Algemene Rekenkamer

Miracle cure or sticking plaster?

The results of negotiations on the prices of medicines

2020

Preface

Along with the rest of the world, the Netherlands has been firmly in the grip of the coronavirus (SARS-CoV-2, which causes the disease known as COVID 19) since the beginning of the year. The measures taken by the Dutch government since March have had a huge impact on the daily lives of everyone in the country. The same applies to us: we, too, are feeling their effects.

There is no link between this audit of negotiations on the prices of medicines and the quest to find a vaccine and medicines to combat the SARS-CoV-2 pandemic. Our findings and conclusions have not been altered by the grave developments caused by the coronavirus in 2020.

Despite the difficult circumstances, we were able to complete this publication and the Minister for Medical Care and Sport was able to respond to our conclusions and recommendations. This illustrates how the Dutch democratic system, including independent audits performed by the Netherlands Court of Audit, continues to operate – even in the exceptional circumstances prevailing in the spring of 2020.

Original title

Algemene Rekenkamer (2020). *Paardenmiddel of noodverband? - Resultaten prijsonderhandelingen geneesmiddelen*

Inhoud

Summary

Healthcare spending in the Netherlands is projected to total almost €80 billion in 2020. This figure is expected to continue to grow sharply in the years ahead, both in absolute terms and as a proportion of total public expenditure. There remains a need, therefore, to contain the rise in healthcare spending and hence to continue to make choices. Choices in medical care are particularly poignant as they often have a face – that of patients, people for whom the availability of medicines or the presence of insurance cover for the cost of treatment may well be a matter of life and death. This dilemma is reflected time and again in the recurring debate on the provision of insurance cover for expensive, new medicines – and the prices that we pay for these medicines.

In 2012, the Minister of Health, Welfare and Sport started negotiating with manufacturers on the prices of medicines. Negotiations became increasingly commonplace in the years that followed and were incorporated as an integral part of policy in 2016, when the Ministry published its strategy on medicines. This was prompted by the growing number of expensive medicines – some of them extremely expensive – on which the Minister was required to take a decision. The high prices that manufacturers demand for medicines may lead to non-cost-effective medical care and/or to sharp rises in expenditure. Given the agreements made to allow healthcare spending to rise only to a very limited degree, other types of care may be crowded out by expensive medicines. The then Minister of Health, Welfare and Sport said that she was unable to sufficiently mitigate this trend with the instruments she had at her disposal at the time. By negotiating at a national level with manufacturers on the price of medicines, the Minister of Health, Welfare and Sport (now known as the Minister for Medical Care and Sport) aimed to keep new medicines accessible for patients at affordable prices.

We audited the results of these price negotiations for the period between 2012 and 2018. We examined whether the 32 price agreements helped to achieve cost-effective medical care and control spending on medicines.

Where available (i.e. in 13 out of the 32 cases), our audit was based on the prices recommended by the Dutch National Health Care Institute. Where negotiations result in the recommended price being agreed, medical care may be said to be cost-effective. For the other 19 cases, where no recommended prices were available, we compared the results of the negotiations with their intended aim.

We concluded that the centralised price negotiations between the Ministry of Health, Welfare and Sport and the pharmaceutical companies are likely to make a positive contribution to controlling expenditure on expensive medicines, and, by extension, to controlling healthcare spending as a whole. We also found, however, that the Ministry of Health, Welfare and Sports did not succeed in attaining the price recommended by the Dutch National Health Care Institute in five out of 13 cases. This means that, in these five cases, the negotiations did not lead to cost-effective medical care. In a number of other cases, the Minister already decided not to set the price recommended by the National Health Care Institute as her target price for the negotiations. We therefore find that, to date, price negotiations have had only a limited effect in achieving cost-effective care.

The negotiations also help to control spending on medicines. We were unable to assess the extent to which this was indeed the case, not only because there is no standard for measuring their effectiveness, but also because other instruments also help to control expenditure. We do, however, believe that the Minister for Medical Care and Sport should seek to achieve bigger reductions in spending, particularly in negotiations on medicines used during the course of hospital treatment (known as 'hospital medicines'). The fact is that spending on hospital medicines has grown sharply in the past few years, even though the latest outline agreement on specialist medical care (dating from 2018) states that there should be little or no increase in spending on specialist medical care. In fact, we believe that, if this trend continues, there is a risk of spending on hospital medicines crowding out other types of specialist medical care.

It goes without saying that the Minister should continue to negotiate with manufacturers as long as prices for new medicines continue to be high or extremely high. Without wanting to detract from the results achieved to date, the Minister needs to achieve better negotiation results in the future. We already referred to the situation affecting specialist medical care. In addition, it is clear from the *Medicines Horizon Scan* published by the National Health Care Institute that it expects a large number of new medicines to come onto the market in the years ahead, and that some of these will absorb a large amount of expenditure. If anything, therefore, the need to control spending on medicines would appear only to have become more urgent.

We were also interested in ascertaining whether the Minister for Medical Care and Sport would be able to adopt a tougher negotiating stance, not only in the long term, but also in the near future. We believe that this would be possible, first and foremost by seeking to create sufficient public support for the principle of turning down a final offer from a pharmaceutical company that the Minister believes to be unacceptable.

We also wish to bring up the issue of consistency with the Minister's strategy on medicines, and more specifically with policies that may influence the balance of power between market parties, such as the promotion of biosimilars, the use of pharmaceutical compounding, and compulsory licensing.

This brings us to the following recommendations for the Minister of Medical Care and Sport:

- Toughen your negotiating stance by:
  - stating explicitly that, in accordance with the recommendations made by the Dutch National Health Care Institute, the negotiations should be aimed at reaching a price at which care is cost-effective as a minimum requirement;
  - gearing negotiations towards ensuring that the level of spending rises at a slower pace than in recent years.
- Give Parliament more information about whether the negotiations were successful in terms of achieving the prices recommended by the Dutch National Health Care Institute.
- When implementing the Medicines Policy Plan and taking decisions in this connection, assess whether these decisions help to improve the Ministry of Health, Welfare and Sport's negotiating position.
- Be prepared to turn down a final offer from a pharmaceutical company that you feel is unacceptable. If such an eventuality does indeed arise, inform parliament in good time and explain clearly to society at large why this decision was taken.

1 Introduction

1.1 Growing healthcare spending

According to the Dutch Ministry of Health, Welfare and Sport, public health expenditure in the Netherlands will increase to almost €80 billion in 2020. This figure includes expenditure on curative care (e.g. GPs and hospital care) as well as long-term care (e.g. care homes).

In its medium-term survey of 2022–2025, published at the end of 2019, the Netherlands Bureau for Economic Policy Analysis projects that healthcare spending will continue to grow sharply in the years ahead, also in comparison with spending on education and social security, for instance (Netherlands Bureau for Economic Policy Analysis 2019). The Netherlands Bureau for Economic Policy Analysis claims that, while population growth, and the ageing population in particular, are the main factors behind the increase in healthcare spending, two other important factors are the increase in the cost of healthcare per person and the introduction of new treatment methods. Undoubtedly, this also includes new medicines.

1.2 A new policy tool

First negotiations in 2012

The year 2012 marked the start of negotiations on the prices of new medicines between the Ministry of Health, Welfare and Sport and two pharmaceutical companies. The negotiations concerned two new anticoagulants, which it was thought might benefit more than 200,000 patients. At the time, the Dutch Health Care Insurance Board (now known as the National Health Care Institute) stated that spending on these new medicines could rise to €150 million per year (Healthcare Insurance Board, 2012).

In November 2012, the Minister of Health, Welfare and Sport informed Parliament about the negotiations and the agreements made (Ministry of Health, Welfare and Sport 2012). She reported that she had made price agreements with the manufacturers not only because she wanted to make the new medicines available to physicians and patients, but also because she feared potentially soaring expenditure and believed at the time that health insurers were not capable of negotiating lower prices with pharmaceutical companies on their own.

The agreements provided, among other things, for lower initial prices, followed by further price cuts as the volume of sales rose. The Minister said that the cost savings could potentially rise to several tens of millions of euros, depending on the sales volumes. The contract was

concluded for a period of three years. After those three years, the Minister contended, the entry of two new anticoagulants on the market would create sufficient market competition for price negotiations to be left to the market parties from then on.
The centralised price negotiations on anticoagulants were followed by more rounds of negotiation. Between 2012 and 2018, the Minister for Health, Welfare and Sport concluded price agreements for 32 medicines (see Figure 1). In 2017, the monetary value of price agreements (calculated on the basis of asking prices) totalled slightly over €450 million, representing around 7% of the total sum of €6.5 billion spent on medicines in that year.

The Minister has made 32 price agreements since 2012

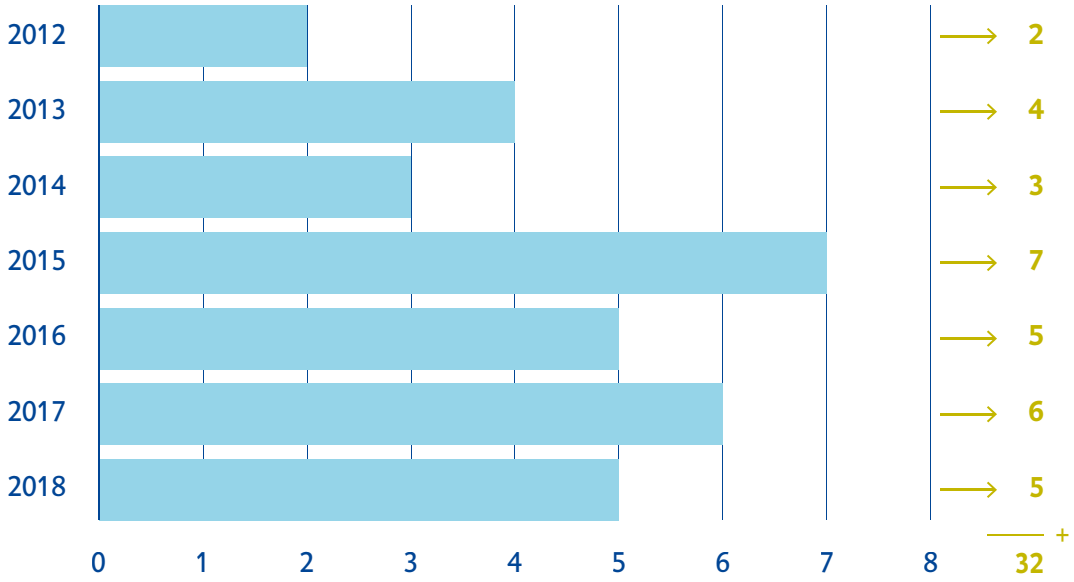


Figure 1 *Price agreements reached in 2012-2018 (n = 32)*

When the Minister for Health, Welfare and Sport informed Parliament about the first price negotiations in November 2012, she said that she did not expect the instrument of price negotiations to be used across the board, but only in those cases that required a tailored approach. At the same time, she indicated that it would be good to gain more experience with this new policy tool.

The Ministry of Health, Welfare and Sport embarked more often on price negotiations in the years after 2012, as Figure 1 shows. To this end, the Ministry set up a new unit called the Drug Price Negotiation Unit. In the first years after its launch, the Unit went through a pilot phase.[1]

"The rise of ever more expensive medicines"

In early 2016, the Minister of Health, Welfare and Sport published a new Medicines Policy Plan entitled: 'New drugs available to patients fast and at an acceptable cost' (Ministry of Health, Welfare and Sport 2016). The Minister explained that the existing instruments for controlling spending on medicines were no longer sufficient:

"…the growth of increasingly expensive drugs is putting more and more pressure on the affordability, and hence on the sustainability, of the healthcare system. The current system of developing and commercialising medicines is tough to maintain in the long term. One way or another, the bill will have to be paid: by an increase in insurance premiums, by raising deductibles or income-dependent premiums, by denying patients access to certain new drugs (by not paying for them) or by removing other types of care from the basic insurance package." (Ministry of Health, Welfare and Sport 2016).

That said, not all new medicines are designed to achieve previously unattainable results. Likewise, some of the medicines on which the Ministry of Health, Welfare and Sport negotiated have more therapeutic value than existing treatments, which also explains the social pressure to include these medicines in the basic package of insured care.

Examples of medicines with a high price and/or high level of spending on which the Ministry of Health, Welfare and Sport conducted price negotiations.

Medicine brand name	Condition/Illness	Manufacturer's asking price as reported by the National Health Care Institute
Myozyme	Pompe disease (classic form)	€706,666 p.p.p.y.*
Myozyme	Pompe disease (non-classic form)	€422,314 p.p.p.y.
Orkambi	Cystic fibrosis (CF)	€169,386 p.p.p.y.
Soliris	PNH (disease of the blood) aHUS (disease of the blood causing renal failure)	€360,000 p.p.p.y.
Spinraza	SMA (severe muscular disease)	€499,800 (year 1)
Spinraza	SMA (severe muscular disease)	€249,900 (year 2 and following)
Lojuxta	Homozygote familial hypercholesterolaemia, an inherited disease causing high blood levels of cholesterol (a typeof fat).	€529,000 p.p.p.y.
Opdivo	Melanoma (form of skin cancer) Lung cancer	€42,000 per course of treatment
Xarelto	Atrial fibrillation (cardiac arrhythmia)	€932 p.p.p.y.**
Vosevi	Chronic Hepatitis C	€51,000 per 12 weeks

* *p.p.p.y. = per patient per year*

** *Projected number of patients: over 200,000 after three years*
Projected aggregate expenditure per year: €150m after three years

Source: Advisory reports published on these medicines by the National Health Care Institute

In her new Medicines Policy Plan, the Minister specified her objective as being that of keeping new medicines accessible at acceptable prices: "I want to achieve a stronger negotiating position for the purchaser, so as to ensure the price of a medicine bears a closer relationship with its actual cost and added value." (Ministry of Health, Welfare and Sport 2016). She discussed various measures to achieve this objective, one of which was extending the centralised price negotiations. To this end, the Drug Price Negotiation Unit was given (after the pilot phase had been completed) a structural role and its staffing capacity was expanded to eight FTEs. The evaluation of the pilot phase had shown that the majority of the market parties (i.e. healthcare providers, health insurers, patient support groups and pharmaceutical companies) supported the idea of centralised negotiations on the prices of medicines in those cases in which the market is not capable of doing this on its own (Ecorys 2016).

1.3 Why have we audited the price negotiations?

Undeniably, the Ministry of Health, Welfare and Sport has succeeded in negotiating discounts on the pharmaceutical companies' asking prices, thanks to centralised price negotiations. Since 2016, the Minister of Health, Welfare and Sport (now the Minister for Medical Care and Sport) has informed Parliament annually about the aggregate discount achieved on medicines (section 5 of this report has more information on spending reductions). To date, the medicines in question have all been included in the basic package of insured care, and patients have adequate access to them in practice (Common Eye & SiRM 2019; Dutch Healthcare Authority 2019). However, the question is whether the negotiated prices were 'acceptable' in all cases. At which point are negotiated discounts adequate?

For the Ministry of Health, Welfare and Sport, the negotiating target follows from the Medicines Policy Plan. This means that the Minister for Medical Care and Sport works out an 'acceptable price' by assessing, on a case-by-case basis, not just the medicine's cost-effectiveness and the total level of spending (or expected spending), but also the availability or accessibility of the medicine for patients, and whether or not it is used for treating a rare disease. This assessment may result, for instance, in the Minister for Medical Care and Sport attaching less value to the cost-effectiveness of treatment if total expenditure at a macro level is relatively low.

In performing this audit, we wish to assess the degree to which the price negotiations led by the Ministry of Health, Welfare and Sport have helped to achieve cost-effective health care and to control spending on medicines.

Our audit criterion is that, in all cases, the centralised price negotiations much result in a price that ensures cost-effective healthcare (section 1.4 below contains more information on the concept of cost-effectiveness). This is not the only factor at play, however. For a number of medicines, even though the asking price already equates with cost-effective care, total expenditure (at a macro level) may nonetheless be very high, due to the large projected number of patients. In these cases, the centralised price negotiations must therefore be aimed at limiting spending (or aggregate spending) on medicines.[2]

1.4 The basic principles of our audit

Criteria for cost-effective health care

The reference standard that we used for cost-effectiveness is the recommended price issued by the National Health Care Institute. This recommended price is based on a medicine's therapeutic added value on the one hand, and the generic benchmark used in the Netherlands of one extra quality-adjusted life year (QALY), i.e. €80,000, on the other.[3] The discount negotiated on a medicine by the Ministry of Health, Welfare and Sport should at least result in a price that is the same as the National Health Care Institute's recommended price. This is the price at which healthcare is cost-effective.

Cost-effectiveness

The concept of cost-effectiveness expresses the relationship between additional costs and increasing returns (in this case health gains) of treatment. For example:

- the current treatment of illness 'A' costs €10,000 per patient per year;
- a new medicine for treating illness 'A' costs €50,000. This medicine gives patients suffering from illness 'A' an extra 0.25 of a year in good health compared with the current treatment. This is 0.25 QALY.

The new medicine's cost-effectiveness is calculated by dividing its additional cost (i.e. €50,000 less €10,000 = €40,000) by the health gain (i.e. 0.25 QALY). The new medicine's cost-effectiveness thus works out at €40,000/0.25 QALY = €160,000/QALY.

The maximum price at which the new medicine is cost-effective, assuming a limit of €80,000 per QALY, is: (€80,000*0.25) + €10,000 = €30,000.

Nonetheless, the reference value of €80,000 per QALY is relatively high. Studies have estimated the average price of one extra year of life in good health (QALY) for the Dutch healthcare sector as a whole at less than €20,000 (Meerding et al. 2008). For cardiovascular hospital care, the price of one QALY is estimated at €41,000 (Van Baal et al. 2018). This means that paying for new treatments at a reference value of €80,000 per QALY raises the risk of the treatment crowding out other forms of care. As we have already indicated, our

audit was based on the prices recommended by the National Health Care Institute. Virtually all of these recommended prices were based on a reference value of €80,000 per QALY. Thinking in terms of cost-effectiveness is not intended primarily to cut costs. It does, however, help to make choices in healthcare, for example by asking whether, on balance, more health gains can be achieved by allocating healthcare resources differently.

Negotiations on medicines that are already cost-effective

In some cases, a manufacturer's recommended retail price, i.e. the list price or asking price, already equates with cost-effective care. In these situations, the National Health Care Institute did not issue a recommended price. Many of its reports on such medicines do, however, include an estimate of the annual sales volume. As we have said, the anticipated level of expenditure may nonetheless be so high at a macro level as to cause the National Health Care Institute to advise the Minister of Health, Welfare and Sport (or, as is now the case, the Minister of Medical Care and Sport) to enter into price negotiations.

It is difficult to assess the outcome of price negotiations. There is no clear reference standard available for the proportion of expenditure absorbed by a medicine. In addition, the government has other tools available to it for controlling spending on medicines, making it impossible to state precisely how much centralised price negotiations help to control spending. We do believe, however, that the negotiations should aim to make an effective contribution towards achieving moderate growth in spending on medicines. Broadly speaking, the main reason for this is that healthcare must continue to be affordable and rises in health insurance premiums must be contained. The second, more specific, reason is that the risk of crowding out other forms of medical care must be limited as much as possible. Given the very modest growth in spending in the coming years set out in the government's latest Outline Agreement on specialist medical care, we believe that there is indeed a realistic crowding-out risk. See section 2.2 for more information on this topic.

Audit scope

We reviewed the 32 price agreements reached by the Minister of Health, Welfare and Sport or the Minister of Medical Care and Sport between 2012 and 31 December 2018. In the case of 13 of the 32 agreements, we had access to prices recommended by the National Health Care Institute (see Figure 2). In these cases, we assessed the extent to which the negotiated outcomes approached the recommended prices.[4]

In the first years of centralised price negotiations, the National Health Care Institute did not recommend prices

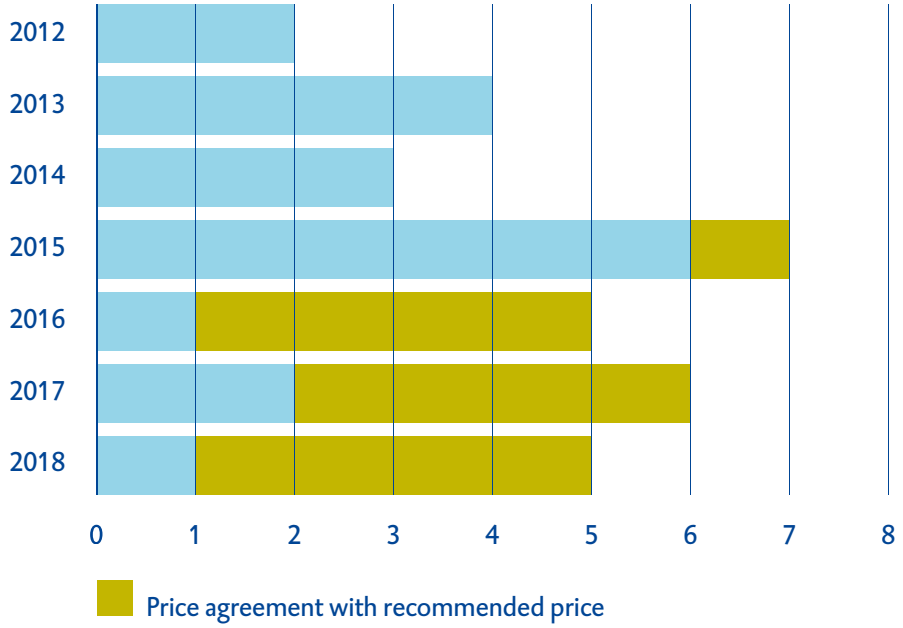


Figure 2 *The 13 price agreements in relation to which the National Care Institute issued a recommended price*

We first examined whether the Minister's negotiating targets corresponded with the recommended prices. We then compared the negotiated outcomes with the recommended prices in order to ascertain whether the National Care Institute's recommended price had been achieved when the price agreement was signed (t = 0). Lastly, we used data on actual prices in order to assess whether the negotiation targets were indeed achieved in practice (t = 1, 2, etc.).

In the 19 cases in which the medicines were already cost-effective at the manufacturer's asking price (12) or for which the National Care Institute had not issued a recommended price (7), we compared the negotiated outcome with the Minister's pre-set target.[5]

Individual negotiations not audited

Dutch healthcare providers purchase medicines from pharmaceutical companies and conduct their own price negotiations. Before the time of centralised negotiations, they already negotiated on the prices of all medicines, i.e. including the expensive ones. We did not examine how the financial results obtained from decentralised negotiations compared with those achieved by the centralised price negotiations conducted by the Ministry of Health, Welfare and Sport.

Limitations of the report

The findings published in this report cannot be traced back to individual medicines or small groups of medicines, as the agreements concluded between the Minister and the various pharmaceutical companies are confidential. Where medicines are mentioned by name, the information is in the public domain.

1.5 Format of the report

Chapter 2 contains background information on the context in which the Ministry of Health, Welfare and Sport conducts its price negotiations, i.e. the health insurance system, healthcare spending, the medicines market, and the government's medicines policy.

Chapter 3 describes the negotiating procedure. It discusses in more detail the National Health Care Institute's recommendations and the Minister for Health, Welfare and Sport's (or, as the case may be, the Minister for Medical Care and Sport's) negotiating targets.

Our audit findings are set out in chapter 4. We distinguish between those medicines that were not cost-effective at the manufacturer's asking price at the start of negotiations, and those that were.

Chapter 5 examines the information that the Minister for Medical Care and Sport submits to Parliament about the negotiated outcomes.

Chapter 6 lists our findings and recommendations. The final chapter, chapter 7, contains the response of the Minister of Medical Care and Sport and our own afterword.

2 The background to price negotiations

2.1 Inclusion in the basic package of insured care

Healthcare policies distinguish between medicines that are available from pharmacies (known as 'out-of-hospital medicines') and medicines used during the course of hospital treatment (known as 'hospital medicines'). The two groups of medicines are subject to their own separate arrangements for inclusion in the basic package of insured care and for funding.[6]

Health insurance policies do not cover out-of-hospital medicines until they have been included in the medicine reimbursement system. The Minister of Health Care and Sport decides whether a new medicine should be included in the package of insured care on the basis of a recommendation from the National Health Care Institute. This is known as a *closed system*.

Hospital medicines, on the other hand, are subject to an open system. In principle, 'state-of-the-art' medicines are automatically included in the basic package. In 2015, in the knowledge that more and more expensive hospital medicines were being included in the basic package, the Minister of Health, Welfare and Sport decided to introduce the principle of a 'waiting room' for medicines (Ministry of Health, Welfare and Sport 2015). This enables the Minister to temporarily halt the automatic inclusion of a new, expensive medicine based on financial criteria. Pending the approval of the new medicine, the Minister asks the National Health Care Institute for a recommendation on its effectiveness and cost-effectiveness (see chapter 3).

The Minister negotiates on the prices of both out-of-hospital and hospital medicines. Until 2017, the majority of negotiations concerned out-of-hospital medicines (see Figure 3). Medicines for treating chronic hepatitis C (HCVs) and direct oral anticoagulants (DOACs) are two examples of such medicines.

Number of negotiations on hospital medicines on the rise since 2016

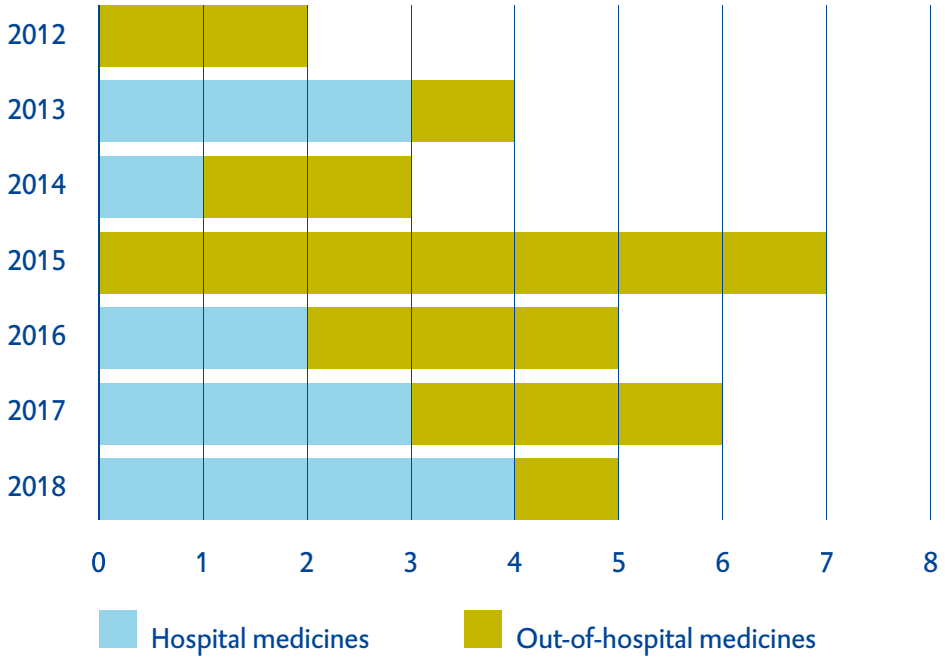


Figure 3 *Price agreements concluded between 2012 and 2018, by out-of-hospital and hospital medicines (n = 32)*

The number of negotiations on the prices of hospital medicines has been climbing every year since 2016. In 2018, the majority of negotiations concerned hospital medicines; this is not expected to change in the foreseeable future.

In December 2019, the National Health Care Institute published the sixth edition of its *Medicines Horizon Scan* (see text box[7]), according to which a large number of new medicines is likely to come on to the market in the Netherlands in the near future: an estimated 465 new medicines (over 250 of which are hospital medicines) are expected to be assessed for inclusion in the basic package of insured care in the next two years. The latest Medicines Horizon Scan expects to see a sharp rise in the number of new medicines (including the use for other indications of current medicines already included in the basic package) compared with previous editions (National Health Care Institute 2019). In a number of cases, the new medicines in question represent a projected annual cost of over €100 million.

Medicines Horizon Scan

The Minister of Health, Welfare and Sport developed the Medicines Horizon Scan together with healthcare stakeholders in order to optimise knowledge about new medicines in the pipeline and to identify future trends. The objective of the Horizon Scan is to inform stakeholders at an early stage about medicines that are scheduled to enter the market and their potential effects. The Horizon Scan lists all anticipated new medicines (both proprietary medicinal products and the use for other indications of medicines already included in the basic package) that will be coming on stream in the next two years. This information allows market parties to organise their purchasing activities better, make clearer agreements about the use of these medicines, and start organising the necessary care and funding in good time (Ministry of Health, Welfare and Sport 2015).

An *International Horizon Scanning Initiative* (IHSI) has also been launched, under which nine countries* have agreed to share information among each other. They expect that the initiative will firmly boost their ability to negotiate with manufacturers about access to medicines and reasonable medicine prices.

* Belgium, Denmark, Ireland, Luxemburg, the Netherlands, Norway, Portugal, Sweden and Switzerland.

2.2 Trend in spending on medicines

Public spending on medicines in the Netherlands has been rising year on year, with over €6.5 billion spent in 2017. The bulk of this figure (approximately €4.5 billion in 2017) was spent on out-of-hospital medicines (Ministry of Health, Welfare and Sport 2019a; Dutch Healthcare Authority 2019).

Modest trend in spending on out-of-hospital medicines

Spending on out-of-hospital medicines has risen by 1.5% per year on average in recent years (see Figure 4). Adjusted for transfers,[8] spending on out-of-hospital medicines has shown a slightly higher growth of 2.4%. The 'preference policy' (under which health insurers do not pay more than the price of the least expensive brand in a group of comparable medicines) plays an important role in this moderate rise.

Moderate growth in spending on out-of-hospital medicines in 2013-2017

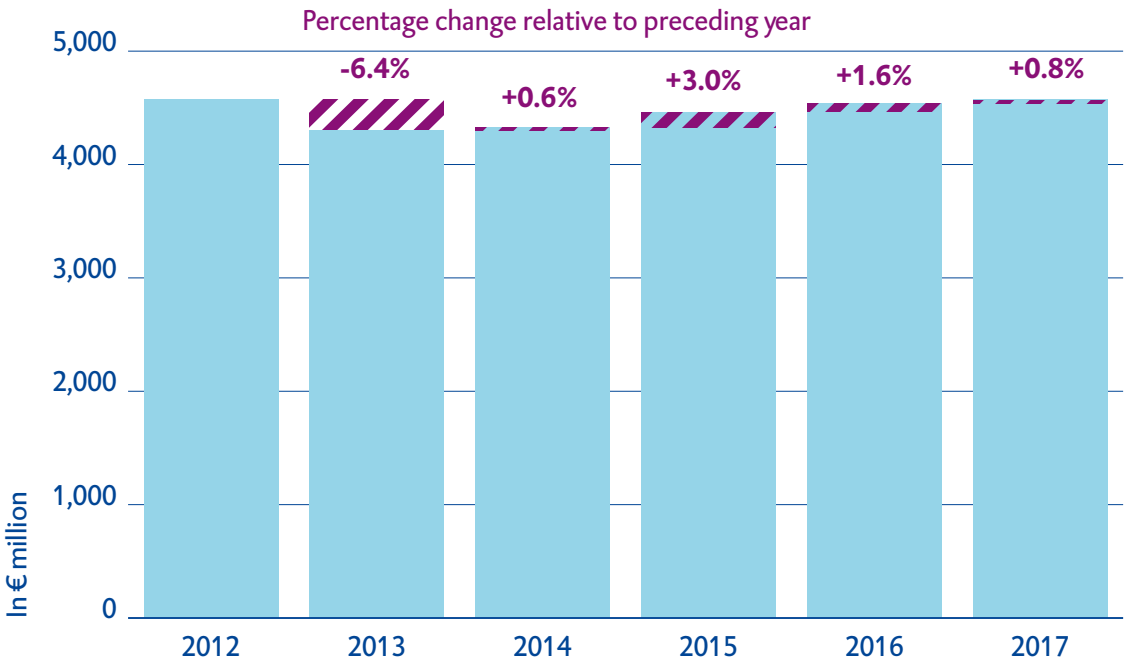


Figure 4 *Trend in spending on out-of-hospital medicines*

Source: Ministry of Health, Welfare and Sport, 2015–2018 Annual Reports

Sharp growth in spending on hospital medicines

The remainder (around €2 billion in 2017) is spent on hospital medicines. Contrary to spending on out-of-hospital medicines, spending on hospital medicines has been growing sharply – by an annual average of over 8.2% since 2013 (see Figure 5). Adjusted for transfers, the rise in spending on hospital medicines is slightly less pronounced, at 6.4%.

At the same time, based on the Outline Agreements, the maximum permissible growth in spending on specialist medical care has been severely limited in recent years (see Figure 5). The latest Outline Agreement on specialist medical care is set to curb maximum spending growth even further, viz. to 0% in 2022, from 0.8% in 2019 (Ministry of Health, Welfare and Sport 2018a). This is reflected by the spending ceilings for specialist medical care (see Table 1).

Tabel 1 *Spending ceilings for specialist medical care (in €m)*

Year	2019	2020	2021	2022
Spending ceiling for specialist medical care	23,02.4	23,761.7	23,870.2	23,863.5

Source: Ministry of Health, Welfare and Sport (2019)

Spending on hospital medicines is outpacing the maximum agreed growth in spending on specialist medical care

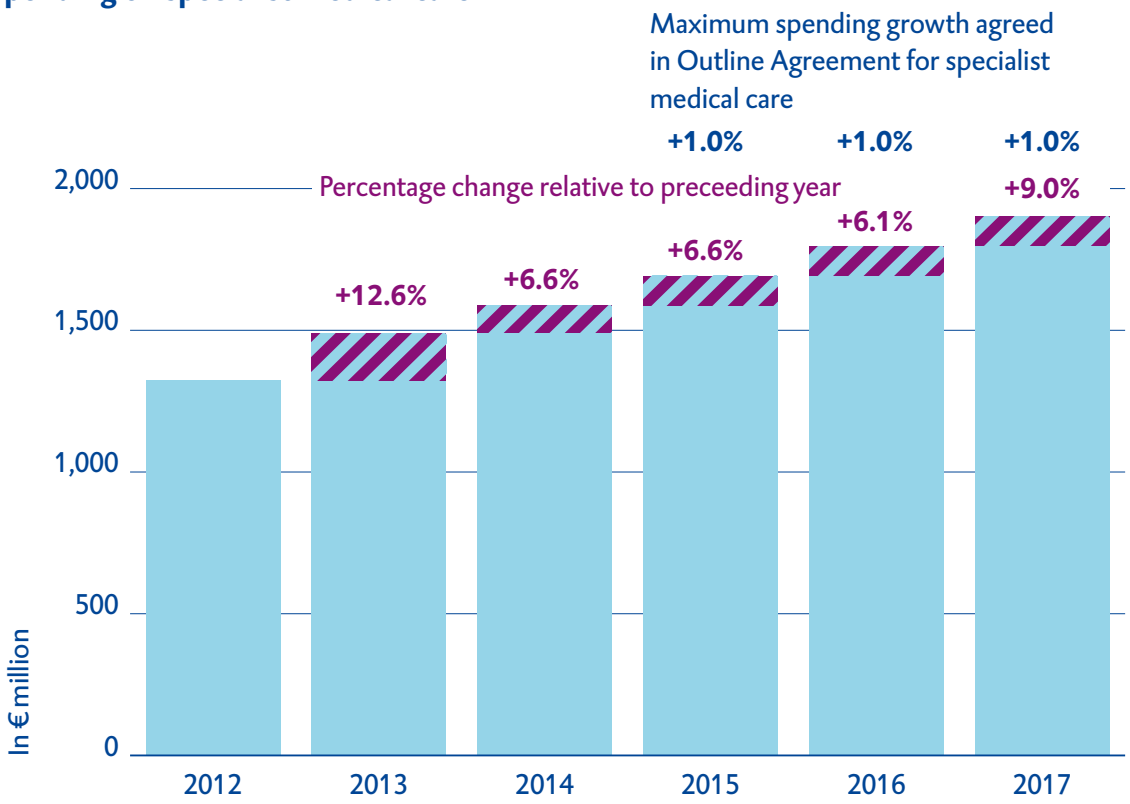


Figure 5 *Trend in spending on hospital medicines v. maximum growth in spending on specialist medical care as set out in Outline Agreement*

Source: Dutch Healthcare Authority (2019)

The combination of surging spending on hospital medicines on the one hand and very limited maximum growth in spending on specialist medical care as a whole on the other, will become more and more constrictive. After all, health insurers are obliged to pay for both regular hospital care and expensive medicines (the cost of most of which[9] is covered by a process of subsequent calculation, see text box) from the same budget.

Funding of hospital medicines

Since 2012, hospitals have recovered their costs from health insurers with the aid of a closed episode-of-care (EOC) model. The price of an EOC care product is the average of all healthcare expenses incurred for the treatment of a given condition. As expensive medicines come with a high cost that may vary considerably from one patient to another, the cost of such medicines is kept separate from the price of EOC care products. Hospitals submit a separate 'add-on' statement to health insurers to cover the costs of expensive medicines. These costs are often also kept separate from the sales volume limits agreed with health insurers, so that hospitals are not exposed to any risks.

The latest Outline Agreement on specialist medical care includes measures intended to create more scope for growth in spending on hospital medicines. For instance, it has been agreed to promote less expensive biosimilars (i.e. imitations of biological medicines).[10] Hospitals are also required to embrace the transformation to delivering 'the right care in the right place at the right time' and to discontinue certain activities so that more care is delivered outside the hospital walls (e.g. by GPs). As an incentive, the Outline Agreement on specialist medical care incorporates transformation grants for prevention, innovation and substitution (i.e. delivering care at another (lower) point in the care supply chain).

These measures need to be effective. Research by the Dutch Healthcare Authority has shown, however, that very few transformation grants for replacing care have been distributed to date (Dutch Healthcare Authority 2019a). Moreover, the Dutch Healthcare Authority found that not a great deal of progress had been made in replacing specialist medical care with primary medical care (Dutch Healthcare Authority 2019b, Dutch Healthcare Authority 2019c). The soaring expenditure on hospital medicines coupled with the maximum limits imposed on the growth in spending on specialist medical care, therefore, risk crowding out other forms of care in the same sector.

2.3 Monopoly position for new medicines

Developing and marketing a new medicine is a protracted process involving considerable investments with no guarantee of success. In order to encourage the development of new medicines, national and international agreements have been put in place enabling manufacturers to apply for a patent on a new active ingredient in their medicine. The patent gives the applicant the exclusive right to receive all the revenue generated by the medicine containing the new active ingredient during a given period of time. When the patent expires, other manufacturers are also allowed to sell medicines containing the same active ingredient. This usually leads to competition, as 'generic' medicines sold by other manufacturers are often much cheaper than the original.

If a medicine is patented and there are very few or no alternative treatments for a specific ailment, the manufacturer has a (temporary or permanent) monopoly position for the medicine in question.[11] This affects 'orphan medicines' in particular. These are medicines for treating extremely rare diseases which are covered by extra measures for protecting the manufacturer and stimulating the development of new medicines.[12]

There is a growing tendency for manufacturers with a temporary or permanent monopoly for a certain new medicine to demand an extremely high price for the medicine in

question. To date, manufacturers have been very reluctant to provide information on the price breakdown of their medicines. The high prices seem to be based primarily on the 'willingness to pay' principle, i.e. it stems from what national governments or healthcare authorities are prepared to pay (National Health Care Institute 2015).

As a wealthy country, the Netherlands has a high willingness to pay (Common Eye & SiRM 2019; Cameron et al. 2018). Despite critical comments and sometimes negative opinions expressed by the National Health Care Institute, to date all new medicines on which the Ministry of Health, Welfare and Sport has negotiated have been admitted to the basic package of insured care.[13] Social pressure has played a part in this. At the same time, the measures taken by the government in recent years to combat high or extremely high medicine prices – including centralised price negotiations – show that there is a limit to the willingness to pay for these medicines.

2.4 The Ministry of Health, Welfare and Sport's negotiating position

The principle underlying centralised price negotiations is that they strengthen the negotiating position vis-à-vis the manufacturer, in comparison with decentralised negotiations (e.g. by hospitals and health insurers or combinations of the two).

In practice, the Ministry of Health, Welfare and Sport's negotiating position differs from case to case. The Ministry does not have a strong position in innovative medicines on which the manufacturer holds a monopoly and to which no alternatives are likely to emerge in the near future. Orkambi and Spinraza are examples of such medicines. Some negotiations involve treatments that have been on the market for some time and with which doctors and patients have become accustomed, e.g. Soliris. In these cases, too, the Ministry of Health, Welfare and Sport is not in a particularly strong position. It has a stronger negotiating position if competitive medicines have come on to the market, or are expected to do so in the near future. This applies for instance to medicines for treating chronic hepatitis C viruses (HCVs), eight of which have come on stream since 2014.

In the context of our audit, we examined whether the Ministry's negotiating position can be described in more detail by distinguishing different characteristics of market relations (see Appendix 3 for information on our audit approach). These characteristics are listed in Table 2 below. They may differ from one situation to another, which may therefore explain why the strength of the Ministry's negotiating position tends to vary.

Table 2 *Characteristics of strong or less strong negotiating positions*

No.	Characteristics
1.	**Competing medicines:** The Ministry of Health, Welfare and Sport has a stronger negotiating position if competing medicines are already on the market or are likely to be launched in the near future.
2.	**Limited remaining patent:** If the patent on a medicine has a limited time to expiry, this should also bolster the Ministry's negotiating position. This does not apply if there is no alternative medicine in the pipeline.
3.	**Development history of a product/Low development cost:** The Ministry is in a stronger negotiating position if the development cost was relatively low (e.g. because the medicine was bought from another manufacturer at a late stage of development).
4.	**Manufacturer has a weak cash position with borrowed capital:** The Ministry is in a stronger position if the manufacturer generates little or no turnover from other medicines.
5.	**Additional indications:** The Ministry is in a stronger position if additional indications are expected to be added in the near future, as more indications mean more sales. This is a reason for aiming for price reductions at an early stage.
6.	**Risk reduction:** As sales of a medicine become more certain, the Ministry's position improves. Lower prices are possible as the manufacturer runs less of a risk.
7.	**Creating competition:** The Ministry's negotiating position improves if it can create competition itself.

If many of these characteristics apply, the Ministry may be in a stronger negotiating position. Our analysis has not, however, revealed a clear connection between a higher score and better negotiated outcomes. What is clear is that the Ministry's negotiating position is not static; it may change in response to developments such as the arrival of competitive treatments.

Correlation between price negotiations and other measures

The government's medicines policy is aimed at a plethora of objectives, including the safety and availability of medicines. Also, the policy includes an extensive set of tools for regulating medicine prices and controlling spending on medicines:

- the *Medicine Prices* Act sets maximum prices for medicines sold on the Dutch market, by taking the average purchase prices of comparable medicines in four reference countries designated by law; and
- the national *Medicine Reimbursement System* places a ceiling on payments (by health insurers) for interchangeable out-of-hospital medicines.

The Minister of Health, Welfare and Sport published her new *Medicines Policy Plan* in early 2016 (Ministry of Health, Welfare and Sport 2016), specifically in order to ensure that new medicines remain affordable and accessible in the future. As we have said, the central aim of the measures in the policy plan is to build a stronger negotiating position for (or on

behalf of) the purchaser. This approach was reviewed at the start of 2019 (Common Eye & SiRM 2019). The evaluation report claims that the 'low-hanging fruit' has now been picked, but that medicine prices, although lower, remain high and that the time has now come to aim for higher-hanging fruit. Remarkably, however, no recommendations are made with the immediate purpose of improving the outcome of centralised negotiations between the Ministry of Health, Welfare and Sport and pharmaceutical companies. The only exception is a recommendation to develop a joint negotiating strategy together with other European countries – in particular as part of the BeNeLuxA partnership. The idea is that it will be easier to turn down a manufacturer's final offer if the Netherlands is not alone in doing so.

In its 2017 report, the Dutch Council for Public Health and Society describes even more direct methods for strengthening the Ministry's negotiating clout vis-à-vis pharmaceutical companies: "The Council recommends that if, after negotiations, a pharmaceutical company is not prepared to sell a medicine at a socially acceptable price, the Minister should be prepared to use instruments such as compulsory licensing, import licensing, stimulating pharmacy preparations, conditionally allowing patients to order medicines abroad, and taking action against abuse of a dominant position, in order for medicines to become available to patients at acceptable prices." (Council for Public Health and Society 2017).

In response to the Council's recommendations, the Minister for Medical Care and Sport wrote that compulsory licensing could play a role "if a manufacturer continues to demand an extremely high price for a therapeutically important medicine." This is despite the fact that compulsory licensing is not without problems and cannot be adopted overnight (Ministry of Health, Welfare and Sport 2017). In the meantime, the Minister for Medical Care and Sport together with the Minister for Economic Affairs and Climate Policy has set up a committee to examine the use of compulsory licensing in a broader context (Ministry of Health, Welfare and Sport 2018).

We did not audit the implementation of the Medicines Policy Plan. We have, however, taken note of the finding made in the interim evaluation that the way in which the policy has been implemented, by the Ministry of Health, Welfare and Sport among others, is "somewhat fragmented" (Common Eye & SiRM 2019). This is why we would ask the Minister for Medical Care and Sport to look at the relationship between the centralised price negotiations and the other components of the Medicines Policy Plan. Specifically, we urge the Minister for Medical Care and Sport, when implementing the Medicines Policy Plan and taking decisions in this connection, to assess whether these decisions can help to improve the Ministry of Health, Welfare and Sport's negotiating position.

3 From recommendation to result

3.1 Introduction

At the time of the first price negotiations in 2012, about the (then) new anticoagulants Pradaxa and Xarelto, the Ministry's Drug Price Negotiation Unit had not yet been set up. The National Health Care Institute – then known as the Healthcare Insurance Board – recommended that the Minister for Health, Welfare and Sport should negotiate about medicine prices in view of the large amount of money spent on these medicines. Price negotiations were possible at the time due to the fact that the Minister needed to take a decision on whether to include two new out-of-hospital medicines in the basic package of insured care. The waiting room procedure, which the Minister first used in 2015 to suspend payments for new hospital medicines in order to pursue price negotiations, did not exist at the time.[14]

All in all, there have been quite significant changes since 2012. This chapter discusses the current procedure for reaching a price agreement. Section 3.2 describes the broad outlines of the procedure. Section 3.3 zooms in on the recommendations made by the National Health Care Institute. Section 3.4 looks at how, in the 32 price agreements that we audited, the Ministry's negotiating target compared with the National Health Care Institute's recommendations.

3.2 The outlines of the negotiating procedure

This section outlines the negotiating procedure. It is a broad view; the procedure has not always unfolded in this way. The current procedure generally consists of the following five stages (see Figure 6):

1. Negotiations are opened following the submission of an advisory report from the National Health Care Institute.[15] In some cases, the reports springs from the reassessment of a medicine.[16,17] The report includes, among other things, information on the medicine's effectiveness, the manufacturer's asking price, cost-effectiveness, and the financial impact of a positive decision.
2. Based on the Institute's recommendation, the Ministry prepares a *price negotiation memorandum*, in which the Minister for Medical Care and Sport is asked for a negotiating mandate. During this stage, the Ministry consults with stakeholders, i.e. associations of medical professionals, health insurers and patient lobby groups. The price negotiation memorandum states the negotiating target, e.g. the discount the Ministry wishes to achieve. The Minister for Medical Care and Sport may ignore the National Health Care Institute's recommendation (see section 3.4).

3. The negotiations with the manufacturer can start once the Minister has agreed with the proposed mandate.
4. After the negotiations have been completed, the Ministry draws up a *negotiated outcome memorandum* for the Minister, describing the negotiated outcome. The memorandum also details alternatives, such as the consequences of a decision not to approve the outcome.
5. If the Minister approves the negotiated outcome, the contract with the manufacturer is signed and the price agreement enters into force.

The current negotiating procedure follows a fixed template

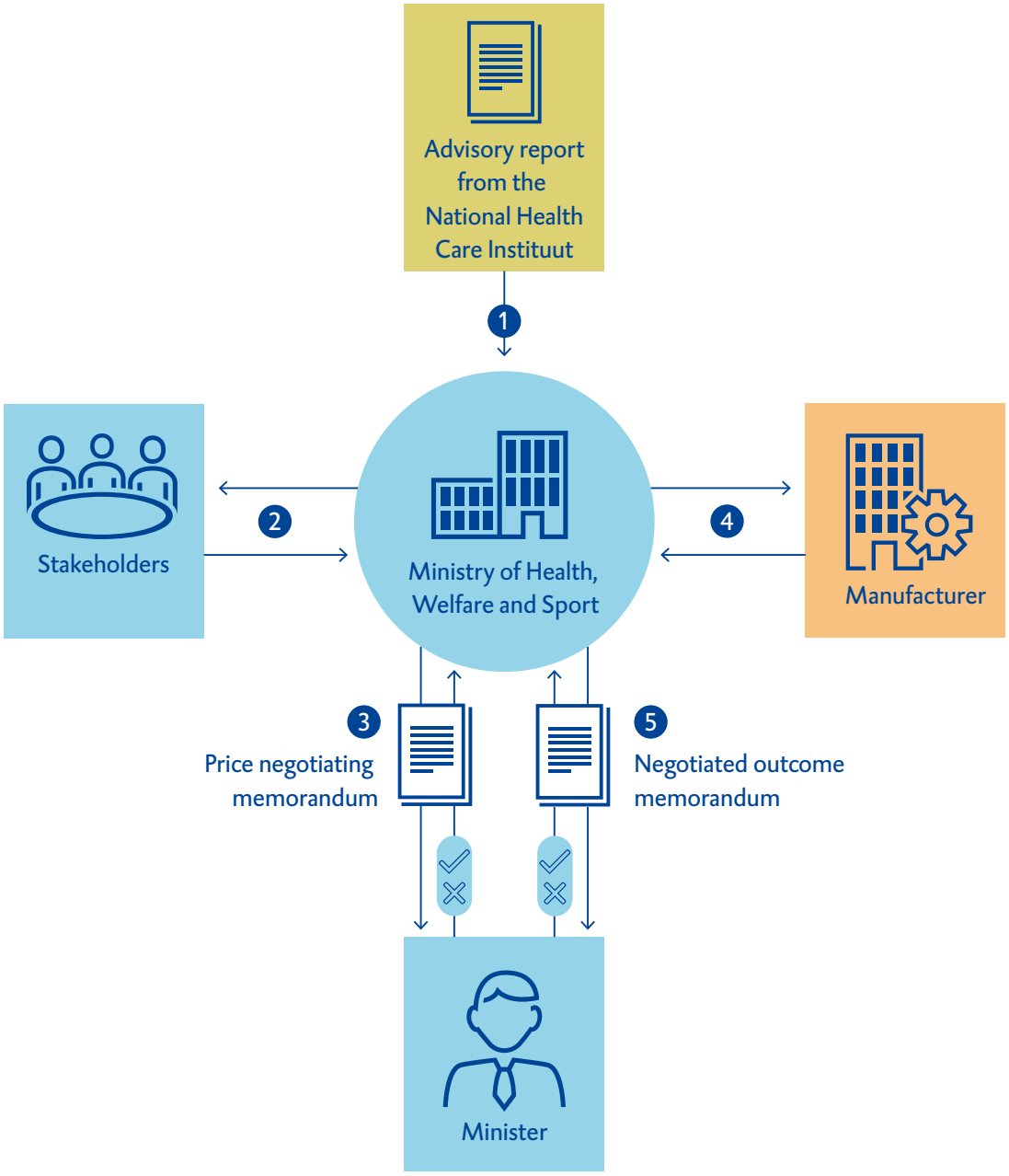


Figure 6 *The price negotiating procedure in five stages*

In practice, even today, negotiations may follow a different pattern. The negotiations virtually always consist of a number of rounds. Sometimes, the outcome is presented to the Minister halfway.[18] In one case (i.e. Orkambi), the Minister halted negotiations with the manufacturer as the outcome was not satisfactory. In the end, the Minister of Health, Welfare and Sport reached a price agreement with the manufacturer after all following further talks.

3.3 The recommendations of the National Health Care Institute

In the case of new out-of-hospital medicines, and also of hospital medicines placed in the 'waiting room for medicines', the National Health Care Institute makes a recommendation to the Minister for Health, Welfare, and Sport about their inclusion in the basic package of insured care. The National Health Care Institute made a recommendation for each of the 32 price agreements included in our audit. These recommendations may be broken down into three categories (see Figure 7):

Most of the advisory reports produced by the National Health Care Institute do not include a recommended price

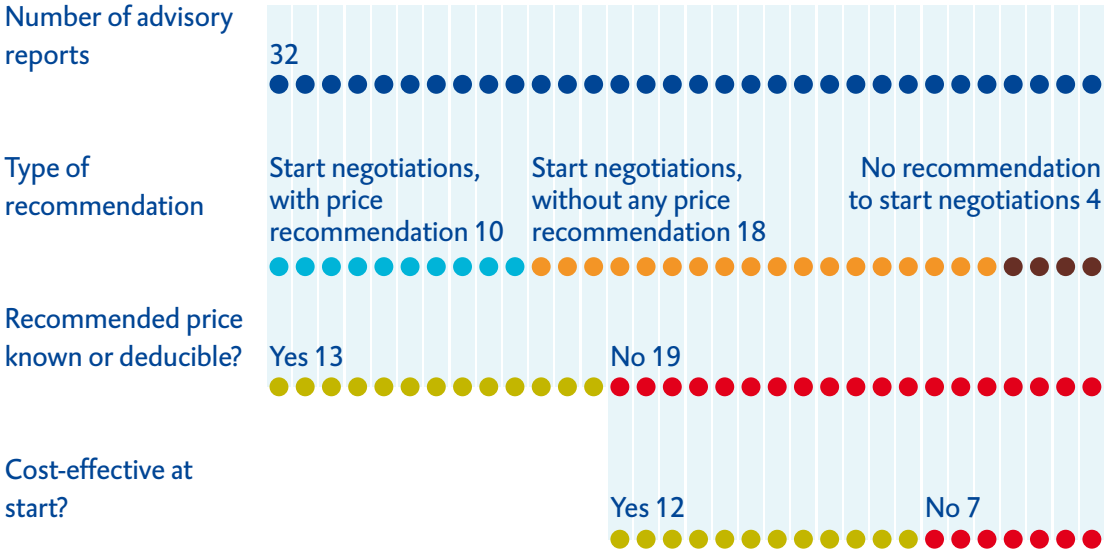


Figure 7 *Categorisation of the National Health Care Institute's recommendations*

Start negotiations, with price recommendation

The National Health Care Institute mentioned a recommended price in 10 advisory reports, in the form of a percentage discount with which the manufacturer needed to lower its asking price in order to arrive at a cost-effective price.

Start negotiations, without any price recommendation

In 18 cases, the National Health Care Institute recommended that the Minister for Health, Welfare and Sport should start negotiations in order to safeguard the accessibility and affordability of the basic package of insured care, without mentioning a recommended price.[19] In the case of two medicines the National Health Care Institute referred to:

- the price of a similar medicine; stating that the inclusion of the new medicine should not lead to a rise in expenditure; and
- the amount spent on the medicine; this should not exceed €2.5 million annually.[20]

We asked the National Health Care Institute whether it could deduce a recommended price for these 18 medicines after all, based on the available information. This proved to be possible in three cases. This means that, in the next chapter, we can compare the negotiated outcome with the recommended prices in 13 (10 + 3) cases.

No recommendation to start negotiations

In the case of four medicines, the National Health Care Institute did not recommend starting negotiations.

- In three cases, these were the first price negotiations that the Ministry of Health, Welfare and Sport had conducted with the manufacturers. Price negotiations were not commonplace at the time. The Drug Price Negotiation Unit had not been set up at that point and the National Health Care Institute's reports did not include price negotiations as an option.
- In one case (Jakavi), the National Health Care Institute recommended not including the medicine in question in the basic package of insured care.[21]

3.4 The Ministry of Health, Welfare and Sport's negotiating targets

This section discusses the Ministry of Health, Welfare and Sport's negotiating targets, as presented to the Minister in the price negotiation memoranda. We first examine the cases in which the National Health Care Institute included a recommended price in its advisory report (section 3.4.1). We then look at the remaining cases, in which the National Health Care Institute did not include a recommended price in its report, and the Ministry was therefore obliged to set the negotiating target based on other considerations.

3.4.1 Recommended price issued

In 10 cases, the National Health Care Institute recommended a price along with the recommendation to start negotiations. Our audit shows that the Minister did not adopt this recommended price as her negotiating target in all cases; see Figure 8.

The Minister did not adopt three of the 10 recommended prices

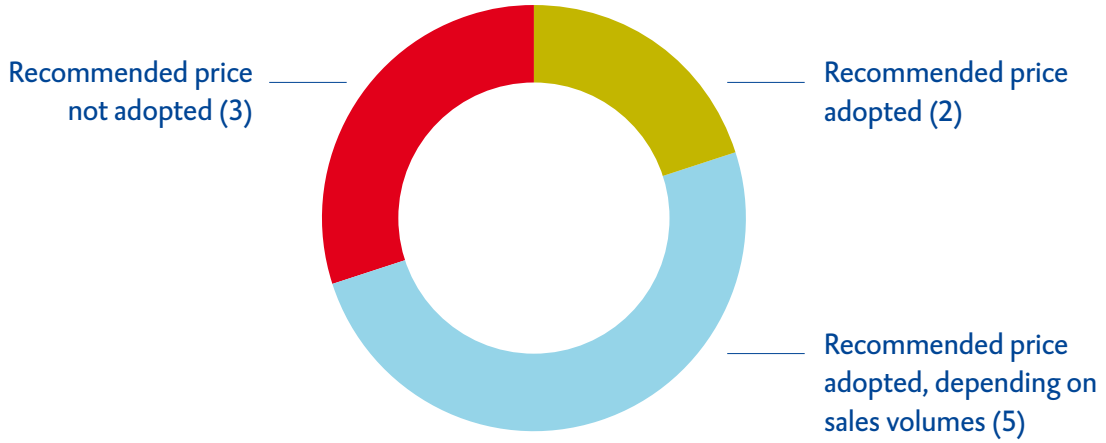


Figure 8 *Recommended price adopted as negotiating target*

In the case of three medicines, either the Minister of Health, Welfare and Sport or, as the case may be, the Minister for Medical Care and Sport did not adopt the National Health Care Institute's recommended price in the price negotiation memorandum. This means that, by definition, a cost-effective price is not expected as the negotiated outcome.

In the remaining seven cases, either the Minister of Health, Welfare and Sport or, as the case may be, the Minister for Medical Care and Sport did adopt the Institute's recommended price in the price negotiating memorandum. In five of these cases, attaining the percentage discount recommended by the Institute depended on the medicine generating a certain minimum annual volume of sales. For more information, see section 4.4., which discusses price-volume agreements.

3.4.2 No recommended price issued

Cost-effective at the asking price

Twelve of the 22 medicines for which the National Health Care Institute did not recommend a price were cost-effective at the manufacturers' asking price. These consisted of four direct oral anticoagulants (DOACs) and eight medicines for treating chronic hepatitis C viruses (HCVs).

The National Health Care Institute had good reasons for not issuing a recommended price in these cases. The reason why it recommended starting price negotiations was the projected high level of expenditure on these new medicines.

Not cost-effective yet at the asking price

The National Health Care Institute did not issue a recommended price prior to negotiations on 10 of the 22 medicines. There may have been different reasons for this (see endnote 5):

- in seven cases, these medicines were not cost-effective at the manufacturers' asking price;
- in three cases, it was impossible to establish their cost-effectiveness based on the data supplied by the manufacturer.

In nine of these 10 cases, the National Health Care Institute urged the Minister to start negotiations, but without recommending a price. So the Minister adopted the Institute's recommendation by the mere fact of starting negotiations.

Criterion for maximum level of spending

In those cases in which the National Health Care Institute does not recommend a price (or in which the Ministry of Health, Welfare and Sport does not adopt the recommended price), the Ministry bases its negotiating target on other considerations. The Ministry does not focus so much on the price (P) as on the anticipated annual level of spending on a new medicine (P x Q). Often, the object of negotiations is to place a cap on the level of spending on a new medicine.

Uncertainties surrounding the use of a medicine

Estimates of the annual use of a new medicine (i.e. the number of units, expressed as Q) are often surrounded by uncertainties. For instance, it is not simply a matter of the total number of patients who are eligible for a new medicine. Factors such as the dosage or the speed of uptake of the new medicine by doctors and patients are also important.

We were unable to obtain a clear picture of the factors taken into account by the Ministry of Health, Welfare and Sport in setting its negotiating target. As discussed above, spending on hospital medicines in particular has surged in the past few years. However, as the Ministry does not set a separate target for controlled growth in spending on medicines as part of overall expenditure on specialist medical care, there is no benchmark against which to judge the projected level of spending on a particular medicine.

4 The outcome of price negotiations

4.1 Introduction

This chapter presents the outcome of the 32 price negotiations held between 2012 and 2018. We first discuss the 13 negotiations the outcomes of which we were able to compare with a recommended price (section 4.2). We go on to discuss the results of the other 19 negotiations (section 4.3). The chapter concludes by examining the question of why many of the negotiations culminated in price-volume agreements (section 4.4).

4.2 Outcome of negotiations compared with recommended prices

In a total of 13 cases, we were able to compare the outcome of negotiations with a price recommended by the Dutch National Health Care Institute (see Figure 9).

In the case of 13 medicines, we know how big the discount (i.e. the recommended price) needs to be in order to achieve cost-effective care

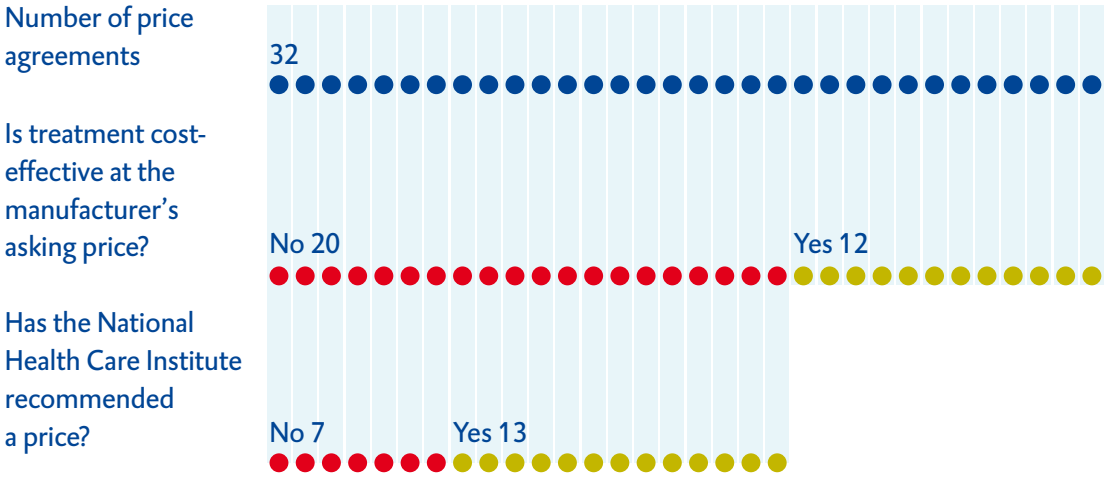


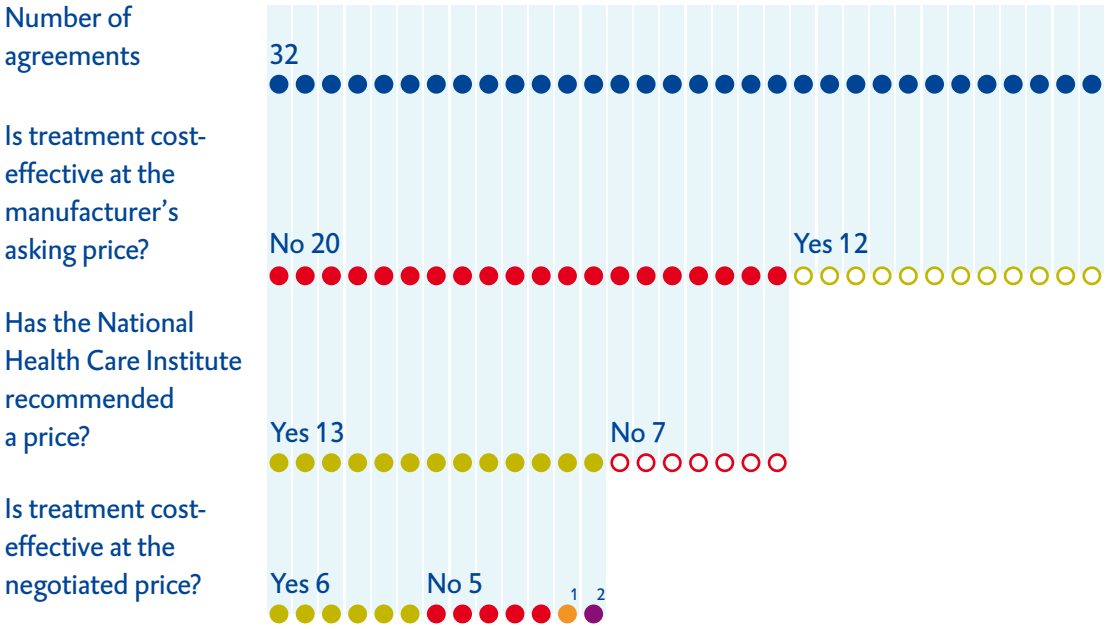
Figure 9 *Price negotiations and availability of recommended prices*

In five of the price negotiations, we found that the Ministry of Health, Welfare and Sport did not succeed in bringing the price down to the recommended price (see Figure 10). This means, in other words, that care is not cost-effective in these cases.
In six of the price negotiations, the Ministry did succeed in bringing the price down to that recommended by the National Health Care Institute. In other words, the Ministry agreed a discount with the manufacturer that resulted in the medicine in question being cost-effective.

In the case of one particular medicine, the price negotiated by the Ministry for the third year of the price agreement was the same as the recommended price. The price negotiated for the first two years was higher than the recommended price.

In the case of one other medicine, we were not able to ascertain whether the Ministry succeeded in bringing the price down to the level of the recommended price.

The discount negotiated on the price of five of the 13 medicines is not big enough to achieve cost-effective care



[1] *The recommended price was achieved during the third year of the price agreement.*
[2] *We were unable to ascertain whether the recommended price was achieved.*

Figure 10 *Outcome of price negotiations where a recommended price is available*

4.3 Outcome of negotiations in cases where no recommended prices were available

In cases where no recommended prices were available, we compared the outcomes of price negotiations with the targets set by the Minister of Health, Welfare and Sport in the price negotiation memoranda. This applied to 19 of the medicines included in the scope of our audit.

4.3.1 Cost-effective medicines

The Ministry of Health, Welfare and Sport negotiated on the prices of 12 medicines (i.e. four direct oral anticoagulants (DOACs) and eight medicines for treating chronic hepatitis C viruses (HCVs)) that were already cost-effective at the manufacturer's asking price.

We found that the Ministry achieved its negotiating target in relation to 11 of these medicines. In other words, the Ministry achieved additional reductions in spending on medicines that were already cost-effective.

The Ministry achieved its negotiating target in 11 out of 12 negotiations on cost-effective medicines

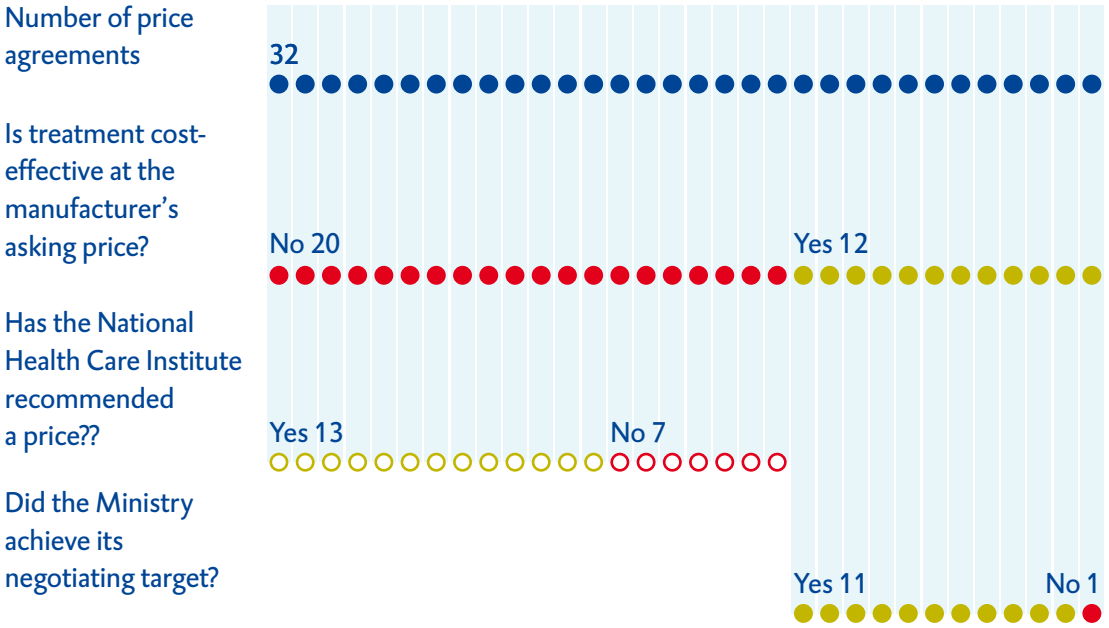


Figure 11 *Negotiated outcomes in the case of cost-effective medicines*

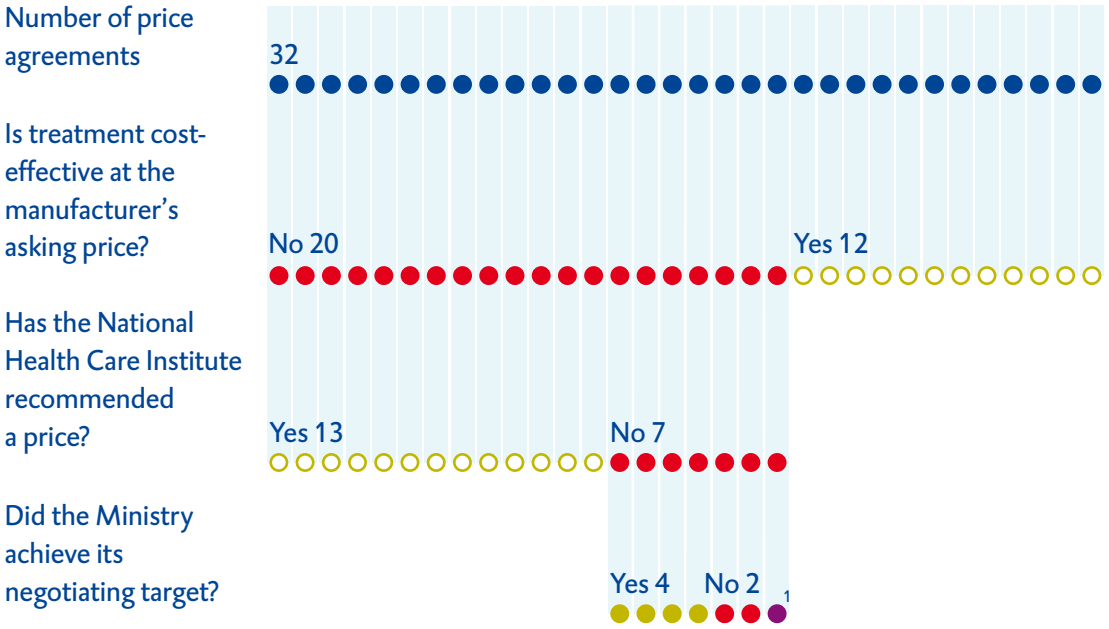
Although the Ministry of Health, Welfare and Sport failed to achieve its negotiating target in the case of one medicine, it did manage to achieve additional cuts in spending on this medicine.

4.3.2 Non cost-effective medicines

There is a final group of seven medicines that were not cost-effective at the manufacturer's asking price, but for which no recommended prices were available.[22] Here too, we compared the negotiated outcomes with the targets set in the price negotiation memoranda.

The Ministry of Health, Welfare and Sport achieved its negotiating target in four cases. It did not achieve its target in two cases. In the case of one medicine, we were unable to ascertain whether or not the target had been achieved. We were not able to determine for any of the seven cases whether the use of the medicines in question is now cost-effective thanks to the outcome of the price negotiations.

The Ministry achieved its negotiating target in relation to four of the seven non-cost-effective medicines for which no recommended prices were available



[1] *Not known.*

Figure 12 *Outcome of negotiations on seven non-cost-effective medicines for which no recommended prices were available*

4.4 Price-volume agreements

In the case of 25 of the price agreements we examined, the Minister of Health, Welfare and Sport (or, as the case may be, the Minister for Medical Care and Sport) entered into 'price-volume agreements' with the manufacturers. Under a price-volume agreement, the size of the discount offered on a medicine rises in line with the volume of sales. This generally involves working with a graduated discount scale in which the size of the discount is linked to a given turnover bracket (e.g. up to €5 million, from €5 to €10 million, and €10 million and above).

The advantage of price-volume agreements is that they enable a (soft) ceiling to be placed on the highest turnover bracket, thus compelling the manufacturer to offer a very high discount on all sales above a certain threshold.
The drawback with price-volume agreements is that, if the level of sales ends up being lower than projected, the percentage discount is (on average) lower than the figure estimated when the negotiations were concluded (as quoted in the negotiated outcome memorandum).

Depending on the circumstances, this could result in the recommended price not being achieved and/or the maximum spending limit being exceeded and treatment not being cost-effective.

We found that the estimated percentage discount cited in the negotiated outcome memorandum was generally achieved in practice. In the case of one medicine, we found that, although the Ministry of Health, Welfare and Sport succeeded in attaining the level of discount it had set itself as a negotiating target, this figure was not achieved during the first year of the price agreement. The targeted discount was, however, achieved during the second year of the agreement.

Extension of price agreements

The price agreements for certain medicines can be extended. We found that in a number of these cases the Minister gave much less priority to the need to reduce the level of expenditure on the medicine in question.[23]

5 Information on reductions in spending

5.1 Introduction

This chapter discusses how the Dutch parliament is informed about the outcome of the price negotiations.

The Minister of Health, Welfare and Sport (or, as the case may be, the Minister for Medical Care and Sport) has made clear, on a number of occasions in the past (Ministry of Health, Welfare and Sport, 2014; Ministry of Health, Welfare and Sport, 2015a; Ministry of Health, Welfare and Sport, 2016a; Ministry of Health, Welfare and Sport, 2017a, and Ministry of Health, Welfare and Sport, 2018), that it is not able to make any pronouncements about the nature of any *individual* financial arrangements, as the manufacturers have to date always insisted that these arrangements should remain confidential. Nonetheless, the Minister does inform Parliament, in his or her annual progress reports, about the aggregate reductions in spending that have been achieved (see section 5.2).

In reporting to Parliament, the Minister compares the negotiated outcomes with the manufacturers' asking prices. We have added to this information further details on the negotiated outcomes as compared with the prices recommended by the National Health Care Institute (section 5.3). This allows us to paint a clearer picture of the extent to which the price negotiations have helped to achieve cost-effective care.

5.2 Reported reductions in spending

Ever since 2014, the Minister of Health, Welfare and Sport (or, as is now the case, the Minister for Medical Care and Sport) has sent Parliament annual progress reports on the financial price agreements concluded (Ministry of Health, Welfare and Sport, 2014). Since 2016, these reports have also contained information on the aggregate reduction in spending achieved on a yearly basis (Ministry of Health, Welfare and Sport, 2016a).[24] These reductions are calculated as the difference between aggregate expenditure at the manufacturers' asking prices and aggregate expenditure at the negotiated prices.

Table 3 shows, for the medicines for which the Ministry of Health, Welfare and Sport has negotiated price agreements, the aggregate reduction in expenditure on an annual basis between 2015 and 2018. These are the same amounts as those reported to Parliament by the Minister in recent years.

There has been a sharp increase in recent years in the monetary value of the medicines on which the Ministry of Health, Welfare and Sport negotiates (as calculated on the basis of the manufacturers' asking prices). The total amount involved in 2017 was over €450 million, representing around 7% of aggregate spending on medicines in the same year, i.e. €6.5 billion. The value of the medicines on which the Ministry conducted price negotiations rose further in 2018, to over €750 million.

Table 3 *Aggregate annual reduction in spending on medicines on which the Minister of Health, Welfare and Sport reached price agreements (in €m)*

Year	2015	2016	2017	2018*
No. of active price agreements**	16	19	25	30
Expenditure without price agreements (at manufacturers' asking price)	262.7	371.7	454.4	754.3
Expenditure with price agreements (at negotiated prices)	196.0	264.4	319.3	482.3
Reduction in spending	66.7	107.3	135.1	272.0
as % of expenditure without price agreements	25.4%	28.9%	29.7%	36.1%

** The 2018 figures are based on provisioinal data.*

*** The report centres on the 32 price agreements reached between 2012 and 2018. Most price agreements are valid for 1, 2 or 3 years. Given that not all the 32 price agreements came into force on the same date, the number of active price agreements varies from year to year.*

Source: Ministry of Health, Welfare and Sport (2019b).

Our audit was not designed to give an opinion on how this information is produced. At the same time, we see no reason to question the accuracy of the reported figures. Moreover, they are produced during a process that involves calculating, under the guidance of a 'trusted third party', the size of the discounts that the manufacturers need to pay the health insurers. We believe that the opposing interests involved in this process of the manufacturers on the one hand and the health insurers on the other, help to ensure that the discounts are accurate. In other words, we have no reason to doubt that these figures provide a true and fair view of the situation.

The figures show that both the number of active price agreements and the total amount spent (without price agreements) are on the increase. In other words, the value of the price agreements is growing, in both absolute and relative terms. At the same time, the price agreements account for only a relatively small proportion (6.8% in 2017) of aggregate expenditure on medicines (over €6.5 billion).

It is worth bearing in mind that, even if the Ministry of Health, Welfare and Sport (or any other national body) did not conduct any centralised price negotiations, it would still be possible to negotiate discounts with manufacturers. There is no reason why individual health insurers and healthcare-providers could not negotiate with manufacturers. We did not seek to ascertain whether the discounts negotiated by the Ministry of Health, Welfare and Sport were bigger than those that could have been negotiated by health insurers and healthcare-providers acting on their own. What was clear from the evaluation of the pilot stage of the centralised price negotiations, however, was that the majority of the parties involved supported the principle of conducting centralised negotiations in those cases where the parties were not fully equipped to negotiate themselves (Ecorys 2016).

5.3 Information on whether cost-effectiveness has been achieved

The reported figures on reductions in spending do not show whether the negotiations conducted by the Ministry of Health, Welfare and Sport resulted in prices at which the medicines in question are cost-effective, i.e. whether the prices were brought down to those recommended by the National Health Care Institute. A number of experts have questioned whether this is indeed the case (Canoy & Tichem 2018; Brouwer 2018).

One way of providing Parliament, the parties involved and healthcare experts with more information on the outcomes of the negotiations (i.e. alongside the data on reductions in spending) would be for the progress reports presented to Parliament to contain information on whether the negotiations succeeded in bringing down the manufacturers' asking prices to the level recommended by the National Health Care Institute. For example, the Minister for Medical Care and Sport could provide additional information, in relation to medicines for which the Institute recommended prices, on the difference between the annual level of spending at the negotiated prices and the annual level of spending at the recommended prices (see Figure 13).

Negotiated outcome compared with recommended price

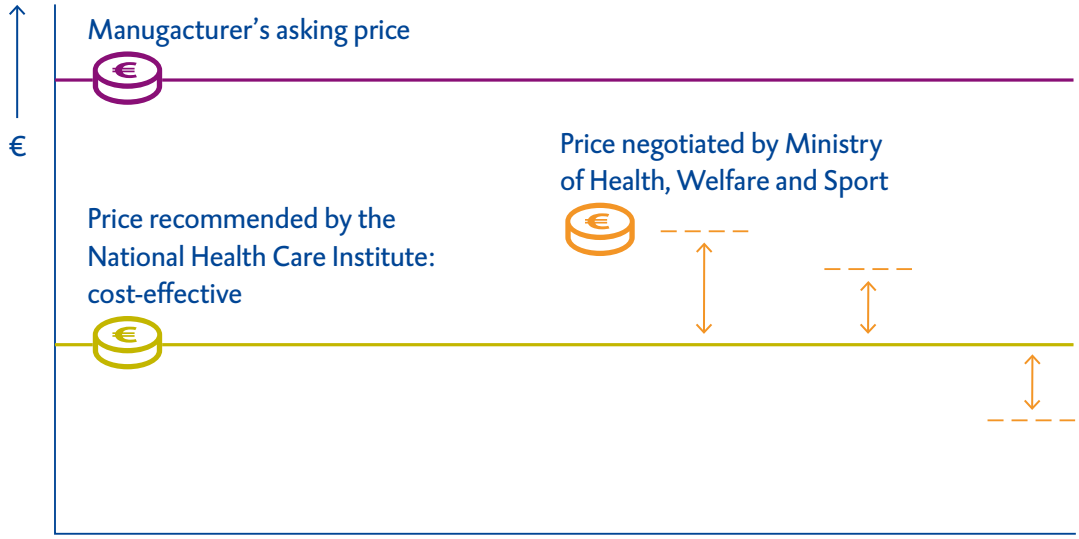


Figure 13 *The asking price, negotiated price and recommended price of a single medicine*

Results of additional calculation

We asked the Ministry of Health, Welfare and Sport to calculate what the total level of spending on the 13 non-cost-effective medicines (see chapter 4) would have been if spending had been based on the prices recommended by the National Health Care Institute. The results are shown in Table 4. The levels of spending at the manufacturers' asking prices and at the negotiated prices are also shown to facilitate comparison.

Table 4 *Expenditure on 13 non-cost-effective medicines at the recommended prices (in €m)*

Year	2015	2016	2017	2018*
Expenditure without price agreements (at manufacturers' asking prices)	5.6	57.4	196.0	462.9
Expenditure with price agreements (at negotiated prices)	3.6	43.9	119.7	256.5
Expenditure at recommended prices	2.8	34.3	112.2	234.5
Difference in level of spending: asking prices v. recommended prices	0.8	9.6	7.5	22.0

** The 2018 figures are based on provisional data.*

Source: Ministry of Health, Welfare and Sport

We believe that the difference in the level of net expenditure (resulting from the higher price that the Minister for Medical Care and Sport was prepared to pay in a number of cases as compared with the recommended price) may be regarded as a premium paid by society in order to ensure that patients have access to the medicines in question.

We want to emphasise that the figure in question (for example, the figure of €22 million applying in 2018) results from netting 13 pluses and minuses as compared with the prices recommended by the National Health Care Institute. We believe that this manner of presentation is unfortunate in that every form of care should in itself be cost-effective. In other words, we feel that the 'financial pluses' should not be regarded as offsetting the 'financial minuses'. For this reason, we believe that it would have been preferable to report the total financial pluses and the total financial minuses. Unfortunately, there is no scope for providing detailed information in this publication, as we want to prevent individual price agreements from being traceable with the aid of the information provided.

As far as spending is concerned on the 19 medicines for which no recommended prices were available, the picture presented in the progress reports submitted to Parliament remains the same. This information is given in Table 5 for the sake of completeness.

Tabel 5 *Spending (with and without price agreements) on the 19 medicines for which no recommended prices were available (in €m)*

Year	2015	2016	2017	2018*
Expenditure without price agreements (at manufacturers' asking prices)	257.1	314.2	258.3	291.4
Expenditure with price agreements (at negotiated prices))	192.3	220.6	199.6	225.7
Reduction in spending achieved	64.8	93.6	58.7	65.7

** The 2018 figures are based on provisional data.*

Source: Ministry of Health, Welfare and Sport

6 Conclusions and recommendations

Cost-effective care

It is reasonable to assume that the centralised price negotiations that the Ministry of Health, Welfare and Sport conducts with the manufacturers of medicines help to control spending on expensive medicines. At the same time, we found that, in five of the 13 cases, the Ministry of Health, Welfare and Sport failed to bring the price down to the price recommended by the National Health Care Institute (see chapter 4). In other words, the negotiations did not result in cost-effective care in these five cases.

We wish to emphasise that, in these cases as well as in others, the Minister for Medical Care and Sport is entitled to decide whether a particular medicine should be included or retained in the basic package of insured medical care. Such a decision generally springs from a desire to ensure that the medicine in question is made available to patients, particularly if there are no comparable alternatives. However, the objective of all negotiations should at the very least be achieving a cost-effective price level. In a number of cases, the Minister entered into the negotiations on the assumption that he or she he would not be able to bring the price down to the recommended price.

Where non-cost-effective treatment is provided and is covered by the basic health insurance package, this has the effect – in a context of the fixed spending ceilings set out in the government's 'Outline Agreement' – of crowding out other types of medical care that are more cost-effective. Moreover, the decisions to provide and pay for such care, and the reasons underlying these decisions, are matters for which the government is politically accountable. While this may not be the case formally speaking, it is in practice. For this reason, we urge the Minister to give Parliament more information about whether the negotiations were successful in terms of achieving the prices recommended by the National Health Care Institute. One of the possible ways of doing this would be by providing the information given in chapter 5 about the level of expenditure that would have been incurred at the recommended prices.

Contribution towards controlling expenditure

There has been a sharp increase in recent years in the monetary value of the medicines on which the Ministry of Health, Welfare and Sport negotiates (as calculated on the basis of the manufacturers' asking prices). The total amount involved in 2017 was over €450 million, representing around 7% of aggregate spending on medicines in the same year, i.e. €6.5 billion.

The negotiations also help to control spending on medicines. We are not able to gauge the extent to which the negotiations help to control spending (whether in absolute or in relative terms). This is due in part to the absence of a reference standard, but also arises from the fact that other policy tools also help to control spending. There is, however, a need for the Minister for Medical Care and Sport to seek to achieve larger reductions in spending, particularly when negotiating on the price of medicines used during the course of hospital treatment (known as 'intramural medicines' or 'hospital medicines'). Spending on hospital medicines has rocketed in recent years, despite the fact that the latest Outline Agreement (signed in 2018) states that there should be little or no rise in spending on specialist medical care as a whole. We believe therefore that, if this trend continues, there is a risk of spending on hospital medicines crowding out other types of specialist medical care.

Future prospects

It goes without saying that the Minister should continue to negotiate with manufacturers as long as the prices of new medicines remain high or extremely high. Without wanting to detract from the results achieved to date, the Minister for Medical Care and Sport needs to toughen his negotiating stance in order to achieve better results in the future.

The main reason for this is that the *Medicines Horizon Scan* published by the National Health Care Institute makes clear that the Institute expects an increasing number of expensive medicines to come onto the market in the coming years, many of which will absorb a large amount of expenditure. If anything, therefore, the need to control spending on medicines would appear only to have become more urgent.

Secondly, we wish to point out that the prices recommended by the National Health Care Institute (on which this audit is based) are a fairly modest criterion by which to judge cost-effectiveness. In the case of conditions with a high disease burden, the reference value used in the Netherlands is a maximum of €80,000 per quality-adjusted life year (QALY). Studies show that the average amount spent per QALY in Dutch hospitals is considerably lower than this. For this reason, the figure of €80,000 per QALY should be seen more as a starting point for negotiations than as a target.

In other words, the Minister for Medical Care and Sport needs to improve the negotiated outcomes. Whether this is possible, however, is another matter. While we did not look into how the Ministry of Health, Welfare and Sport negotiates with pharmaceutical companies, we did wonder whether it would be possible for the Ministry to strengthen its negotiating position, not just in the long term, but also in the near future. To date, the Minister has

decided that every single medicine on which negotiations have been conducted should be included in the basic package of insured care. Without wishing to question the gravity of the dilemmas to which we have already referred, these decisions may well have undermined the Ministry's negotiating position. The issue could also be phrased as follows: are there any circumstances in which the Minister for Medical Care and Sport would be prepared to reject an unfavourable final offer from a pharmaceutical company? Would it be possible to secure the political and social support needed in order to adopt such a stance?

We also wish to bring up the issue of the relationship with the Minister's strategy on medicines (i.e. the Medicines Policy Plan), and more specifically with policies that may influence relations between market parties, such as the promotion of biosimilars, the use of pharmaceutical compounding, and compulsory licensing. We recommend that the Minister for Medical Care and Sport, when implementing the Medicines Policy Plan and taking decisions in this connection, also assess whether these decisions can help to improve the Ministry of Health, Welfare and Sport's negotiating position.

This brings us to the following recommendations for the Minister of Medical Care and Sport:

- Toughen your negotiating stance by:
  - stating explicitly that, in accordance with the recommendations made by the National Health Care Institute, the negotiations should be aimed at reaching a price at which care is cost-effective as a minimum requirement;
  - gearing negotiations towards ensuring that the level of spending rises at a slower pace than in recent years.
- Give Parliament more information about whether the negotiations were successful in terms of achieving the prices recommended by the National Health Care Institute.
- When implementing the Medicines Policy Plan and taking decisions in this connection, also assess whether these decisions can help to improve the Ministry of Health, Welfare and Sport's negotiating position.
- Be prepared to turn down a final offer from a pharmaceutical company that you feel is unacceptable. If such an eventuality does indeed arise, inform parliament in good time and explain clearly to society at large why this decision was taken.

7 Minister's response and Court of Audit afterword

The Minister for Medical Care and Sport responded to our audit report on 18 March 2020. His response is reproduced *verbatim* in section 7.1. Our own afterword follows in section 7.2.

7.1 Minister's response

"Your audit report entitled 'Miracle cure or sticking plaster? The results of negotiations on the prices of medicines' was enclosed with your letter of 13 February 2020. I endorse your conclusion that it is reasonable to assume that the centralised price negotiations conducted by the Ministry of Health, Welfare and Sport help to control spending on expensive medicines, and hence healthcare spending as a whole. I have read your report with great interest. This letter begins with a brief discussion of the purpose of negotiations on the prices of medicines and goes on to respond to your conclusions and recommendations.

Negotiations on the prices of medicines

The aim of the price negotiations and the financial arrangements is to ensure that patients in the Netherlands are given affordable and lasting access to new medicines as they come on to the market. This is an important issue in the light of the constant stream of new medicines – which is in itself good news for patients and society in general. Innovation is important and must therefore be made worthwhile for the innovators. At the same time, there is a growing tendency for new medicines to come with a high price that is not transparent. Some medicines cost society tens of millions of euros a year; others cost even more. A high level of spending on a single medicine has the effect of crowding out spending on other forms of medical care. This applies just as much as to treatments that are not cost-effective. This is also a point that you raise in your report. And this is why there need to be safeguards – to ensure that the prices paid for medicines are in the public interest, particularly if a new medicine is unique on the market.

I believe that negotiations are an ideal, flexible tool for striking a reasonable balance between the price that governments (or purchasers of care services) are willing or able to pay, and the price at which pharmaceutical companies are willing to sell their product. The centralised price negotiations have had the effect of reducing – and in some cases sharply reducing – overall spending on each of the 32 expensive new medicines in question. In many cases, we were able to bring the price down to a cost-effective level, and in certain cases even to negotiate a lower price. In my view, this means that the centralised price negotiations are of great value in ensuring that patients have lasting access to expensive new medicines.

Cost-effetiveness

Your report points out that not all negotiations have led to a cost-effective price for the medicines in question and that you believe that, in this sense, the negotiations have had only limited effectiveness in achieving cost-effective care. Although I agree with you about the importance of attaining cost-effective treatments, I do feel that it is equally important to take account of certain details that put things into perspective. You claim in your report that a cost-effective price was not achieved in five cases (out of the total of 13 cases whose cost-effectiveness you analysed). I would like to point out that, in one of these five cases, there was no cost-effective guide price on which the Ministry of Health, Welfare and Sport could base its negotiations and that in another case the negotiated outcome was, I believe, actually cost-effective. In the three other cases, you are right in saying that the recommended cost-effective price was not achieved. Unfortunately, it is not possible to provide any further details about the medicines in question without indirectly breaching the confidentiality of the price agreements reached in relation to the other medicines. I would like to stress that, as a general principle in any negotiation, I always prioritise the need to achieve at the very least a cost-effective price. Against this background, I intend where possible to adopt your recommendation that negotiations should be aimed at reaching a price at which care is cost-effective as a minimum requirement. At the same time, situations may arise in which this is not realistic or feasible, for example where a cost-effective price may not prove to be a financially viable price for the manufacturer. Where we are talking about effective treatments from which patients can benefit, the Ministry may decide that it is in their medical interest to pay for the cost of their treatment, even if the price is not entirely cost-effective. Clearly, this should not be a licence for manufacturers to charge excessively high prices. Even in these cases, therefore, I will continue to adopt a critical negotiating stance.

Controlling and limiting spending on medicines

You write in your report that, although the negotiations also help to control spending on medicines, you were not able to gauge the extent to which the negotiations help to control spending (whether in absolute or in relative terms). This was due in part to the absence of a reference standard, but also to the fact that other policy tools also help to control spending. Your report uses figures for 2017 published by the Dutch Healthcare Authority in its *Nza Monitor*. It is clear from the more recent figures for 2018 (see the progress report on financial arrangements sent to the Dutch House of Representatives on 3 November 2019) that there has been a sharp increase in the monetary impact of the negotiations on aggregate expenditure on hospital medicines, and that this impact is now substantial. In 2018, around €400 million worth of spending on hospital medicines was covered by financial arrangements, out of aggregate expenditure of €2.3 billion. This is twice as much as in 2017.

You also point to the need to continue to control spending on expensive medicines in the future, in the light of both the rising level of cost faced by hospitals and the prospect of many new medicines coming onto the market in the years ahead. You write that it goes without saying for this reason that the Minister should continue to negotiate with manufacturers and – with prices set to rise – should try and achieve better results.
I would like to stress first of all that new treatments are good news for both patients and society as a whole. This is on the proviso, however, that manufacturers ask a reasonable price for each of these new treatments and that a reasonable price is ultimately paid for them.
I would like to respond to your recommendation that negotiations should be geared towards curbing the growth in spending (on expensive hospital medicines) that we have witnessed in recent years, by saying that we are already putting this recommendation into effect by adopting a transitional model. The fact is that we only started negotiating on the prices of expensive hospital medicines in 2015. Moreover, when parliament adopted a statutory basis for the 'waiting room for medicines' in July 2018, the financial criteria applying to the waiting room were also tightened up. As a result, the National Health Care Institute now assesses a larger number of medicines, which also means that more medicines are subject to negotiations. This, too, may be seen as a response to the growing level of expenditure about which you expressed your concern. It is also in line with the arrangements made in the Outline Agreement on Specialist Medical Care, in which both the market parties and the government pledged to tighten up the controls applying to the admission of expensive medicines. In other words, the stricter criteria applying to the waiting room mean that all new medicines that absorb a relatively large proportion of the spending budget are now subject to certain financial arrangements. At the same time, the proportion of the budget taken up by expensive medicines that have been available for some time now – and on which no financial arrangements were made when they first became available – will decline in the future thanks to the expiry of patents and the introduction of price-competitive medicines. As a result of these factors, the financial arrangements are likely to play an even more important role in the future in controlling expenditure on hospital medicines, as described above.

In other words, I share your opinion about the need for these negotiations and take on board your findings as an encouragement to continue to use them as a policy tool. In doing so, I will also put more pressure on pharmaceutical companies to be more transparent about the prices of their products and to justify their high prices. I will also continue to invest in partnerships with other countries, both within and beyond Europe, with a view to preventing excessively high prices and giving patients lasting access to new medicines.

Recommendations relating to the National Health Care Institute

You recommend providing Parliament with clearer information about whether negotiations are successful in terms of achieving the prices recommended by the National Health Care Institute. I commend you for highlighting this point in your report. I fear, however, that an annual update will be difficult to implement in practice, as the provision of such information may prove to be contrary to the confidentiality arrangements demanded by pharmaceutical companies. At the same time, I am prepared to look into possible ways and means of supplying Parliament with more information about whether or not the prices recommended by the National Health Care Institute were achieved in the negotiations. This is a point that I will pick up on in the 2020 progress report on the financial arrangements, which I will be sending to Parliament in the autumn of this year.

Link between negotiations and the 2016 Medicines Policy Plan

You also bring up the issue of consistency with the implementation of the strategy on medicines (i.e. the Medicines Policy Plan), referring in this connection to policies such as the promotion of biosimilars, the use of pharmaceutical compounding, and compulsory licensing. In short, you recommend that I should be constantly aware of how the Policy Plan and the tools such as those referred to above can bolster the Ministry's negotiating position. Clearly, in the event of negotiations not leading to a favourable conclusion, it is important that there are alternative means of giving patients access to these medicines. Tools such as pharmaceutical compounding help to give patients access to the treatments they need. In addition, as you point out, a committee has been set up in order to examine the possibility of using compulsory licensing as a policy tool. I do not wish to anticipate the committee's report. Both these and other aspects of the Medicines Policy Plan should not be seen as separate tools, but as forming part of a coherent whole and as being in line with international law.

Finally, you say that I should be prepared to turn down a final offer from a pharmaceutical company that I feel is unacceptable and, if such an eventuality does indeed arise, that I should inform Parliament in good time and explain clearly to society at large why this decision was taken. This is an important recommendation that concerns the wider societal need to be more open about what is a complicated decision-making process.
Saying 'no' may, of course, mean that patients do not receive their medication. Our aim is to strike a reasonable balance between fostering innovation on the one hand and providing affordable care on the other. In an ideal situation, society as a whole would have a clear idea of the factors determining the prices charged by manufacturers and the business model on which their investments are based.

I intend to continue to press the pharmaceutical industry for transparency in justifying the prices of medicines. I also recognise the importance of raising the degree of transparency in relation to the prices as agreed and the prices as actually paid. While I believe that turning down an unfavourable offer cannot, of course, be an end in itself, I do accept that we should not be afraid to do so in those cases in which a particular negotiated outcome is not in the public interest. I agree with you about the importance of informing Parliament in such an eventuality, although I feel this should take the form of a *post-hoc* report on those cases in which negotiations do not produce a favourable result. In such an event, I should be able to explain what I would have been prepared to pay for the medicine in question.
In more general terms, I am keen to do more to promote transparency in relation to the prices of expensive medicines, the cost of insurance cover, and the decisions taken about these, and I am planning to inform Parliament in more details about my intentions in this respect."

7.2 Court of Audit afterword

We hope that the Minister's undertaking to do more to promote transparency in relation to the prices of expensive medicines and the cost of insurance cover results in the publication of concrete plans once the coronavirus crisis is behind us. We are also curious to see whether his promise to look into possible ways and means of supplying Parliament with more information about whether or not the prices recommended by the National Health Care Institute were achieved in the negotiations, leads to concrete action. What the government can do at this point in time is to work as actively as possible in implementing the Medicines Policy Plan and the associated recommendations, such as those made by the Council for Public Health and Society. In the short term, this would reduce the pressure placed on the accessibility and affordability of healthcare. At the same time, it would help the government to explore and perhaps even push back the boundaries of the current system, so that – in the longer term – experience can be gained with elements of a new business model.

The Minister states that, where possible, negotiations should be aimed at reaching a price at which care is cost-effective as a minimum requirement. We should like to take a firmer line here: negotiations should *always* be aimed at achieving cost-effective care, especially as the Minister is scarcely able to judge – without any information on the cost – at which price the manufacturer breaks even.
We should also like to draw attention to the phrase 'as a minimum requirement'. Although our audit sought to assess whether the negotiations resulted in cost-effective prices, these should not be regarded as a negotiating target. A simple sticking plaster that is capable of

preventing an infection or worse is of great value. However, in terms of the accessibility and affordability of our healthcare system, it is a good thing that the price is but a fraction of this value.

In relation to the risk identified in our report of spending on hospital medicines ('intramural medicines') crowding out other types of specialist medical care, the Minister claims that the Ministry is negotiating on a growing number of expensive medicines. We wish to point out in this connection that the growing aggregate monetary value of all the negotiations does not in itself say anything very meaningful about the extent to which they help to control spending on medicines. If, say, the Ministry does not succeed in negotiating any discounts, the negotiations will not help at all in controlling expenditure, even if they do represent a huge monetary value. As it has been agreed that there may be little or no increase in the cost of specialist medical care as a whole in the coming years, it is imperative that the next round of negotiations results in agreement on very competitive prices.

Appendix 1 Bibliography

Brouwer, W.B.F. (2018). *De politiek ontloopt moeilijke keuzes over medicijnen - tegen een hoge prijs*. Trouw, 17 November 2018.

Cameron et al. (2018) On what basis are medical cost-effectiveness thresholds set? Clashing opinions and an absence of data: a systematic review. Global Health Action, 2018. Vol 11. 1447828.

Canoy M. and Tichem J. (2018). *Lagere medicijnprijzen hoeven innovatie niet in de weg te staan*. Financieel Dagblad, 7 May 2018.

Common Eye & SiRM (2019). *Op naar hoger hangend fruit - Ex durante evaluatie genees-middelenvisie 2016-2018*. Utrecht: Common Eye & SiRM.

Council for Public Health and Society (2017). *Ontwikkeling nieuwe geneesmiddelen Beter, sneller, goedkoper. Bijlage bij Geneesmiddelenbeleid.* Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. Dutch House of Representatives, 2017–2018 session, 29 477, no. 453. The Hague: Sdu.

Dutch Healthcare Authority (2019). *Monitor geneesmiddelen in de medisch-specialistische zorg*. Utrecht: Dutch Healthcare Authority.

Dutch Healthcare Authority (2019a). *Monitor Transformatiegelden medisch-specialistische zorg 2019*. Utrecht: Dutch Healthcare Authority.

Dutch Healthcare Authority (2019b). *Stand van de zorg 2019 - Aan de slag*. Utrecht: Dutch Healthcare Authority.

Dutch Healthcare Authority (2019c). *Monitor inhoud contracten medisch-specialistische zorg 2018*. Utrecht: Dutch Healthcare Authority.

Ecorys (2016). *Evaluatie pilot financiële arrangementen – Eindrapport*. Rotterdam, 15 January 2016: Ecorys.

Healthcare Insurance Board (2012). *Dabigatran (Pradaxa) bij preventie van cerebrovasculair accident*. Diemen: Healthcare Insurance Board.

Meerding, W., Polder, J., de Hollander, A., & Mackenbach, J. (2007). *Hoe gezond zijn de zorguitgaven? De kosten en opbrengsten van gezondheidszorg bij infectieziekten, kankers, en hart- en vaatziekten. In Zorg voor euro's - 6 (RIVM)*. Bilthoven.

Ministry of Health, Welfare and Sport (2012). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2012–2013 session, 29 477, no. 207. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2012a). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2011–2012 session, 29 477, no. 186. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2014). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2013–2014 session, 29 477, no. 289. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2015). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2014–2015 session, 29 477, no. 343. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2015a). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2014–2015 session, 29 477, no. 328. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2016). *Geneesmiddelenvisie. Bijlage bij Geneesmiddelenbeleid.* Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2015–2016 session, 29 477, no. 358. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2016a). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2015–2016 session, 29 477, no. 386. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2017). *Geneesmiddelenbeleid*. Letter from the Minister for Medical Care to the Dutch House of Representatives. 2017–2018 session, 29 477, no. 453. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2017a). *Geneesmiddelenbeleid*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. 2017–2018 session, 29 477, no. 442. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2018). *Geneesmiddelenbeleid*. Letter from the Minister for Medical Care to the Dutch House of Representatives. 2018–2019 session, 29 477, no. 532. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2018a). *Bestuurlijk akkoord medisch-specialistische zorg 2019 t/m 2022. Bijlage bij Invoering Diagnose Behandel Combinaties (DBC's)*. Letter from the Minister of Health, Welfare and Sport to the Dutch House of Representatives. Dutch House of Representatives, 2017–2018 session, 29 248, no. 311. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2018b). *Geneesmiddelenbeleid*. Letter from the Minister for Medical Care to the Dutch House of Representatives. 2018–2019 session, 29 477, no. 520. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2019). *Vaststelling van de begrotingsstaten van het Ministerie van Volksgezondheid, Welzijn en Sport (XVI) voor het jaar 2020*. Dutch House of Representatives, 2019–2020 session, 35 300 XVI, no. 2. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2019a). *Jaarverslag en slotwet Ministerie van Volksgezondheid, Welzijn en Sport 2018*. Dutch House of Representatives, 2018–2019 session, 35 200 XVI, no. 1. The Hague: Sdu.

Ministry of Health, Welfare and Sport (2019b). *Geneesmiddelenbeleid*. Letter from the Minister for Medical Care to the Dutch House of Representatives. 2019–2020 session, 29 477, no. 623. The Hague: Sdu.

National Health Care Institute (2015). *Kosteneffectiviteit in de praktijk*. Diemen: National Health Care Institute.

National Health Care Institute (2019). *Horizonscan Geneesmiddelen*. See: https://www.horizonscanmedicines.nl/nieuws/publicatie-horizonscan-10-december-2019. Last accessed on 23 December 2019.

Netherlands Bureau for Economic Policy Analysis (2019). *Verkenning Middellange termijn 2022-2025*. The Hague: Netherlands Bureau for Economic Policy Analysis.

Van Baal P.H.M., Perry-Duxburry M., Bakx P., Versteegh M.M., van Doorslaer E., & Brouwer W.B.F. A cost-effectiveness threshold based on the marginal returns of cardiovascular hospital spending. Health Econ. 2018. https://doi.org/10.1002/hec.3831.

Appendix 2 List of price agreements for 2012–2018

Nr.	Medicine: Substance name	Medicine: Brand name	Hospital or out-of-hospital medicine?	Manufacture	Included basic insurance as from	Until
1.	pirfenidone	Esbriet	Out-of-hospital	Roche	1 Apr 14	31 Dec 17
2.	nintedanib	Ofev/ Vargatev	Out-of-hospital	Boehringer Ingelheim	1 Nov 15	31 Dec 17
3.	dabigatran	Pradaxa	Out-of-hospital	Boehringer Ingelheim	1 Dec 12	Talks ongoing on extension
4.	rivaroxaban	Xarelto	Out-of-hospital	Bayer	1 Dec 12	Talks ongoing on extension
5.	apixaban	Eliquis	Out-of-hospital	Pfizer/ B-MS	1 Jun 13	Talks ongoing on extension
6.	edoxaban	Lixiana	Out-of-hospital	Daiichi-Sankyo	1 Nov 15	Talks ongoing on extension
7.	sofosbuvir	Sovaldi	Out-of-hospital	Gilead	1 Nov 14	31 Dec 18
8.	daclatasvir	Daklinza	Out-of-hospital	B-MS	1 Mar 15	31 Dec 18
9.	ombitasvir-paritaprevir-ritonavir-dasabuvir	Viekirax/ Exviera	Out-of-hospital	AbbVie	1 Oct 15	31 Dec 18
10.	sofosbuvir-ledipasvir	Harvoni	Out-of-hospital	Gilead	1 Nov 15	31 Dec 18
11.	elbasvir-grazoprevir	Zepatier	Out-of-hospital	MSD	1 Jan 17	31 Dec 18
12.	sofosbuvir-velpatasvir	Epclusa	Out-of-hospital	Gilead	1 Apr 17	31 Dec 18
13.	glecaprevir-pibrentasvir	Maviret	Out-of-hospital	AbbVie	1 Mar 18	31 Dec 18
14.	sofosbuvir-velpatasvir-voxilaprevir	Vosevi	Out-of-hospital	Gilead	1 Jul 18	31 Dec 18
15.	Ivacaftor	Kalydeco	Out-of-hospital	Vertex	1 Jun 15	Talks ongoing on extension
16.	lumacaftor-ivacaftor	Orkambi	Out-of-hospital	Vertex	1 Nov 17	31 Dec 20
17.	lomitapide	Lojuxta	Out-of-hospital	Amryt	1 Nov 15	31 Dec 24
18.	evolocumab	Repatha	Out-of-hospital	Amgen Europe	1 Apr 16	31 Dec 22
19.	alirocumab	Praluent	Out-of-hospital	Sanofi	1 Jun 16	31 Dec 22
20.	alglucosidase alfa	Myozyme	Out-of-hospital	Sanofi	1 Jan 14	31 Dec 19
21.	agalsidase alfa	Replagal	Hospital	Shire Human Genetic Therapies	1 Jan 14	31 Dec 20
22.	agalsidase beta	Fabrazyme	Hospital	Sanofi	1 Jan 14	31 Dec 20
23.	ruxolitinib	Jakavi	Hospital	Novartis	1 Jan 14	31 Dec 18
24.	Pertuzumab	Perjeta	Hospital	Roche	1 Jan 17	31 Dec 19
25.	eculizumab	Soliris	Hospital	Alexion	1 Jan 18	31 Dec 20
26.	nivolumab	Opdivo	Hospital	Bristol-Myers Squibb	1 Mar 16	31 Dec 19
27.	pembrolizumab	Keytruda	Hospital	MSD	1 Jul 17	31 Dec 19
28.	palbociclib	Ibrance	Hospital	Pfizer	1 Aug 17	31 Dec 20
29.	ribociclib	Kisqali	Hospital	Novartis	1 May 18	31 Dec 20
30.	atezolizumab	Tecentriq	Hospital	Roche	1 Jun 18	31 Dec 19
31.	nusinersen	Spinraza	Hospital	Biogen	1 Aug 18	31 Dec 20
32.	daratumumab	Darzalex	Hospital	Janssen	1 Sep 18	31 Dec 21

Appendix 3 Our audit approach

Our aim in undertaking this audit was to ascertain whether the price negotiations conducted by the Ministry of Health, Welfare and Sport helped both to bring about cost-effective care and to control spending on medicines. Our audit was based on the assumption that cost-effective care is achieved if the negotiated price is the same as that recommended by the National Health Care Institute. We sought to ascertain whether:

- during price negotiations with manufacturers, the Ministry of Health, Welfare and Sport succeeded in bringing the price down to the level recommended by the National Health Care Institute; and
- how much would have been spent on the medicines in question if the negotiated price had been the same as the recommended price in each case.

The audit data

We audited all 32 arrangements made between 2012 and 2018 (see Appendix 2). We made use of both published and confidential data, and also interviewed a number of representatives of the parties involved. Finally, external experts assisted us with one particular part of the audit.

Published data

The Dutch National Health Care Institute has published advisory reports on each of the 32 medicines and the associated clinical indications. In most cases, these advisory reports contain a pharmacotherapeutic report in which the Institute assesses the therapeutic value (i.e. the efficacy) of the medicinal product in question, and a pharmaco-economic report in which the Institute assesses the manufacturer's data on the product's cost-effectiveness. The manufacturer's original asking price for the product is stated in the pharmaco-economic report. In ten of the 32 advisory reports, the Institute states the percentage discount that needs to be given on the asking price in order for treatment with the product to be cost-effective. Our audit report refers to the combination of the manufacturer's asking price and the percentage discount as the 'recommended price'.

In addition to the advisory reports published by the National Health Care Institute, we also made use of letters sent to the Dutch House of Representatives about the financial arrangements and the policy on medicines.

Confidential data

Our most important audit data consisted of the 'price negotiation memoranda' and the 'negotiated outcome memoranda' that Ministry officials presented to the Minister of

Health, Welfare and Sport or, as the case may be, the Minister for Medical Care and Sport. These documents describe the Ministry's proposed strategy and negotiating target before the start of negotiations (in the case of a price negotiation memorandum) or the outcome of the negotiations (in the case of a negotiated outcome memorandum). Once the Minister of Health, Welfare and Sport or, as the case may be, the Minister for Medical Care and Sport accepts the negotiating target set out in the price negotiation memorandum, negotiations can start. In order for a price agreement to be concluded, the Minister first needs to approve the negotiated outcome as set out in the negotiated outcome memorandum. The memoranda are confidential. In addition to inspecting the price negotiation memoranda and the negotiated outcome memoranda, we also asked the Ministry of Health, Welfare and Sport to provide us with sales figures for the medicines in question and the structure of the price arrangements (i.e. the percentage discounts associated with each turnover bracket) where these were not explicitly stated in the negotiated outcome memoranda.

Interviews

We conducted a number of interviews during the course of the audit with officials from the Ministry of Health, Welfare and Sport. We also interviewed members of staff at the National Health Care Institute.

The audit process

As is clear from the following table, the audit was performed in four stages.

Table 6 *Audit stages*

Stage	Contents
1.	Analyse the negotiating targets set by the Ministry of Health, Welfare and Sport (as set out in the price negotiation memoranda). Identify the prices recommended by the National Health Care Institute and examine whether these are reflected by the Ministry's negotiating targets.
2.	Assess whether: • in the case of the 13 medicines for which the National Health Care Institute had issued a recommended price, the Ministry of Health, Welfare and Sport succeeded in bringing the manufacturer's asking price down to this level in the price negotiations. • in the case of the 19 medicines for which no price had been recommended, the Ministry of Health, Welfare and Sport achieved its negotiating target as set out in the price negotiation memorandum.
3.	Examine whether the market conditions applying to a given medicine affect the Ministry's negotiating position. We received assistance on this point from the Institute for Medical Technology Assessment (iMTA). The iMTA analysed the market conditions with reference to a number of different elements. With the help of the iMTA, we then tried to describe the individual negotiated outcomes (in qualitative terms). Note: the iMTA did not see any of the negotiated outcomes.

Stage	Contents
4.	Ask the Ministry of Health, Welfare and Sport to calculate, in relation to all 13 medicines for which a recommended price had been issued, how much would have been spent if it had succeeded in bringing the asking price down to the level of the recommended price.

A brief description of each stage:

Stage 1: Compare the negotiating target with the price recommended by the National Health Care Institute

Of the 13 recommended prices available to us for the purpose of our audit, ten were based directly on the advisory reports produced by the National Health Care Institute. We asked the Institute to take another look at the information that manufacturers were required to produce as part of the routine assessment procedure. As a result, the Institute proved able to quote recommended prices (i.e. a percentage discount) for three further medicines. As the Ministry of Health, Welfare and Sport did not have these recommended prices at the time of the relevant negotiations, we passed them on to the Ministry, which agreed that they were appropriate as recommended prices.

Stage 2: Compare the negotiated outcome with the recommended price or negotiating target

This stage involved comparing the negotiated outcomes as set out in the negotiated outcome memoranda with the recommended prices (in 13 cases) or the targets set in the price negotiation memoranda (in 19 cases).

The first step was to assess whether the agreed percentage discount as set out in the negotiated outcome memorandum (t = 0) was at least equal to the recommended price. In a number of price agreements, the Ministry also agreed discounts for certain existing clinical indications for which the medicine had already been included in the basic insurance package. We decided not to take the latter discounts into account in calculating whether the Ministry had succeeded in achieving the recommended price for a new clinical indication. Where the financial arrangement was based on a graduated scale, i.e. the larger the volume of sales, the bigger the discount, we then sought to ascertain whether these percentage discounts had indeed been achieved in practice (t = 1, 2, etc.).[25]

Stage 3: Negotiating position and negotiated outcome: identify and describe

The Ministry's negotiating position varies from one medicine to another. The Institute for Medical Technology Assessment (iMTA) helped us to identify relevant market conditions that could have affected the Ministry's negotiating position (see Table 2 in section 2.4). We discussed a report drawn up on this subject by the iMTA during a joint meeting with the Ministry of Health, Welfare and Sport and iMTA on 4 April 2019.

The iMTA then attempted to analyse the market conditions for each of the 32 medicines. The market conditions were formulated in such a way that, the greater the number of pluses, the stronger the Ministry's negotiating position was assumed to be.
In the final step, we tried to find a link between the number of relevant market conditions (i.e. the negotiating position) on the one hand and the outcome of the price negotiations on the other. We did not find any indications to suggest that such a link exists.

Stage 4: The Ministry's calculations: assumptions
Chapter 5 discusses the information provided to Parliament about the outcome of the price negotiations. In the case of the 13 medicines for which a recommended price was available (or for which it was possible to deduce a recommended price), we asked the Ministry of Health, Welfare and Sport to work out what the aggregate level of expenditure on these medicines would have been if it had paid the recommended prices.

At our request, the Ministry based these calculations on an assumption that treatment for all indications would have been paid at the price recommended by the National Health Care Institute.
This is an important point as the Ministry sometimes negotiates on the price of treatment for a *new* clinical indication, even though the medicine in question has already been included in the basic health insurance package for another, *already existing* indication. In certain cases, the Ministry includes existing clinical indications in the negotiations. However, on the basis of the available data, the Ministry is not always able to say for which particular indication a medicine has been used. The problem is that the recommended price applies specifically to one particular (in this case the new) indication. Because we apply the available recommended price to both *new* and *existing* indications, this may therefore mean that the level of expenditure as calculated for *existing* indications may be either too high or too low than is the case in practice.

Appendix 4 Topics and actions as set out in the Minister of Health, Welfare and Sport's Medicines Policy Plan (2016)

No.	Topic	Actions
1.	Accessibility of new medicines	1. Examine ways and means of ensuring that medicines become available more quickly and at an affordable price 2. Harmonise, where possible, the requirements for market admission (EU) and insurance cover (national).
2.	Take action in response to the high prices of medicines	3. Ensure that health insurers and healthcare providers are better equipped to purchase medicines. 4. Set up a 'purchasing expertise platform' for medicines. 5. Draw up a set of guidelines clarifying the scope available under the Competitive Trading Act for joint purchases of medicines. 6. Launch an 'expensive medicines monitor' containing up-to-date information on purchases of expensive medicines and patient experiences. 7. Encourage every hospital to set up a medicines committee in which the relevant parties discuss and formulate policies on expensive medicines. 8. Reduce prices by adjusting the system for admitting medicines to the basic health insurance package and for refunding the cost of such medicines. 9. Perform recalculations in the 'system for refunding the cost of medicines', leading to lower refund ceilings and limiting the unrestricted influx of hospital medicines. 10. Extend the scope of price negotiations undertaken by the Drug Price Negotiation Unit. 11. Foster international collaboration in order to facilitate easy access to medicines, promote innovation, ensure that medicines remain affordable and raise transparency among member states.
3.	New ways of developing and selling medicines	12. Impose conditions on research grants so as to prevent that Dutch taxpayers from paying twice for medicines. 13. Create opportunities for alternative methods of developing and selling medicines, so that affordable, transparently priced medicines come onto the market.
4.	Appropriate use of medicines	14. Support the development of diagnostics, so that patients and physicians have access to a larger pool of knowledge about appropriate dosages and the right points at which to start and end treatments. 15. Launch a five-year programme for promoting 'personalised medicines', with a budget of €10 million. 16. Adjust the guidelines on medication reconciliation and ensure that pharmacists receive more accurate information from laboratories, that clinical indications are stated on prescriptions, and that patients adhere more closely to their therapies. 17. Promote the use of biosimilars.

No.	Topic	Actions
5.	Striking the right balance on the pharmaceutical market	18. The protection of intellectual property rights and investment interests must be commensurate with the aim of promoting innovation. Identify more clearly which products are subject to the EU regulation on orphan medicines. Initiate a debate on how to strike the right balance between protecting the market for orphan medicinal products on the one hand and the supply of new products on the other. 19. The Netherlands Authority for Consumers & Markets (ACM) should continue to closely monitor pharmaceutical companies in order to identify any instances of inappropriate behaviour. Where necessary and feasible, the ACM should act to correct such behaviour.
6.	Better information	20. Draw up an information action plan that clearly specifies the roles, objectives, working methods and responsibilities in relation to product registrations. 21. The Medicines Evaluation Board should set up a database containing information on doctors' prescription habits. 22. We are planning to improve the independent information for patients by making this both easily comprehensible and readily accessible.

Appendix 5 Glossery

Biosimilar – A biosimilar is a product that is highly similar to a biological medicine. As biosimilars are similar but not identical to the original product, every biosimilar needs to go through a separate approval procedure. Like all other medicines, a licence needs to be obtained for a biosimilar before it can be sold on the market. Again, as with all medicines, a biosimilar's safety is subject to constant monitoring following its approval.

Compulsory licence – A licence the contents of which are carefully defined, and which the Minister of Economic Affairs and Climate Policy issues to a designated individual in the public interest of overruling a patent. Granting a compulsory licence to a pharmaceutical company to produce patent-protected medicines during a state of emergency is a good example.

Disease burden – This term is used to describe the state of a patient's health compared either with patients suffering from another complaint or with healthy people. The more serious the complaint, the greater the disease burden.

Graduated discount scale – A graduated discount scale is based on a number of sales volume brackets (for example, 0 – 100 doses of the medicine in question) to which a given price applies. Most price-volume agreements work with a number of turnover volume brackets, each of which is associated with a different percentage discount. The custom is for the discount offered by the manufacturer to rise as the volume of sales rises.

Hospital medicines – Medicines distributed in hospital.

Indication – The condition that a medicine is used to treat is known as an indication, or clinical indication in full. A medicine can be used to treat more than one condition (or indication). A medicine is initially registered as being used to treat just one condition (or indication).

Negotiated outcome memorandum – The Ministry of Health, Welfare and Sport communicates the outcome of negotiations in the form of a 'negotiated outcome memorandum' addressed to the Minister for Medical Care. The memorandum also contains information on alternative options, such as on the consequences of not accepting the outcome of the negotiations.

Out-of-hospital medicines – Medicines obtained from a pharmacy.

Price negotiation memorandum – The Ministry of Health, Welfare and Sport draws up a 'price negotiation memorandum' before the start of negotiations. This document sets out the Ministry's negotiating target, for example the size of the discount it is seeking to achieve. The price negotiation memorandum is based on information obtained from physicians and the recommendations of the National Health Care Institute (which the Minister of Health, Welfare and Sport is entitled to ignore).

Quality-adjusted life year (QALY) – A QALY is an extra year of life spent in good health. The QALY is used in economic discussions of the purpose and effectiveness of a particular healthcare treatment to compare the effects of different treatments with each other.

Recommended price (price recommended by the National Health Care Institute) – The price at which the National Health Care Institute believes that treatment with the medicine in question is cost-effective. The Institute indicates the recommended price in the form of the percentage discount that needs to be applied to the manufacturer's asking price in order to reach a cost-effective price.

State of the art – As the government decides what is and is not included in the basic package of insured care, it has also decided that all insured care should be subject to the 'state of the art'. This means that only forms of care deemed to be effective are included in the packages of insured care under the Healthcare Insurance Act and the Long-Term Care Act.

Substitution – The provision of care of equal quality, but at a lower cost, at another (lower) point in the healthcare supply chain.

Waiting room – In principle, new hospital medicines are included in the basic package of insured care even if they are not covered by a 'ministerial payments decree'. The Minister for Medical Care is, however, entitled to temporarily withdraw a medicine from the basic package on the grounds of its high price. In such an event, the medicine in question is held in what is known as 'the waiting room'.

Appendix 6 Endnotes

1. Since 1 January 2017, price agreements with pharmaceutical companies have formed an integral part of the Ministry of Health, Welfare and Sport's policy on decisions about the inclusion of expensive medicines in the basic package of insured care.
2. For some medicines, both aspects apply: 1) a high asking price, at which care is not cost-effective, together with 2) an expected high level of spending at a macro level.
3. This amount for one QALY has no legal basis. It was first mentioned in a report published in 2006 by the then Council for Public Health and Health Care. The figure of €80,000 is the benchmark for conditions with a high disease burden. For conditions with an average or low disease burden, the benchmarks are €50,000 and €20,000 respectively.
4. In three out of 13 cases, the report did not state a precise percentage, but the National Health Care Institute was able to distil this in retrospect from the available information.
5. The National Health Care Institute did not issue a recommended price for seven medicines with a non-cost-effective asking price. For two of these medicines, the Institute claimed that their cost-effectiveness was not sufficiently substantiated, which made it impossible to calculate a recommended price. For three orphan medicines, the percentage discount would have to be almost 100% in order to ensure cost-effective care. The manufacturer did not assess the cost-effectiveness of the last two medicines. For one of these two, this was not necessary as it was agreed that annual spending would remain below €2.5 million. The National Health Care Institute recommended a price for the other medicine that would not exceed that of a reference medicine with the same therapeutic value.
6. This sentence was edited following the clearance procedure at ministerial level.
7. This box was adjusted following the clearance procedure at ministerial level. There are nine countries rather than eight: Ireland has been added.
8. Between 2012 and 2016, the Ministry of Health, Welfare and Sport transferred medicines that fall under specialist medical care and which are administered at the patient's home, from the medicine reimbursement system to the in-hospital setting. The transfers had two objectives. First, the Ministry wanted to create a uniform entitlement to these specialist medicines, in order to prevent patients from being caught in the middle between funding and service-provision disputes between healthcare providers and health insurers. Second, the idea was that the transfers should lead to lower medicine prices thanks to competitive purchasing practices by hospitals.
9. This sentence was adapted following the clearance procedure at ministerial level. The word 'mostly' was added.

10. Biosimilars are biological medicines that are similar (but not identical) to the original medicine, of which the patent has expired. The (then) Health Care Insurance Board considered biological medicines to be therapeutically interchangeable if the European Medicines Agency or the Dutch Medicines Evaluation Agency designated them as 'similar' following the registration procedure.
11. A medicine with a legally protected monopoly position is also referred to as a 'proprietary medicinal product'. New applications of existing medicines may also be patented, e.g. a new indication, a new sub-population, a new form of delivery, a new dosage regime or a new technical effect.
12. An orphan medicine is a medicine used for treating a rare disease. In addition to patent protection, manufacturers of orphan medicines are granted ten-year market exclusivity (Ministry of Health, Welfare and Sport 2018).
13. This sentence was adapted following the clearance procedure at ministerial level. The phrase: '…that the Ministry of Health, Welfare and Sport negotiated on…'was added.
14. The Minister was able to negotiate on the prices of hospital medicines to treat Pompe and Fabry's disease in 2013 because the (then) Health Care Insurance Board had re-evaluated these medicines under the then policy rule on orphan medicine.
15. For all out-of-hospital medicines, the National Health Care Institute issues a r ecommendation to the Minister on whether or not to include the medicine in the medicine reimbursement system. The Institute may also recommend that the Minister should first start price negotiations with the manufacturer. The Institute often also issues recommendations for hospital medicines placed in the waiting room for medicines. Price negotiations with the manufacturer are often one of these recommendations.
16. In principle, hospital medicines are automatically included in the basic package of insured care. Consequently, the assessment procedure for specialist medicines is part of 'risk-driven package management'. If, after the initial assessment of a medicine, there are doubts about appropriate use and/or cost-effectiveness, the National Health Care Institute may recommend that the Minister initiates a 'conditional funding procedure'. Outcome research may be performed during the conditional funding period. The conditional funding period ends with a second assessment. Based on the results of this second assessment, the National Health Care Institute may also recommend that the Minister should start price negotiations.
17. The original sentence was adapted following the clearance procedure at ministerial level.
18. The original sentence was adapted following the clearance procedure at ministerial level.
19. If the recommendation relates to a second assessment, the National Health Care Institute recommends starting negotiating on price reductions with the manufacturer.

20. The endnote originally included at this point was deleted following the clearance procedure at ministerial level. The deleted information related to hospital medicines.
21. In the case of this medicine, it was decided to start negotiations without a pre-agreed mandate.
22. The National Health Care Institute did not quote a recommended price for seven medicines for which the manufacturer's asking price was not cost-effective. The Institute claimed that there was insufficient evidence about the cost-effectiveness of two of these medicines, which meant that it was unable to calculate a recommended price. In the case of three orphan medicines, the manufacturer would have had to offer a discount of almost 100% in order for treatment to be cost-effective. The manufacturer did not assess the cost-effectiveness of the last two medicines. This was not required for one of these two medicines as it had previously been agreed that spending on the medicine would not exceed €2.5 million per annum. In the case of the other medicine, the Institute recommended a price no higher than that of a reference medicine of equal therapeutic value.
23. The original sentence was adapted following the clearance procedure at ministerial level on the grounds that it contained traceable information.
24. Because DTCs (diagnosis treatment combinations) remain valid for a relatively long time, the Minister of Health, Welfare and Sport's progress report on the year t contains information on the reductions in spending in the year t-2. Since 2017, the progress reports have also contained provisional data on the year t-1.
25. Where the negotiated outcome is a fixed percentage discount, the percentage of the discount actually achieved in practice is not affected by the volume of sales.

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The Hague, July 2020