), VWS and parties in the field how developments in implementation can be brought to light more quickly, if possible throughout the year. Good monitoring succeeds or fails based on the supply of information. Parties in the sector request their rank and file to cooperate. Wherever possible existing channels of information are used. If necessary other reliable sources will be used for the brief periods. The NZa reports to the Administrative Consultation Framework Agreement Specialist Medical Care on the results of the monitoring.

**2. Drugs procurement by the pharmaceutical industry**

a. Additional improvement in the procurement of drugs from the manufacturer

Healthcare providers and insurers improve their procurement by concentrating on, among others, 1) more collaborative procurement; 2) agreeing to other types of contracts, such as contracts which take into account price decreases in the event of indication expansion and increased volume; 3) continued professionalization of procurement, for instance through setting up an effective procurement organization for expensive drugs and 4) communicating information about new drugs or expanded symptoms treatment generated at a national level to healthcare providers and insurers.

Healthcare providers and insurers are supported through 1) a summary of best practices in the field (national and international) (action: NVZ, NFU, ZKN and ZN); 2) a more detailed reading of the scope of the Dutch Competition Act in order to help parties determine the possibilities and limits for procurement collaboration under competition regulations (action: VWS and ACM); and 3) better information about national developments (see 1a).

b. VWS negotiations in the case of expensive drugs

These cases involve drugs with added value and high (macro-economic) costs in which it can be assumed due to the drug's market situation that parties cannot sufficiently cover the financial risks.

The potential to apply financial arrangements is improved, 1) through expansion of the capacity of the Drug Price Negotiation Unit at VWS in 2015/2016; 2) based on the horizon scan, obtain more information at an early stage regarding the introduction of new expensive drugs and 3) in consultation with relevant parties, based on signals of high risk, prioritize which drugs should be negotiated centrally.

These negotiations will also take into account potential indication expansion or other possible applications.

c. Improve VWS negotiating position through European cooperation

VWS spearheads the drive to achieve better affordability of expensive drugs in cooperation with other European countries.

In order to bring about a more integrated approach to Health Technology Assessment (HTA, the method used to underpin decisions on inclusion in insurance packages), the European Commission established the European Strategic Network on HTA. The Netherlands participates actively in this network and annually carries out various HTA-assessments, together with other EU members.

In addition, the Netherlands recently entered into a cooperative association with Belgium and Luxemburg. These countries exchange strategic information regarding price and reimbursement policy, jointly assess insurance package questions and shortly will begin a pilot project for collaborative price negotiation. Other EU member states have been invited to join this cooperative effort.

The Netherlands is poised to begin actively working toward further collaboration regarding price and reimbursement policy in Europe. In addition to the structural exchange of price information, and cooperation at the European level involving Horizon Scanning, The Netherlands calls attention to the theme 'access to innovative drugs at affordable prices'. This is a priority during the EU Presidency in 2016.

#### d. Appeal to pharmaceutical industry to practice socially responsible behaviour

Both VWS and parties in the field appeal to the pharmaceutical industry to practice socially responsible behaviour when it comes to realistic price determination, reducing the price upon indication expansion, and offering transparency of prices and costs at an early stage.

### **3. Allocation of funds between healthcare providers and within healthcare organizations**

#### a. Clear and smart agreements in contracting for expensive drugs

Healthcare providers and insurers are encouraged to make clear and smart deals. In contracting, the following points deserve focus:

- Locally expected amount of expensive drugs (existing as well as expected drugs, in the case that drugs enter the market over the course of the year), in part based on the nationally generated information;
- The possibility for other types of agreements. Referring to the Dutch Healthcare Authority (NZa) report, parties should consider making price times volume (PxV) agreements. This type of contract is a better way for both parties to meet their responsibilities in providing patients with expensive drugs.
- The importance of timely consultation between provider and insurer, when the provider encounters obstacles in individual situations in providing expensive drugs due to financial limitations and/or due to the fact that the provision of the drug falls outside the terms of the contract.
- Follow dispersion and concentration trends in the healthcare sector; in this way developments such as more comprehensive cancer networks can be taken into account.
- Communicating nationally generated information regarding new medicines, indication expansion, etc., to the level of healthcare provider and insurer.

The annual fact sheet macro-economic framework by ZN, ZKN, NFU and NVZ calls for explicit attention to the above.

#### B. Monitoring

Twice a year, the Dutch Healthcare Authority (NZa) monitors the agreements made among healthcare providers and insurers, and their implementation. Monitoring is geared toward the following subjects:

- The contract form agreed upon and concomitant conditions (PxV or other form);
- The procurement form and contract type (whether in collaboration with insurers or in a collective) in which drugs are purchased by the pharmaceutical industry.
- Whether or not agreements have been made regarding evaluation of the developments and timely consultation in the event of obstacles;
- Bottlenecks experienced by hospitals and/or insurers and how these parties cope.

Parties in the sector appeal to their rank and file to cooperate with the above.

The Dutch Healthcare Authority (NZa) issues a report on the results of this monitoring to the administrative consultation framework agreement specialist medical care.

d. Good allocation by healthcare provider

Healthcare providers make sure that expensive drugs are allocated properly within their institutions.

#### **4. Responsible Use**

##### Encouraging responsible use of care

- Responsible use is encouraged through various current projects, such as suitable prescription, the developing of guidelines, the Quality and Suitability Agenda (K & D) (tackling 30 disease) and the campaign Choosing Wisely, the activities of the workgroup medicines of the quality board of the Dutch Association of Medical Specialists (FMS), and the programme Waste in Healthcare.
- Professional associations and healthcare providers cooperate in order to encourage timely planning, before the implementation of a new expensive drug. A plan is drawn up describing indication area, patient population, dosage and start and stop criteria, and the drug receives a specific localisation (responsible use). When it is welcome, patient organizations are brought in.
- Establishing registries for monitoring efficacy and safety of new expensive drugs is an important condition in further refining the localization of the drug.
- Encourage the use of multidisciplinary advice groups and medicines commissions in the institutions, with representation from the knowledgeable medical and pharmaceutical professionals and financial administrators.
- Encourage professional groups, healthcare providers, insurers and patient associations to use less expensive, equivalent alternatives, including biosimilars, to the greatest extent possible. Biosimilars are less expensive alternatives for expensive biologicals. Medical practitioners prescribe these biosimilars when it is medically possible and responsible. When a patient is transferred from a biological to a biosimilar, suitable clinical monitoring must be done, in consultation with the patient<sup>1</sup>. The infrastructure concerning biosimilars is being improved through cooperative effort.

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<sup>1</sup> The Dutch Association of Medical Specialists (FMS) published an extensive position paper on the use of biosimilars in early 2015.

- Scientific research on biomarkers, which can predict a drug's effect on an individual patient, are encouraged through the Innovative Medicine Initiative (IMI) (a public-private joint venture between the European Commission and the industry). VWS has made funds available through various programmes to enable participation in international projects. The Netherlands Federation of University Medical Centres (NFU) will look into whether or not budgeting for biomarkers accepted in the insurance package is causing problems, and in what way these problems can be tackled.
- The National Health Care Institute (ZiNL) will also play a role in bringing about responsible use of care through, among others, encouraging the development of guidelines.

## 5. Systemic

### a. Limit automatic inclusion of expensive drugs in the basic insurance package

The Ministry of Health, Welfare and Sport (VWS) has established a sluice for certain expensive drugs (Letter to the House of Representatives, 9 July 2015, reference 29477, no. 343). Normally intramural drugs flow automatically into the package, as long as the care conforms to the current state of science and practice. With the sluice, risk for certain drugs is treated separately than it would be under the principle of automatic flow into the package. The goal is to make the drug accessible as fast as possible, as insured care, and also keep it accessible in the long term. This can only be done if there is an acceptable price and cost projection, and if responsible use is guaranteed. During the period that the drug is in the sluice, the package manager can assess the drug, a financial arrangement can be agreed with the manufacturer, and agreements regarding responsible use of the new drug can be made.

It has been decided (Letter to the House of Representatives, 18 September 2015, 29477 no. 348) that insurers for drugs entering the sluice carry no risk until the end of the calendar year in which the drug was included in the insurance package. Following this period, risk for these drugs will be carried entirely by the insureds, similar to all other expensive drugs.

### b. Encourage market authorization for innovative products for socially acceptable prices

VWS is making an effort to realize the fast market authorization of innovative products for socially acceptable prices. This is an important theme during the European presidency. This theme also appears in the Medicines Policy Plan which was sent to parliament in January 2016.

### c. A Drugs Prices Law (WGP) maximum rate for all drugs

VWS calculates a Drugs Prices Law (WGP) maximum rate for all drugs which can be considered under the WGP regulations and where this is useful.

### d. Carry out a public discussion on the limits to the affordability of healthcare

Parliament passed a motion (Proceedings of the House of Representatives, reference 29477, no. 340) asking the government to organize a public debate regarding the limits of and the affordability of healthcare. The minister of VWS initiated the discussion regarding affordability of care in 2012. This discussion remains very relevant, particularly when it comes to affordability and accessibility of expensive drugs in the future.

## 6. Finances

- a. VWS is making responsible use of the instrument to contain overall hospital budgets (macrobeheersinstrument, or MBI) as an ultimate remedy.

In the case of transgressions of the framework specialist medical care, VWS will first consult with the parties in the field, as stipulated in the administrative agreement specialist medical care.

The nature and the cause of the possible transgression are looked into, as well as the developments related to expensive drugs. This would involve, for instance: cost developments in the area of expensive drugs, substitution as a result of the use of expensive drugs, and to what extent parties have assumed responsibility in fulfilling the agreements in the integral package of regulations. The results of the Dutch Healthcare Authority's (NZa) contracting monitor also come into play. The developments related to the expensive drugs are considered within the broader context of the agreements in the administrative agreement specialist medical care, in which the total macro-economic policy takes into account cost developments in other areas in specialist medical care.

### **Follow-up**

Parties agree to actively take up implementation of the measures included in this integral set in order to ensure that expensive drugs remain affordable and accessible for patients. Parties will cooperate in safeguarding the progress and the implementation of the complete set of regulations in the administrative consultation specialist medical care.