Ministry of Health, Welfare and Sport

Summary of Medicines Plan

Content

Introduction

Medications play an important role in the quality of life for many Dutch people. Diseases which were once terminal are now treatable thanks to medicines. People recover more quickly, can continue to work even though they are ill, or can continue to live on their own. In the last few years, together with insurance companies, pharmacists, doctors, hospitals, patients and pharmaceutical companies, we have been able to offer patients a broad range of pharmaceutical care while at the same time controlling the cost of medications. This has been possible in part through encouraging the use of generic drugs and in part because hospitals purchase their own medicines and therefore negotiate their own prices. In addition, when it is necessary, we negotiate with drug manufacturers before a product is included in the standard insurance package.

These methods no longer suffice in keeping medications affordable. Therefore, it is time for a change of course in drugs policy. The innovative therapies currently introduced to the market are of a different order than many new drugs over the last few decades. New medicines increasingly are complex methods for treating cancer, or new medications for a small number of critically ill people. These patients' quality of life can be dramatically improved and they can sometimes even be cured outright. In and of itself, this is excellent news. But the disadvantage is that these medications are extremely expensive, in some cases costing up to 500,000 euros annually per patient. The arrival of these medications threatens the affordability of care, and will detract from care for other patients.

Furthermore, the current approval procedures require that the efficacy and the added value of a new drug must be tested with large numbers of patients. This is a problem in the case of medications developed for illnesses affecting small numbers of patients.

Hence, the current system is no longer tenable and needs to change. This is not only in the interest of patients, doctors and those who pay the insurance premiums, but it is also in the interest of the drug manufacturers themselves. After all, if we can no longer pay for their medicines, they in turn will be forced to stop producing them.

In the first place, we want critically ill patients to have faster access to innovative medicines. Therefore, the approval procedures for promising products need to be more flexible, without jeopardizing safety.

At the same time, we aim to tackle the high price of medicines. These high prices are partly a result of the fact that generic alternatives to the new products often do not yet exist. Another important cause of high prices is the extensive protection manufacturers obtain on their patents. This process was originally intended to stimulate innovation, but is currently used by the industry to maintain a monopoly – and thereby a high price -- on new medications for as long as possible. A contributing factor is that the industry is reluctant to provide transparency into how prices are determined. This makes price negotiations more difficult.

The market for medications is an international market. Therefore, we cooperate with other countries in Europe whenever we can. Through bulk purchasing and exchanging price information we improve our negotiating position. Moreover, we aim to initiate a discussion in Europe about the extensive protective regulations which make it possible for many pharmaceutical companies to maintain a long-term monopoly on medications, enabling them to keep prices unacceptably high.

We are proposing a multi-faceted approach which leads to a robust number of concrete steps. By guaranteeing the affordability and accessibility of innovative medicines, our approach can have a major impact on many people's quality of life.

1 Accessibility of innovative medicines

Medications being introduced to the market must be safe and effective. This is, of course, in the interest of the patient. But accessibility and affordability are also in the interest of the patient. Certainly in the case of critical ailments, patients want to have access to new medicines even if they are not yet registered or have yet to prove their efficacy. This is not always possible. Particularly when it comes to exceptional products such as orphan medicines and personalised medicines, current regulations appear to be inadequate for quick approval and quick accessibility for patients.

What are the chances that medications can be made accessible to patients more quickly? At the least we can make sure the requirements for authorization of new medications at the national level and at the EU-level are brought in line. That would reduce the administrative burden, which in turn reduces the time it takes the drug to reach the patient.

Special attention needs to be paid to promising medications for ailments affecting small numbers of patients. Frequently, little information is available about these products, making it difficult to establish their safety and efficacy. These very drugs can represent the difference between life and death for a patient, so the question is: how can we be more flexible in the authorization process. For instance, is it possible to allow conditional authorization, whereby some of the clinical information can be reported later? In order to do this, it is necessary, in consultation with the manufacturer, to identify the minimum requirements these medications must meet. Safety has to remain the first priority. If such a medicine is promising and possibly of critical importance for patients, then we can consider granting immediate, if conditional, approval to the standard insurance package. After a designated period, we would determine whether the medicine is effective and whether or not it can remain in the standard package.

While we prefer registered medications, it should be possible under strict conditions for special compounding pharmacies to prepare medications for local pharmacists. These medicines would be reimbursed if it's clearly in the patient's interest. This often involves tailor-made prescriptions, such as drops for children who have difficulty swallowing pills. These pharmaceutical preparations improve access to medications, as well as lowering the price. As soon as medicines are registered, the price goes up exponentially. This is nearly impossible to explain to a patient. Hence, registration is quite important, but not at any price.

>>Go to action

Action:
Accessibility of innovative medicines

- Look into how flexible means of market authorization could be used more effectively, so that certain products can reach the patient more quickly and at the same time be affordable.
- Ensure that conditions for market authorization at the EU level and approval for the standard insurance package at the national level are, as much as possible, in line with one another. That reduces the administrative costs and cuts the time required for a product to reach the patient.
- Use the Dutch presidency of the EU to work on a more flexible system to allow special, urgently needed medicines onto the market and make them available to patients.

2 Tackle the high price of medications

The drug Sovaldi is an important breakthrough in the treatment of patients with chronic hepatitis C. The problem is that a one-time treatment costs between 48,000 and 96,000 euros. In The Netherlands we have an estimated 20,000 patients with this disease. The supplier defends this price in part by pointing to the great value to the patient and to those affected by the patient's illness. After all, people are able to live longer in good health. But such costs make our healthcare unaffordable. If we continue in this way, it will become nearly impossible to reimburse patients for these medications.

What can we do about the price explosions in the pharmaceutical industry? To start with, we must provide healthcare insurance companies and hospitals a better position in negotiating the price of medications. To accomplish this, it is necessary to have thorough insight into the pharmaceutical market. This involves questions such as; what expensive medications are in development, for whom are they intended, and when do their patents expire? Together with insurance companies and hospitals we aim to make this information more transparent. We are establishing a platform for sharing expertise and information concerning the procurement of drugs. Through this platform, insurance companies and healthcare providers can share their knowledge and experience and explore the possibilities for joint procurement.

These types of collaborations have already proven to be successful. For instance, a procurement collective of academic hospitals and hospital pharmacies are cooperating in an attempt to achieve price reductions. Toward the same goal, insurers are entering into various cooperative efforts with doctors, pharmacists and healthcare organizations. Information is of the essence. Therefore, we are establishing guidelines to clarify what sorts of procurement cooperation are possible under the Dutch Competition Act. In addition, we are creating the Expensive Medications Monitor for an up-to-date overview of what hospitals spend on medications and what agreements hospitals make with healthcare insurers regarding medication procurement. Finally, we are encouraging those hospitals which do not yet have one to create a medications commission in which all parties can determine their policy on expensive medications. We are doing this in order to prevent variations in patient treatment from one hospital to the next due to the price of medicines.

A second method to reduce prices is reforming the system of determining reimbursement levels and approval to the standard insurance package, the Medicines Reimbursement System. By critically evaluating the maximum reimbursement which this system applies to groups of medications, we can, in many instances, reduce the amount of the maximum allowed reimbursement. Plus, in the case of classes of medications which are interchangeable, we can lower the reimbursement as soon as there are competing medications. When more than one medicine is on the market to treat an ailment or a disease, one would expect that competition would lead to lower prices. That is not necessarily the case in our current system. In addition, we can counteract higher prices by imposing limitations on the reimbursement of certain expensive hospital drugs which currently receive automatic approval for the standard insurance package. These limits would be lifted contingent on a new round of price negotiations. For this type of regulation, we will make use of the existing Drug Price Negotiation Unit.

Finally, the market for medication is international and the Dutch market share is too small to exert structural influence on prices or on the behaviour of manufacturers. Therefore, we seek to collaborate with other countries in Europe in various ways, including negotiating jointly and exchanging price information more frequently.

>>Go to action

Action:

Tackle the high price of medications

- Better equip healthcare insurers and healthcare providers for the procurement of medications.
- Establish a platform to exchange expertise and information on the procurement of drugs.
- Establish guidelines stipulating what leeway the Dutch Competition Act allows for cooperation in the procurement of medicines by insurance companies and hospitals.
- Introduce an Expensive Medications Monitor which provides an up-to-date overview of expensive medications purchased by hospitals and presenting patients' experiences with these drugs.
- Help ensure that every hospital has a medications commission in which interested parties discus and determine policy regarding expensive medications.
- Achieve price reduction by changes in the way medications are accepted into the standard insurance package as well as into the reimbursement system.
- Recalculate groups of medications in the Medicines Reimbursement System to create lower limits for reimbursement. In addition, set limits on hospital medications which are automatically placed in the standard insurance package.
- Broader use of the Drug Price Negotiation Unit.
- Initiate international cooperation to improve timely access to medications for patients, to encourage innovation, to keep medicines affordable and to expand transparency between member states.

3 New methods to develop and sell medicines

Only a few dozen patients in The Netherlands suffer from the serious metabolic disease lipoprotein lipase deficiency, or LPLD. The successful drug Glybera was developed for these patients. Research leading to its development was financed by, among others, a government subsidy from the Netherlands Organization for Health Research and Development (known by its Dutch acronym ZonMw). The downside is that the manufacturer of this product charges approximately €1.1 million per treatment. ZonMw receives nothing.

This example begs the question: are we paying twice over? Not only is the medicine extremely expensive, the Dutch taxpayer has already paid for its development through the research subsidy. We would like to prevent this in future. To this end, new methods are needed to develop medicines and bring them onto the market.

How can we do this? Research subsidies are not required to be paid back, and we cannot do much about the price a manufacturer asks for a product. After all, pharmaceutical companies have a patent on new medicines and can drive up the price due to their monopoly. One way or another, we must pay the price. And the bill ends up going to the taxpayer. That's why we seek to put conditions on the financing of medication development. If the medicine is successful, money must flow back to the research programme, or the taxpayer should share in the profits in some other way. We would like drugs manufacturers to provide transparency into how they set their prices. What percentage of the price is based on research, development and production? What percentage is pure profit? In addition, we aim to join forces with other countries to negotiate with manufacturers about price. Hospitals and insurers can also collaborate in their negotiations with drugs manufacturers.

In this way, we aim to make a change in the medicines market. We will make room for other, new ways to develop medicines and bring them to the market. There are already initiatives demonstrating that medicines can be produced with clarity as to the cost and how the price is set. Such initiatives deserve the chance to prove themselves, which is why we are encouraging them.

>>Go to action

Action:

New methods to develop and sell medicines

- Set conditions for research subsidies in order to prevent the Dutch taxpayer from paying twice for medications.
- Create space for alternatives to the development and sale of medicines, so that affordable medicines enter the market with clarity as to what goes into setting the price.

4 Appropriate use of medicines

Certainly in the last few decades, medicines have had a very positive influence on people's health and quality of life. However, the unnecessary use of medications can lead to various unintended effects. In such cases the medication either has no effect, or needless side effects, or can be outright harmful. Plus, it is a waste of money.

Much is already being done towards the proper use of medicines. That needs to continue, since developments in pharmaceutical care move quickly. It is important to know with more precision when patients should start and finish a treatment, and what exact dosage a patient needs. Those administering the treatment as well as pharmacists also want to know how the large number of new medications work in practice. We seek to expand this type of knowledge through supporting 'diagnostic development' by means of a programme to stimulate the acquisition of information. In this way we can come up with new methods to use medicines specifically geared toward individual patients. In addition, we are implementing the programme the Responsible Use of Medicines. With that we are conducting research into how we can best and most safely use current medicines.

The pharmacist is of course particularly well suited to inform people about the best use of medications. Good pharmaceutical care is therefore of utmost importance. In order to realize a constantly improving handover of medicines we are amending the current guideline for medication file transfer. We also aim to ensure that pharmacists receive better information from the laboratories, that the symptoms are stated on the prescription, and that patients do better at keeping to their treatment and at using the medications according to the prescription.

Finally, we are giving special attention to 'biosimilars': cheaper, equivalent variations of expensive biological medications. As long as doctors are careful in prescribing these 'biosimilars' for patients we can save a significant amount without compromising the quality of care. We already do this quite well, but we have much to learn from countries such as Denmark and Norway, where considerable savings have already been made. With the expertise and the experience which we have already acquired here in our own country, we seek to further encourage the use of biosimilars.

>>Go to action

Action:
Appropriate use of medicines

- Support diagnostic developments so that more information about the right dosage and the start and end point for the treatment is available to the patient and to the person administering treatment.
- A five-year programme for stimulating 'personalized medicine', for which 10 million euros is available.
- Amend the current guideline for medication file transfer and ensure that chemists receive better information from the laboratories, and that the symptoms are indicated on the prescription, and that patients do a better job keeping to their treatment.
- Encourage the use of biosimilars.

5 Balance in the pharmaceutical market

The way the pharmaceutical market works has led to innovation and new medicines which are extremely valuable for patients. But those patients, and in fact all Dutch people who pay insurance premiums, find themselves at a disadvantage because pharmaceutical companies have a monopoly when it comes to new medicines. Therefore, we need to seek a healthy balance between rewarding innovation and the affordability of medicinal care.

In the first place, we can re-evaluate the protection pharmaceutical companies enjoy through the patent process when new medicines are approved for the market. At the international level we have already initiated the discussion regarding various additional types of protection possible through EU regulation. Other EU-countries also realize that a good balance between the price of new medicines and their availability to patients is often lacking. Therefore, it is worthwhile to highlight this subject during the Dutch EU presidency in 2016.

A particular problem with protecting new pharmaceutical products are orphan drugs for rare ailments or diseases. In addition to the existing protection, companies receive another ten years of 'market exclusivity' for developing these medicines. Whoever is the first to bring such a medication to the market has a robust monopoly, even though it may not be the best possible medication for the patient. The number of official orphan drugs is on the rise. Of course, this is not a good development for people totally dependent on this sort of medication. Therefore, we need to look carefully, in the EU context, at the broad definition of orphan drugs and at how long they should remain protected.

Second, how manufacturers behave is important. They are not allowed to make agreements to limit competition, just as they are not allowed to abuse their monopoly. This happens nonetheless, taking away any chance patients have for getting access to less expensive medications. It is a tough problem to combat: the patent protection which the producers enjoy at the EU level are often at odds with the Dutch Competition Act. New rulings by the Court of Justice of the European Union are needed to alleviate the situation. From the perspective of the patient, or the payer of the insurance premium, it is not acceptable to have less competition while profit in the pharmaceutical industry continues to grow. At the national level it is difficult to do anything about this, although we are closely following the developments. The European Commission recognizes the problem as well. We are currently awaiting a ruling from the Court of Justice and, if they allow the space for it, we will undertake action.

>>Go to action

Action:

Balance in the pharmaceutical market

- The protection of intellectual property and shareholder interest must be in proportion to the goal, namely encouraging innovation. In addition, the behaviour of companies and their understanding of the rules is crucial.
- We will more clearly determine which products fall under the EU regulations for orphan drugs. Furthermore, we seek to intensify the discussion about the balance between market protection of orphan drugs and the supply of the new products.
- The Netherlands Authority for Consumers and Markets will continue to strictly monitor illicit behaviour by pharmaceutical companies. When necessary and possible this organization will also intervene.

6 Better Information Services

In the case of many of the aforementioned regulations, it is important that we continue to monitor the effect of new products. Registries provide insight into treatments: when a treatment should start and finish, which patients had the most success and whether the cost of the medicine should be reimbursed.

These registries have been established and maintained at the national as well as the international level in various ways and as a result have become fragmented. To help solve this problem we are creating a 'plan of action for information services'. This plan should clarify how the goal, the procedures, the roles and the financing of the registries should be set up. For instance, it is important that doctors register when they have prescribed an expensive medication so we get an indication of how that can differ per practice. The Medicines Evaluation Board is establishing a databank for the collection of this information.

We have also commissioned various organizations to create an independent information service, both for the healthcare providers, as well as for patients. There is plenty of information available but patients in general cannot do much with that information and it is usually not easy to find. We seek to improve that in the short term.

>>Go to action

Action:
Better Information Services

- A plan of action for information services which clarifies the roles, the goals, the procedures and the responsibilities of the registries.
- The Medicines Evaluation Board establishes a databank for information about doctors' prescription practices.
- We will improve independent information for patients so it is comprehensible and easy to find.

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