maatschappelijk
aanvaardbare
uitgaven
geneesmiddelen

Towards societally acceptable prices for expensive medicines

15 October 2025

Autoriteit Consument & Markt

NZa

Zorginstituut Nederland

'Towards societally acceptable prices for expensive medicines' is a report by the Societally Acceptable Expenditure on Medicines programme (*Maatschappelijk Aanvaardbare Uitgaven Geneesmiddelen*, MAUG), which is run by three independent governmental bodies: the National Health Care Institute (Zorginstituut Nederland), the Dutch Healthcare Authority (NZa) and The Netherlands Authority for Consumers and Markets (ACM). At the request of the Ministry of Health, Welfare and Sport (hereinafter Ministry of Health), we examined how to obtain societally acceptable prices for expensive medicines and keep them that way. We based our statements on our observations, expertise, previous opinions, public consultations and conversations with experts.

Note: this English version of the MAUG-report is translated from the original Dutch report entitled '*Naar maatschappelijk aanvaardbare prijzen voor dure medicijnen*'. Whereas the Dutch version has been consulted with, among others, market parties and representatives of healthcare professionals and patients, the present translated document has not been consulted. The process of translation as well as the need to introduce and clarify the Dutch context, might mean that the wording in this document here and there slightly differs from the Dutch version. Wherever the English version differs from the Dutch version, the Dutch text is leading.

Autoriteit
Consument & Markt

NZa

Zorginstituut Nederland

Contents

Summary

Summary

Introduction and approach

Medicines are of great importance for people's health. They improve or maintain health and quality of life. We are willing to pay a lot for those health gains. At the same time, there are concerns. Due to increasing expenditure, (very) high asking prices, and a lack of insight into the company's costs, it is important that the government ensures that prices of expensive medicines are societally acceptable. After all, every euro can only be spent once. If expensive medicines take up too much of the healthcare budget, it will be at the expense of other care.

Concerns from the Lower House of the Dutch Parliament about increasing expenditure on medicines and rising prices led to a resolution in 2021 from a member of parliament, Mrs. Kuiken. In response to this, the National Health Care Institute, ACM and NZa focused within the Societally Acceptable Expenditure on Medicines programme (MAUG) on how to make the prices of expensive medicines societally acceptable and keep them that way. This resulted in this advisory report.

Our aim is to arrive at an acceptable price for a medicine from a societal perspective, in order to gain more health with the available budget. We have deliberately chosen to put the perspective of society (the public) at the centre. For the public at large, it is important that effective medicines are available and continue to become available. It is also important that healthcare in general remains accessible, with affordable premiums. For our advice, we drew on our own expertise, previous opinions, a nationwide public consultation, and interviews with experts.

Updating the assessment framework

The National Health Care Institute advises the Minister of Health about the inclusion of medicines in the basic healthcare package and, if so, at what price. The National Health Care Institute uses criteria to determine if medicines qualify for inclusion in the basic healthcare package, one of them being cost-effectiveness. To determine cost effectiveness, QALYs (quality-adjusted life years, i.e. years of life in good health) are used. The maximum that society is prepared to pay for gaining one extra QALY has an upper limit: the maximum reference value. The maximum reference value is €20,000 per QALY at a low burden of disease, €50,000 per QALY at a moderate burden of disease and €80,000 per QALY at a high burden of disease.

A fair distribution of the surplus

When the price of a medicine is equal to or below the maximum reference value, we say that it is a cost-effective price. However, a cost-effective price is not the same as a societally acceptable price. When paying the maximum reference value, the costs to society are equal to the maximum value of the health gained to society. Consequently, society as a whole does not gain. In that case, the added value (the surplus) goes entirely to the company. This may be acceptable under certain conditions, but only on a temporary basis. To help determine what price is societally acceptable, the National Health Care Institute will update the assessment framework to incorporate more guiding principles.

Guiding principles for the framework

For the updated framework, we see six cohesive guiding principles:

1. Health gains as a central element: the more health gains a medicine provides, the more we are willing to pay for it.
2. Health gains for patients with a high disease burden have a higher societal value: the more severe the patient's disease, the higher the maximum reference value.
3. Uncertainty about effectiveness and cost-effectiveness affects the societally acceptable price: the less certain it is that the medicine will actually provide health gains for the patient, the lower the societally acceptable price may be.
4. The total expenditure influences the societally acceptable price: the higher the overall expenditure on a single medicine for all its patients (the macro-cost impact), the lower the societally acceptable price level for that medicine.
5. The societally acceptable price is dynamic: once it is reasonable to assume investments have been recouped, the societally acceptable price of the medicine drops.
6. The level of innovation affects the societally acceptable price: minor innovations, such as indication extensions, may have a lower societally acceptable price.

The National Health Care Institute will develop these guiding principles and quantify them where possible. The aim is to update the assessment framework during 2026.

Our recommendation to the Minister of Health

- Advocate these guiding principles actively in the public debate.
- Support the National Health Care Institute in its updating of the assessment framework.
- Adopt future package recommendations based on the updated framework for reimbursement decisions.
- Provide a thorough motivation for the reimbursement decisions taken.

Strengthening competition

Competition drives down prices and therefore it is important that competition occurs in a timely and effective way. The government can strengthen competition by removing barriers which impede competition. Our advisory report focuses on the following hurdles:

- Clinical trials set up by pharmaceutical companies to study the effects of a medicine are often not designed to look into whether medicines are interchangeable.
- In some cases, medicines which could be used interchangeably are reimbursed through different budgets, effectively preventing competition between those medicines.
- Price negotiations are carried out by multiple payers: the Ministry of Health, health insurance companies and hospitals. As a result, their bargaining power is weaker.

Our recommendation to the Minister of Health

- Collaborate with the European Commission to ensure that the advice on study design resulting from the Joint Scientific Consultations is made public.
- Explore, at a European level, how to make Joint Scientific Consultations more binding.
- Ensure a level playing field for interchangeable medicines or medicines that are the same, but with a different mode of administration.
- Explore options for increased price competition in the outpatient setting.
- Improve the coordination of price negotiations conducted by different stakeholders.

Rate regulation and supervision

If the market, due to the absence of competition, fails to generate acceptable prices, it is the role of the government to prevent us from paying higher than societally acceptable prices. The updated assessment framework described earlier is an important tool for this. Other possible instruments include rate regulation by the NZa and market oversight by the ACM.

The NZa sets maximum rates for expensive inpatient medicines. The NZa will explore whether it is possible to improve the alignment of these maximum rates to what we regard as the societally acceptable maximum.

Moreover, it is important that the ACM is provided with additional tools for its market oversight. With a 'call-in power' the ACM can review and assess non-notifiable mergers and acquisitions should there be reasonable grounds to believe that they may impair or inhibit competition. The 'new competition tool' will enable the ACM to impose competition-enhancing regulations on specific companies after a market investigation, without having to establish a violation of the competition law.

Our recommendation to the Minister of Health

- Call on the Minister of Economic Affairs, Agriculture and Innovation to give the ACM the call-in power.
- Call on the Minister of Economic Affairs, Agriculture and Innovation to give the ACM the new competition tool.

Review and follow-up

In this report, we describe recommendations and actions for achieving societally acceptable prices for medicines, so that we can realise greater health gains with the available funds. In this context, we note the following:

- With this advice, the MAUG parties aim to encourage and reward genuine innovation. This, however, does not mean that all new medicines should be reimbursed, but that the right medicines should become available, at the right price. We realise that imposing pricing limits when deciding on the reimbursement of medicines may affect the availability of those medicines. However, it would be undesirable to have the overall health of the Netherlands decline rather than improve due to high medicine prices. Difficult decisions are therefore necessary. The public consultation has shown that the public at large understands this.
- For many expensive medicines, it is the minister of health who makes the decision on whether to reimburse that medicine at a certain price. Transparency regarding the minister's decision and its underlying arguments is important for the social legitimacy of the decision. It enables the House of Representatives to assess these decisions on behalf of society.
- In our assessment framework we describe what we consider societally acceptable in the Netherlands. Our willingness to pay does not depend on other countries' willingness to pay. We know that the problems we have outlined in this report also occur in other countries and that those countries likewise look critically at the prices of medicines in relation to health gains. We call on the minister to cooperate with other European countries where necessary.

Continuation

As a follow-up to this report, we will undertake the following actions:

1. For the updated assessment framework, the National Health Care Institute will develop further the aforementioned guiding principles and quantify them where possible. The aim is to have incorporated these guiding principles into a more advanced assessment framework in the course of 2026.

2. The NZa will explore whether it is possible to set the maximum rates for expensive inpatient medicines in a way that keeps them in line with what we consider to be the societally acceptable maximum. The aim is to discuss the initial results of this exploration with stakeholders before the 1st of April 2026.

We are convinced that measures are and will remain necessary for the sustainability of our health care system and its accessibility and affordability for future generations. We will continue our collaboration as governmental parties to follow up on the actions set out in this report and to flag any new actions that are needed. We call on the minister to support us in this endeavour, in our role as overseers of the basic healthcare package, regulators and supervisory competition authorities.

Section

Introduction

Introduction

Why write this advisory report? And who took the initiative for it? Below, we describe how the ACM, NZa and National Health Care Institute came to join forces for this advisory report, under the collective name Societally Acceptable Expenditure on Medicines (MAUG), and what we focused on as MAUG.

1.1 High asking prices, high expenditure and lack of insight into costs

The Netherlands has a healthcare system that is based on solidarity: everyone contributes to healthcare for all. This is done both through the premiums that members of the public pay to their health insurance companies for basic insurance, and through the taxes they pay. The Minister of Health manages our collective healthcare budget in the name and interests of society.

However, our carefully constructed and solidarity-based healthcare system is under pressure. A considerable amount of money is available for care, but it is by no means infinite. We are spending more and more on healthcare, with expensive medicines contributing to the increase. Medicines are of great importance for people's health. They improve or maintain health and quality of life. Our willingness to pay to achieve health gains is high. At the same time, patients, healthcare professionals, health insurance companies and the government are concerned about rising expenditure and high asking prices for some medicines. This is echoed in the Integral Care Agreement (IZA), a set of agreements between the Minister of Health and the parties in the field.

The motivation for starting the MAUG programme, were the concerns about expensive medicines, and therefore does not encompass all medicines. Expensive medicines are often produced and sold by a single company. The asking prices for new medicines are going up and up, often exceeding what we find acceptable. Numerous new and expensive medicines are expected to enter the market. Rising expenditure, (very) high asking prices and a lack of insight into the company's costs mean there is increased urgency for the government to determine when prices are societally acceptable. Clearly, each and every euro can only be spent once. If expensive medicines consume too much of the healthcare budget, it will be at the expense of other care.

Expenditure on expensive medicines in the Netherlands

- In this report, most expensive medicines are those that are used in an inpatient setting, meaning that they are utilised within specialist medical care (including all oncology medicines). Expensive medicines are also used in the outpatient setting, meaning these medicines are dispensed through public pharmacies (outpatient setting).
- Between 2012 (the start of NZa monitoring) and 2023, spending on expensive inpatient medicines rose by 83.4%, from over €1.4 billion in 2012 to nearly €2.6 billion in 2023.*
- In 2023, spending on expensive inpatient medicines was 9.1% of overall expenditure on specialist medical care. For 2012, that figure was 6.8%.*

- The top 25 inpatient medicines with the highest average expenditure per patient per year cost between €2.1 million (no. 1) and €144,000 (no. 25) in 2023. In 2013, the expenditure was between €550,000 (no. 1) and €22,000 (no. 25).**
- Average spending per patient on expensive inpatient medicines without generic competition rose by 15.9% between 2019 and 2023. Average spending per patient on medicines with generic competition fell by 56.9% during that period.***
- Average spending per patient on expensive outpatient medicines without generic competition increased by 28.8% between 2019 and 2023. In contrast to inpatient medicines, we have seen an increase in spending on outpatient medicines with generic competition (+26% in 2019-2023).***

These figures come from the NZa publication Expenditure on drugs in the Netherlands – via hospitals and public pharmacies - Key figures 2019-2023 and provisional figures for 2024. More information on how the figures were produced can be found in this publication.

* These figures include confidential discounts agreed by the Ministry of Health or health insurance companies and other forms of rebates.

** Confidential discounts negotiated with pharmaceutical companies by the Ministry of Health or health insurance companies are not known on a medicine by medicine level. Those discounts are therefore not reflected in these figures. Actual spending is lower, but these figures do provide an indication of the increase in asking prices and expenditure we would incur in the absence of (governmental or other) intervention.

*** In these figures, we do take rebates agreed by the Ministry of Health into account.

1.2 Focus of the MAUG programme

Through MAUG, we aim to maximise health gains for society with the available money, i.e. the collective healthcare budget. We have deliberately chosen to put the perspective of society (the public) at the centre. For the public at large, it is important that effective medicines are available and continue to become available. It is also important that healthcare in general remains accessible, with affordable premiums. The aim of this report is not to reduce overall spending on medicines. Rather, its goal is to arrive at acceptable prices for medicines from a societal perspective, so that we can achieve more health gains with the money that is available.

This report contains recommendations to the Minister of Health, as well as actions we will undertake ourselves. These recommendations and actions lie within the remit of the government and align with other ongoing initiatives which are carried out presently by relevant stakeholders.

Our focus is on how the government can strengthen price competition between medicines and how the government can ensure that prices are societally acceptable when effective competition is lacking. Competition is the key to lower prices for medicines. It is therefore imperative that the government eliminate as many unintended and unwanted barriers to competition as possible. Where there is no competition, or where competition does not or merely leads to price reductions, the government should be clear about the maximum price we find societally acceptable to pay.

Market protection, generic competition and therapeutic competition

If there are no alternatives (a monopoly), a company can charge a higher price for its medicine. The European and Dutch governments temporarily offer companies that sell new medicines protection from competition. The governments do this by issuing patents (much broader than just medicines) and supplementary protection certificates (specific to medicines and plant protection products), and via data exclusivity and market exclusivity (specific for medicines). For medicines that apply to small groups of patients ('orphan drugs'), companies are also granted additional market exclusivity. In this report, we have bundled these forms together under the term 'market protection'. The company temporarily has the exclusive legal right to sell a medicine with a specific active ingredient, which allows it to charge higher prices to recoup its investments and make a profit. Through this, the government rewards the company for developing its medicine and taking the financial risk the medicine's development entails. It also encourages companies to continue investing in new medicines.

The difference between generic competition and therapeutic competition

Other companies are only allowed to make the same medicine when the market protection has expired. We refer to the original medicine as the 'originator' or 'specialty' or 'branded' medicine. The 'copies' of branded medicines can be 'generics' (exact copies of branded chemical medicines) or 'biosimilars' (almost identical versions of more complex, biological branded medicines). Generics and biosimilars have the same active substances and same effect as the originator. If generics and biosimilars come onto the market in the Netherlands, it results in generic competition and often a drop in the price of the originator.

Competition may also arise during the period of market protection. This can happen if there are medicines with different active ingredients on the market for the same indication, i.e. the same (sub)group of patients with a particular health condition. If these alternatives are therapeutically interchangeable and genuinely compete in terms of price, we call this therapeutic competition. A company has no protection against this, not even temporarily. The availability of therapeutic alternatives does not automatically lead to therapeutic competition resulting in price reductions.

1.3 Collaboration between the ACM, NZa and the National Health Care Institute

Concerns from the Lower House of the Dutch Parliament about increasing expenditure on medicines and rising prices led to a resolution in 2021 from a member of parliament, Mrs. Kuiken. It included a statement that we – the ACM, NZa and National Health Care Institute – should work together on a compelling, integrated advisory report on medicine policy. Once the Lower House passed the motion, we drew up a joint working agenda for this.

We implemented our working agenda under a programme called Societally Acceptable Expenditure on Medicines (MAUG). This is a partnership in which each of us examines the issue of 'expensive medicines' from the perspective of our individual roles:

- The ACM does so from its knowledge of market forces, competition and anti-trust.
- The NZa does so from its understanding of the affordability and availability of care.
- The National Health Care Institute does so from its role as insured package manager (in particular, its task of advising the minister on including medicines in the basic healthcare package, and if so, at what price).

Under the auspices of MAUG, we combined each other's perspectives, observations and expertise with previous advisory reports, conversations with experts and a nationwide public consultation.

1.4 Reading guide

The report is structured as follows:

- In Section 1, we describe the rationale for this report, how our collaboration under the programme name MAUG arose, and MAUG's focus.
- In Section 2, we describe our sources and methodology: how we obtained the information for our report and how we arrived at our recommendations and actions.
- Section 3 is where we present the guiding principles that the National Health Care Institute will use within its assessment framework to arrive at societally acceptable prices.
- In Section 4, recommendations are provided on how to remove barriers to competition between medicines, in order to lower medicines prices.
- In Section 5, we describe how rate regulation (NZa) and market oversight (ACM) could potentially play a role in keeping medicine prices societally acceptable.
- Section 6 is the conclusion, with a summary of our advisory report and notes on the continuation of MAUG.

Section

Approach

Approach

How did the recommendations in this advisory report come about? Below we describe the sources we used. We examine in more detail two sources in particular: the public consultation and the interviews with experts.

2.1 Sources

Our recommendations are based on our combined knowledge and previous advisory report, supplemented by a public consultation and interviews with experts. These are explained further below:

- Existing knowledge about the functioning of the market for medicines, in particular (systemic) bottlenecks and strategic behaviours. This includes insights provided by the ACM, the NZa, the National Health Care Institute and the Managed entry agreements team at the Ministry of Health (Buro Financiële Arrangementen Geneesmiddelen, BFAG) of the Ministry of Health.
- Existing knowledge at the National Health Care Institute about pricing and reimbursement procedures and policies – in particular, the insights of the Scientific Advisory Board (hereinafter "WAR") and the Insured Package Advisory Committee (hereinafter "ACP"), two independent advisory committees within the National Health Care Institute.
- Previous studies and advisory reports about managing expenditure on expensive medicines.
- A public consultation (see subsection 2.2).
- Interviews with experts from various domains (see subsection 2.3).

2.2 Public consultation

To determine whether something is societally acceptable and why, you need to understand the public sentiment about it. This includes the topic of medicine prices. This is the reason why MAUG commissioned researchers from the Radboudumc (a university medical centre in the city of Nijmegen) to conduct a public consultation about expensive medicines. It was called the *Burgerraadpleging Dure Geneesmiddelen* (Public Consultation on Expensive Medicines) and it consisted of two parts:

Public Forum
During two weekends in October and November 2024, a total of 24 members of the Dutch public, from a variety of social backgrounds, spoke amongst each other and with experts about the prices of expensive medicines. Between them, they formulated 38 considerations to determine an acceptable price. These were whittled down to a shortlist of 16 key considerations that included health gains (in years of life and quality of life), costs versus benefits, and severity of the condition.

Online survey
We wanted to verify whether the results of the Public Forum were supported more widely in society and therefore, Radboudumc conducted further research using representative sampling. A total of 884 Dutch citizens completed an online questionnaire which was derived from the results of the Public Forum. The answers indicate the considerations and situations on which Dutch citizens are willing to base higher prices for medicines. The findings from the online survey supported the results of the Public Forum.

If you would like to know more about the public consultation, see Annexes 1 and 2.
Annex 1 Rapport 'Niet tegen elke prijs'*, Burgerraadpleging Dure Geneesmiddelen, Radboudumc, juni 2025 (Report 'Not at any price', Public Consultation on Expensive Medicines, Radboudumc, June 2025)*
Annex 2 Burgerstandpunt *van het Burgerforum 'Dure Geneesmiddelen' (Public's Point of View from the Public Forum on 'Expensive Medicines')*

2.3 Interviews with experts

MAUG spoke to sixteen experts from varying professional backgrounds about what they thought societally acceptable spending on medicine comprised. These experts included physicians, patients' representatives, a hospital pharmacist and a pharmacist at a health insurance company. However, they also included employees of pharmaceutical companies, economists, an ethicist, a patent lawyer, an NGO chair and a top civil servant. Everyone interviewed expressed opinions on their own behalf, which did not necessarily reflect their organisations' perspective. Amongst the factors they mentioned, were solidarity, reasonableness of price, market forces, effectiveness, and the overall amount that society spends on a medicine (based on the overall number of patients).

The interviews reflect professional views meaning that participants often relied on their professional experience. This meant that not everyone was able to reflect on all aspects of the issue at hand, but it was precisely the combinations of these professional opinions and reflections that provided MAUG with valuable insights.

If you would like to know more about the interviews, see Annex 3: Resultaten interviews over elementen voor maatschappelijk aanvaardbare prijzen van en uitgaven aan geneesmiddelen *(Results of Interviews about Elements for Societally Acceptable Prices of Expenditure on Medicines)*

Assessment framework for determining societally acceptable prices

Assessment framework

Pharmaceutical companies set the asking price of a medicine. It is up to the government to determine whether that price is societally acceptable. In this section, we describe the current considerations and the changes we propose to update the framework.

3.1 Introduction

A key goal of the health insurance system is to have a basic healthcare package consisting of effective care that is both affordable and accessible. Given that goal, the Minister of Health decides which expensive medicines will be included in that basic package. Various considerations come into play here, among which is the price. It is key that this price is societally acceptable.

The role of the National Health Care Institute
The National Health Care Institute advises the minister whether a new expensive medicine can be reimbursed through the basic healthcare package and under which conditions, such as at what price. To arrive at this advice, the National Health Care Institute uses assessment frameworks, which describe how we assess whether care, including medicines, should be included in the basic healthcare package and, if so, what the societally acceptable price should be. These frameworks apply to assessments performed by the National Health Care Institute itself as well as providing guidance in general terms for other stakeholders, such as health insurance companies.

When does the National Health Care Institute make its assessment?
The National Health Care Institute can carry out an assessment for any medicine, but in practice usually does so at the request of the Minister of Health. For most medicines, the minister decides on inclusion in the basic health insurance, with or without price negotiations. The minister does not seek advice from the National Health Care Institute about all medicines, but does so in the following cases:

- New hospital medicines ('inpatient medicines') for which one of the two following cases applies with regards to the estimated total costs (macro cost impact):
  - €20 million or more overall for all patients and conditions for which the medicine can or will be used.
  - €10 million or more for a specifically described condition and €50,000 or more per patient.

- New medicines dispensed through public/community pharmacies ('pharmacy medicines' or 'outpatient medicines'). These are never directly included in the basic healthcare package: they must always be added to the list by the minister, regardless of price. If the overall costs (the macro-level cost impact) exceed €10 million per annum or if the overall costs are between €1 million and €10 million per annum with costs per patient of €50,000 or more per annum, the National Health Care Institute also assesses the cost-effectiveness.

New hospital medicines that are not assessed initially by the National Health Care Institute are eligible for reimbursement if they meet the statutory criterion of 'established medical science and medical practice' (i.e. proven sufficiently to be effective). Health insurance companies in these cases have a duty to verify this and may choose to negotiate prices for such medicines with the pharmaceutical companies.

Update

The National Health Care Institute will update the assessment framework in order to improve their advice to the Minister of Health on the societally acceptable price of expensive medicines. As part of that process, we use the understanding obtained from the assessments and recommendations of the National Health Care Institute performed over time and insights gained in MAUG (including those from the public consultation and interviews with experts). We describe the guiding principles for this update in this document. The aim is to better determine what we consider societally acceptable prices for medicines. The guiding principles in this framework apply to all medicines, not just those assessed by the National Health Care Institute.

3.2 The current assessment framework

Over the years, the National Health Care Institute has developed an assessment framework that has been carefully put together and makes trade-offs more transparent. It undergoes regular updating to accommodate the latest developments and insights. We have given a brief description here of what the current assessment framework looks like, before going on to discuss the changes we intend to make by means of the current update.

Package criteria

The National Health Care Institute uses four 'package criteria' for assessing whether care (including medicines) can be included in the basic healthcare package[1]:

- **Effectiveness:** does the medicine add value for patients (e.g. in terms of quality of life) and has it been demonstrated to be at least as effective as the standard treatment? This package criterion is enshrined in law, which states that the medicine must meet the standards of 'established medical science and medical practice'. Medicines that do not meet this criterion are not included in the basic healthcare package.[2]
- **Cost-effectiveness:** is there an acceptable balance between the cost of (or additional expense for) a medicine and the health gains?[3] The Ministry of Health is currently exploring whether it would be appropriate to enshrine this package criterion in law too.[4]
- **Necessity:** is the condition for which the medicine is intended severe enough – and is the medicine so expensive that patients cannot afford it themselves?[5]
- **Feasibility:** is inclusion in the basic healthcare package feasible from a practical viewpoint and is it financially viable? Ecological sustainability and workforce capacity e are factors that are becoming increasingly important in this regard.[6]

During the assessment, the National Health Care Institute involves relevant stakeholders, including medical professional groups, patients' associations, health insurance companies and pharmaceutical companies. The National Health Care Institute also asks two independent advisory committees for advice: the Scientific Advisory Board (WAR) and the Insured Package Advisory

1 Pakketbeheer in de praktijk 4 *(Package management in practice 4 (2023), National Health Care Institute)*
2 Beoordeling stand van de wetenschap en praktijk (2023), Zorginstituut Nederland *(Assessment of established medical science and medical practice (2023), National Health Care Institute)*
3 Beoordelingskader kosteneffectiviteit van zorg (2024), Zorginstituut Nederland *(Healthcare cost-effectiveness assessment framework (2024), National Health Care Institute)*
4 Integraal Zorgakkoord, samen werken aan goede zorg (2022), pagina 37 *(Integral Care Agreement, working together for good care (2022), page 37)*
5 Afwegingskader noodzakelijk te verzekeren zorg (2023), Zorginstituut Nederland *(Decision framework for care that necessarily needs to be insured (2023), National Health Care Institute)*
6 Uitvoerbaarheid als criterium om zorg te vergoeden uit het basispakket (2025), Zorginstituut Nederland *(Feasibility as a criterion for reimbursing care from the basic healthcare package (2025), National Health Care Institute)*

Committee (ACP). The WAR issues advice about the scientific support for an assessment. The WAR does so by looking at whether care is effective, which patients it works for, what the expected budget impact is, the severity of the condition, and whether the quality of the cost-effectiveness assessment is sufficient. The ACP then determines what is in society's best interest: from a societal perspective, it advises whether a treatment should be included in the basic healthcare package and, if so, under which conditions.

The National Health Care Institute first assesses the effectiveness. Once a medicine has been shown to be sufficiently effective, the other package criteria are assessed and weighed integrally.[7] Because cost-effectiveness plays a key role in determining the societally acceptable price, we have explained this package criterion in more detail below.

Cost-effectiveness

The following elements are considered when determining cost-effectiveness:

- **The level of health gain:** the National Health Care Institute assesses how much extra health the medicine provides compared to the most cost-effective standard treatment. Health gains are expressed in Quality-Adjusted Life Years (QALYs).

What is a QALY?
A QALY takes account not only of how long someone lives but also their quality of life. One QALY means one year of life in which a person is completely healthy. If a patient lives one year longer due to a treatment but the quality of life is limited, that treatment gains less than one QALY.

- **Costs and savings of a new medicine and the standard treatment**
The National Health Care Institute compares the relevant costs and savings of the new medicine against those of the most cost-effective standard treatment, looking at it from a societal perspective. The 'societal perspective' means including all costs incurred and savings made for society:
  - Within the health service, these could include not only the cost of the medicine but also the cost of administering it, diagnostics, or costs directly related to the condition, such as hospitalisation and medical resources. Potential savings, e.g. due to the substitution of other treatments (including medicines) are also taken into account.
  - Costs and savings for the patient and family, such as travel costs, insurance excess, time spent and costs of informal care.
  - The costs and savings in other sectors, such as in terms of productivity (for instance if someone can go back to work or work more) and sick leave.

As an illustration: if a medicine saves €10,000 in other costs (including healthcare), then using that medicine may cost €10,000 more.

- **Cost-effectiveness analysis**
Relating the difference in costs and savings to the extra health gains provides the National Health Care Institute with an overall picture of what it costs to gain one extra QALY using the new medicine – in other words, the 'cost per QALY gained'. This relationship between the differences in costs and health gains (effects) is referred to as the incremental cost-effectiveness ratio (ICER). The ICER allows us to compare the cost-effectiveness of different types of treatments for different types of conditions.

- **Comparison of the cost per QALY gained against the maximum reference value**
The National Health Care Institute compares the cost per QALY gained against the 'maximum reference value'. In the

7 Argumentenkader dure geneesmiddelen ACP (2024), Zorginstituut Nederland *(ACP argumentation framework for expensive medicines (2024), National Health Care Institute)*

Netherlands, that maximum reference value depends on the burden of disease, which is calculated using the proportional shortfall method.[8] This method assumes that people affected by a condition or disease may lose health in terms of future life years and quality of life. When you compare these 'lost' years and 'lost' quality of life against that of a person without the condition, you get the proportional loss of life years and quality of life. This gives a number between 0.0 (no loss of health) and 1.0 (the disease leads to loss of all future years of life and quality of life). The higher this figure, the higher the relevant maximum reference value.

If the cost per QALY gained is at or below the relevant maximum reference value for a new medicine, the medicine is cost-effective. If the cost per QALY of a new medicine exceeds the relevant maximum reference value, it is not cost-effective. This means there is a genuine risk that it will displace other care that is more favourable in terms of cost-effectiveness, resulting in a loss of health rather than a gain at the population-level.[9]

What does the 'maximum reference value' mean?
The 'maximum reference value' is the maximum that society is prepared to pay for gaining one extra QALY. If the maximum reference value is €50,000, society is willing to pay up to €50,000 for each additional QALY gained with the new medicine (compared to the standard treatment). If a new medicine leads to a win of 2 QALYs for the patient compared to the alternative, the cost may be up to a maximum of €100,000 higher.

8 Ziektelast in de praktijk (2018), Zorginstituut Nederland Ziektelast in de praktijk (2018), Zorginstituut Nederland *(Burden of disease in practice (2018), National Health Care Institute)*

9 Cost-effectiveness was developed for situations where the price was based on actual costs and the cost structure being transparent, such as in operations and other interventions carried out in the public domain. When it comes to the asking prices for expensive medicines, the leading consideration for pharmaceutical companies in setting their asking price is not so much the cost, but the governmental maximum willingness to pay.

The maximum reference value varies with the disease burden category
The more severe the patient's condition, the higher the maximum reference value. This reflects the fact that society is willing to pay more per QALY gained for more severe conditions than for less severe ones. The highest possible maximum reference value is €80,000 per QALY (see below). This highest maximum reference value per QALY applies to the most severe conditions: the disease burden category '0.71 to 1'.

Disease burden category	**Maximum reference value (€) per QALY**
0,10 tot en met 0,40	€ 20.000
0,41 tot en met 0,70	€ 50.000
0,71 tot en met 1,00	€ 80.000

The relationship with opportunity costs
In health economics literature, the term 'opportunity costs' refers to the health gain lost to society (measured in QALYs) if money is spent on one medicine instead of other care. The maximum reference values (€20,000, €50,000 or €80,000 per QALY) primarily reflect the most that society is willing to pay in relation to the burden of disease. A relationship with opportunity costs does exist but no exact derivation: the higher the cost per QALY, the more likely it is that greater health gains could have been achieved elsewhere in healthcare.

What are the opportunity costs in the Netherlands?
The exact level of opportunity costs is difficult to determine, as it depends on the medicine, the price and the alternatives available. Nevertheless, research gives an impression. For example, regular medical specialist care appears to yield an average of one additional QALY for about €73,600[10] and

10 Stadhouders N, Koolman X, van Dijk C, et al. *The marginal benefits of healthcare spending in the Netherlands: Estimating cost-effectiveness thresholds using a translog production function.* Health Economics. 2019; 28: 1331–1344.

cardiovascular hospital care does so for €41,000.[11] It follows from this type of analysis that new medicines costing €80,000 per QALY or more in the Netherlands are likely to deliver fewer health gains than the existing, effective care.[12]

Updating the maximum reference value

A group of experts advises the government to redefine the reference value.[13] The National Health Care Institute supports this and in doing so aims to utilise the latest scientific insights, the results of the MAUG programme and the follow-up actions per the advisory report of the Technical Working Group on the Costs and Benefits of Prevention.[14] The experts recommend the use of a single, uniform reference value for all types of policy that have health gains as their goal. Their advice is to adopt a value of €50,000/QALY provisionally and to have this value redefined by an expert group and then recalibrated periodically. Various elements such as inflation can affect this value. For the time being, the National Health Care Institute will continue to use €20,000, €50,000 and €80,000 per QALY as the maximum reference values.

11 Van Baal P, Perry-Duxbury M, Bakx P, et al. *A cost-effectiveness threshold based on the marginal returns of cardiovascular hospital spending.* Health Economics. 2019; 28: 87–100.

12 Estimates have also been produced internationally. In England, for example, the average cost per additional QALY within the NHS is estimated to be about €9,400 (£8,000). Martin S, Claxton K, Lomas J, et al. The impact of different types of NHS expenditure on health: Marginal cost per QALY estimates for England for 2016/17. Health Policy. 2023; 132

13 Preventie op waarde schatten (2023), Technische Werkgroep Kosten en Baten van Preventie *(Valuing Prevention (2023), Technical Working Group on Costs and Benefits of Prevention)*

14 Beoordelingskader kosteneffectiviteit van zorg (2024), Zorginstituut Nederland *(Healthcare cost-effectiveness assessment framework (2024), National Health Care Institute)*

Societal weighting of the package criteria

The National Health Care Institute weighs the four package criteria as a whole, with advice from the ACP. This committee assesses new medicines against the package criteria in an integrated manner and considers whether the outcomes are societally acceptable. In doing so, it considers the interests of patients who are eligible for reimbursement of a particular treatment and those of patients with other conditions, as well as the interests of premium payers. It does so by using the principle that the basic healthcare package should provide the maximum health gains for the entire population. Using compelling arguments, it can be contended that a cost-effective medicine should nonetheless not be included in the package, or conversely that a non-cost-effective medicine should be (see the flowchart). Such arguments relate, for example, to the necessity or feasibility of inclusion in the basic healthcare package. Ultimately, a recommendation is made regarding inclusion in the basic healthcare package, possibly with additional conditions, e.g. concerning the maximum societally acceptable price (and therefore a minimum price discount). Additional conditions may also be imposed, e.g. regarding appropriate use.

Insured Package Advisory Committee (ACP)

The ACP is an independent committee that is part of the National Health Care Institute. It was legally established in 2008 and consists of nine members from various professional and social backgrounds. In its recommendations, the ACP indicates among other things whether a medical intervention such as an expensive medicine should be eligible for reimbursement from the basic healthcare package and (if so) at what price and under what conditions. The Committee discusses its considerations in public: the meetings are open to all, and relevant documents are publicly available on the website of the National Health Care Institute. The Committee carefully deliberates and weighs up all the arguments for its final recommendation. It ultimately sends this recommendation to the board of the National Health Care Institute, which in turn will take account of the ACP's advisory report in its final recommendation to the Minister of Health.

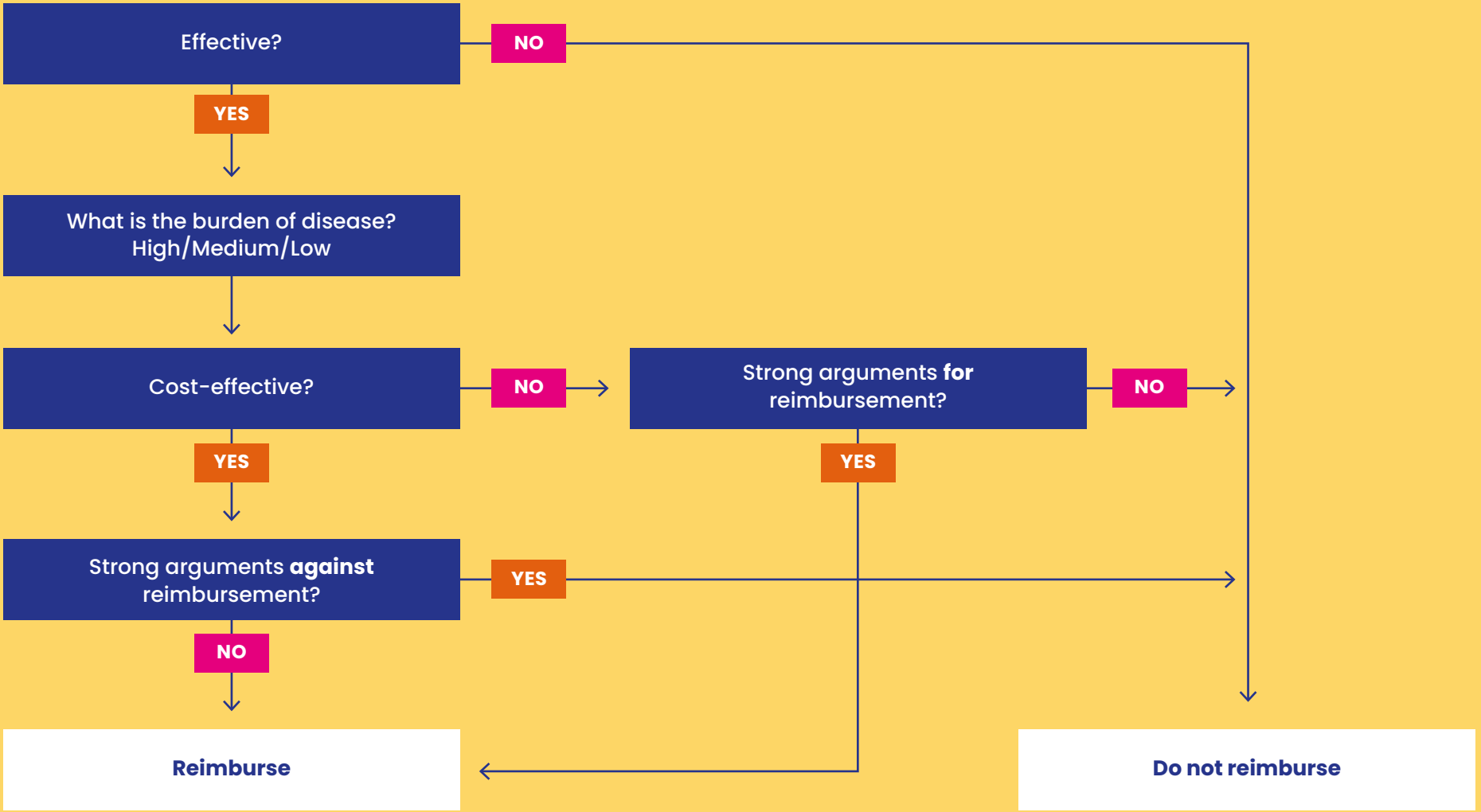
The deliberative process

Recommendations are produced using what is known as a deliberative process. The National Health Care Institute understands a deliberative process as a process of logical reasoning and questioning as well as through addressing other opinions and arguments.[15] This culminates in a carefully balanced recommendation about whether or not to reimburse care from the basic healthcare package. Importantly, there is always room during the process for new arguments. An exhaustive overview of all the criteria and arguments that could play a role is not possible – after all, new arguments can always appear. The extent to which society thinks certain arguments are important may also change over time. However, the fundamentals of the process of consideration are constant: applying criteria in a deliberative and interactive policymaking process.[16]

15 Oortwijn W, Husereau D, Abelson J, et al. *Designing and Implementing Deliberative Processes for Health Technology Assessment: A Good Practices Report of a Joint HTAi/ISPOR Task Force.* International Journal of Technology Assessment in Health Care. 2022; 38(1): 869-886.

16 Pakketadvies in de praktijk (2017), Zorginstituut Nederland
(Package advice in practice (2017), National Health Care Institute)

Schematic representation of weighing up the package criteria



ACP Guiding framework for expensive medicines

Previous ACP advisory reports and the ACP report entitled 'Argumentenkader dure geneesmiddelen' *('Guiding framework for expensive medicines')* show that relying solely on the maximum reference value does not always lead to societally acceptable pricing. The ACP also uses other considerations when assessing the reasonableness of the price.
This also applies to the additional arguments the ACP has developed over the years for assessing the reasonableness of a medicine's price, in particular:

- **Reasonableness of the price.** The ACP recommends looking more explicitly at the development, research and production costs of a medicine – and at the profit margin. The less proportionate the latter is to the costs, the less reasonable a high asking price is. For example, the ACP may believe this is the case for indication extensions. The Committee thinks that it can usually be said in such cases that the investments made have largely been recouped with the earlier indications. It is not desirable to use more public funds than is necessary.

- **Uncertainty about effectiveness and cost-effectiveness.** In recent years, uncertainty has played an increasingly important role in recommendations provided by the ACP. If the uncertainty is high, the Committee is of the opinion that this could be a reason to use a price lower than the maximum reference value. Otherwise, society will be running too great a risk of reimbursing ineffective or non-cost-effective care. The money for that reimbursement is then no longer available for care that yields more health gains. On top of that, the Committee believes that high prices are difficult to justify in situations where better research (and therefore less uncertainty) would have been possible.

- **Macro cost impact and budget impact.** These concerns are also often weighed up in the ACP's considerations. The Committee points out that every euro can only be spent once. Given there is a limit to what society is willing to pay for care, this requires careful choices.

  The ACP argues that the risk of crowding out other effective care, e.g. the use of community nursing, is higher if the overall expenditure of a new medicine is high. A high macro cost impact or a high budget impact may be an issue in cases of high asking prices for medicines and/or a large number of patients who will be treated with them. To the Committee, this is a good reason to insist on a lower price, especially where there is a great deal of uncertainty about the effects of a medicine.

We have included the trade-offs that the ACP already makes when assessing expensive medicines in this advisory report.

Public consultation results and interviews with experts

In addition to the experience of the National Health Care Institute and the ACP in issuing recommendations, we have included the perspectives of other stakeholders in this advisory report.

What matters to the public when setting societally acceptable limits on medicine prices and expenditure? What do the experts say about this? The answers to these questions come from a nationwide public consultation and interviews with experts. The findings confirm that the current assessment framework is valuable but also note that it could be sharper, more specific and broader in several respects.

- **From the public's perspective**

To get a clear picture of the public's perspective, the project team commissioned a public consultation. The public consultation consisted of two parts: a public forum and a nationwide survey. The public forum showed that participants can identify themselves with the National Health Care Institute's approach. They appreciated how carefully reimbursement decisions are made and understood the difficult trade-offs that are sometimes required when doing so.
Much of what the public considers important in such trade-offs is already systematically incorporated in the current assessment framework. They mentioned the following elements:

- The severity of the condition.
- Preventing death.
- Promoting social participation.
- Improving the quality of life.
- Avoiding other illnesses or treatments.
- Aiming for a favourable cost-benefit ratio.
- Uncertainty about effectiveness and safety.
- Fairness in pricing. The public at large wants to contribute financially to good health care, but thinks it is important that:
  - the price of the medicine is proportionate to the development costs;
  - the companies reinvest a significant part of their profits in medicine development;
  - the price of the medicine in the Netherlands is not significantly higher than abroad;
  - the price of the medicine is transparently motivated;
  - the price of the medicine is proportionate to the level of innovation, i.e. medicines that are no longer new or have only been slightly innovated do not remain expensive.

- **The perspectives of experts**

In our interviews with experts, we also noticed a widely shared desire for a fairer balance between public investment and private remuneration. Equally widely supported was the importance of (certainty regarding) effectiveness as a criterion for the willingness to reimburse.

At the same time, we noted clear differences between the views of the people with whom we spoke. For example, some believe that an assessment based solely on cost-effectiveness gives enough of a foundation for determining the societal acceptability of prices and expenditure. Others see such assessments as necessary but do not see them as a sufficient basis for an acceptable price in every situation. They therefore argue for additional approaches to look at how fair prices are, e.g. the consideration of the company's actual costs plus a reasonable profit margin when setting prices.

Furthermore, some interviewees felt that a higher price or expenditure may be societally acceptable in cases such as a high disease burden or a serious unmet medical need, but only if the medicine provides demonstrable added value.

3.3 Guiding principles for updating the assessment framework

The current assessment framework gives the National Health Care Institute an understanding of the cost-effectiveness of new expensive medicines and the risk of them crowding out other care. It is important to keep this cost-effectiveness and risk of displacement of care centre-stage when determining the societally acceptable price for such medicines in the future. The societally acceptable price level is part of the National Health Care Institute's recommendations on the inclusion of care in the basic healthcare package.
The current assessment framework is evolving: in recent years, an increasing number of arguments have come into play in the advisory process. A key aspect here is how arguments feed into the final advice about the price. In this report we have therefore looked in depth at the elements that should play a systematic role in arriving at a soundly formulated societally acceptable price.

A new medicine brings benefits: health gains for patients and society, and revenue for the pharmaceutical company. At the same time, there are also costs to society (the medicine costs money) and to the company (the medicine has to be developed and produced). If there is a positive difference between benefits and costs, we speak of a surplus. A societally acceptable price is one where this surplus is shared equitably between the company and society.
Using the maximum reference value does not improve the bottom line for society. The benefits of the medicine to society are in that case fully outweighed by accepting the maximum cost-effective price. To determine a societally acceptable price, the consumer and company surpluses must therefore be taken into account:

- **Consumer surplus[17]:** the difference between the maximum that society would be prepared to pay for health gains and what it actually pays. If that difference is positive, society benefits. If it is zero, it neither wins nor loses. If it is negative, society loses out.

- **Company surplus:** the difference between the minimum price that the company needs (to cover costs and make a reasonable profit) and the price it receives. If that difference is positive, the company benefits. If it is zero or negative, the company breaks even or incurs a loss.

We believe that a fair distribution of surplus in the case of medicines means that the benefits go in part to society and not entirely to the pharmaceutical company. In other words, the consumer surplus must be sufficient. Sometimes it may be acceptable for society to temporarily break even. The consumer surplus may therefore be low or zero when a medicine first comes onto the market. But in the long run, society must also benefit, and the consumer surplus must therefore increase: only then do we believe that an innovation is truly worthwhile.

Our opinion is that a different distribution is fairer (i.e. societally acceptable). The following is important in this regard:

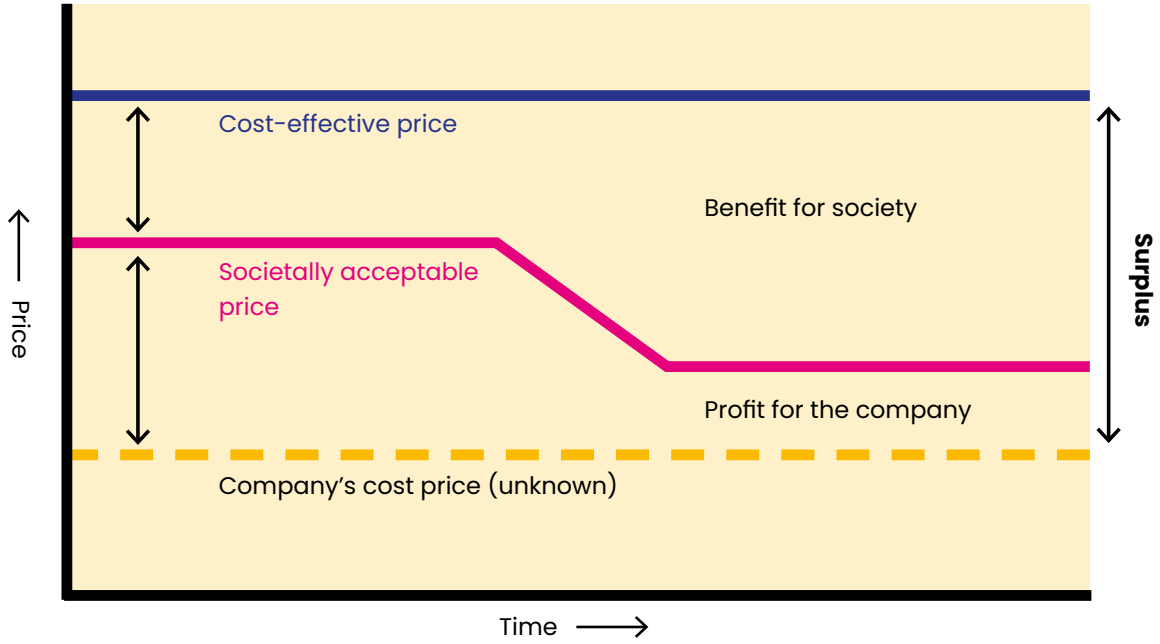
- **A cost-effective price is not the same thing as a societally acceptable price**
  The maximum reference values for each disease burden category (see subsection 3.2) show the maximum that society is willing to pay for a new medicine in exceptional circumstances. Pricing based on the maximum reference value is deemed cost-effective, but then there is no consumer surplus. Analysis of previous recommendations shows that there are frequentlyarguments for recommending prices below the maximum reference value to get a fairer distribution of the surplus. In other words, the

17 The term 'consumer' here means society, i.e. the Dutch public as a whole. We could also perhaps refer to it as a 'public surplus'.

societally acceptable price is in many cases lower than the price based on the maximum reference values. Arguments that justify a lower price from society's point of view are, for example, low development costs or marginal innovation. In further developing the framework, this should be included in the weighing when arriving at a specific price recommendation.

- **A high price must be temporary**
  Het Using the current assessment framework, the National Health Care Institute determines the maximum price for the medicine at the moment when it is included in the basic healthcare package. It does not take account of circumstances that may change over time, e.g. the point at which it is likely that the company has recouped its investment. Because the National Health Care Institute does not take this into account, a medicine can remain in the basic healthcare package at a high price for an unnecessarily long time if no competition is created. The societally acceptable price decreases over time. This ensures that the price comes down after a reasonable period for recouping the costs, and society benefits for a time afterwards.

The societally acceptable price changes over time



If the entire **surplus** goes to the company, the health of society stays the same (in the sense that we pay exactly what it is worth in health gains) or goes down (if more health gains could be achieved elsewhere for the same money).

Guiding principles of further development of the assessment framework

Based on the above, the National Health Care Institute will update its assessment framework. The aim of the framework is unchanged: to utilise the healthcare budget so that our public money yields as many health gains as possible for society. The guiding principles of the revised framework are detailed below. These guiding principles are never considered in isolation, but always in a cohesive manner. In addition, other, sometimes context-specific, considerations continue to play a role.

- **Guiding principle 1: Health gains as a central element**
  Medicines are reimbursed so as to realise health gains for patients. In other words, the more effective a medicine is, the more health gains it brings to patients and the more we are willing to pay for it. We express health gains in QALYs (see 3.2).

- **Guiding principle 2: Health gains for patients with a high disease burden have a higher societal value**
  The more severe the patient's condition, the higher the maximum reference value: the extra amount that society is prepared to pay per QALY compared to the standard treatment. The amounts per disease burden category and the categories used are up to €20,000 for a low burden of disease, up to €50,000 for a medium burden of disease and up to €80,000 per QALY for the highest burdens.

- **Guiding principle 3: Uncertainty about effectiveness and cost-effectiveness affects the societally acceptable price**
  The less certain it is that the medicine will actually provide health gains for the patient, the lower the societally acceptable price will be. This is especially true when better studies would have been possible. Uncertainty arises when, for example, clinical studies show only short-term effects, but the medicine is supposed to provide long-term improvements, or if there are shortcomings in the study design or study implementation. e.g. when the medicine has not been directly compared to the standard of care.

- **Guiding principle 4: The macro cost impact affects the societally acceptable price**
  The higher the overall expenditure for a single medicine for all its patients (the macro cost impact), the lower the societally acceptable price level for that medicine. When an expensive medicine is used by a lot of patients, overall expenditure on the medicine quickly accumulates. This increases the risk of other care being crowded out – care that could potentially have a more favourable cost-effectiveness ratio. Moreover, the company is able to recoup its investment more quickly and therefore makes more profit. It is therefore reasonable from a societal perspective that when the macro cost impact is high, a larger share of the surplus should go to society.

- **Guiding principle 5: The societally acceptable price is dynamic**
  A societally acceptable price may be higher in the first years after inclusion in the basic healthcare package than it is later on. We think it is reasonable to pay a higher price temporarily for a medicine so that the company can recoup its investment. Once it is plausible the investment has largely been recouped, the societally acceptable price of the medicine drops. This creates a greater consumer surplus over time. The societally acceptable price is therefore dynamic rather than static.

  The price of the standard treatment is not static either. An actual or expected price decrease for the standard treatment affects the societally acceptable price of the new medicine.

- **Guiding principle 6: The level of innovation affects the societally acceptable price**
  In case of minor or marginal innovation, such as indication extensions, a medicine may have a lower societally acceptable price. The risks and investments are generally lower, as there is no need to develop an entirely new medicine. There are therefore good reasons for assuming that the consumer surplus can be greater. In the case of evergreening (see inset), a medicine may have

benefits for the patient, for example because of a new form of administration that leads to a reduction in the patient's burden experienced during treatment. There may also be benefits for healthcare providers, for example because of savings on workforce capacity. In terms of health gains, however, these benefits are limited. We therefore think that in case of evergreening of medicines there should be a high consumer surplus.

Drug hijacking, a form of drug repurposing (see inset), is unacceptable from society's perspective.

Evergreening
This is a strategy used by pharmaceutical companies: timing additional patents strategically so as to impede competition to their medicines. Generally, a company modifies a medicine slightly, for instance by a new frequency of administration, a different form of administration (such as a tablet instead of an injection), combination with another medicine, or small changes to the molecule. Each of these alterations can lead to an additional patent. While such adaptations do sometimes facilitate use, they often do not offer any additional health gains. If a large proportion of patients switch to the modified medicine, then generics and biosimilars of the originator are left with just a small proportion of patients for whom they can compete. This may mitigate the effect of generic competition and more generally reduce the incentive to develop biosimilars. When this happens, the modified medicine may again obtain a long period of market protection. The list price is often much higher than the pricing of the originator, where there is already generic or biosimilar competition. The National Health Care Institute found several medicines which could be classified as forms of evergreening in 2025 based on the Horizon Scan of medicines.

Drug repurposing & drug hijacking
In case of drug repurposing, an existing medicine is licensed for a new condition. The principle behind drug repurposing is positive: it is an efficient application of existing knowledge to make a desired treatment available more quickly. Research for this is often carried out in academic settings and involves cheap, generic medicines.

When companies apply for market protection for a medicine that is already being used in practice and then want to start selling it at a much higher price than that of the original medicine, we call it 'drug hijacking'. These are often medicines that are specifically prepared in pharmacies, or licensed medicines that are being used off-label. We refer to that as 'well-established use'. Drug hijacking only occurs occasionally. This is usually a case of registration as an orphan drug, combined with a price that is dozens or even hundreds of times higher than the original price.

3.4 Conclusion

The assessment framework that is to be developed aims to give a more concrete definition of what the maximum societally acceptable price for a medicine is. There is a greater focus on distributing the benefits more fairly between pharmaceutical company and society, so that more health gains for patients can be obtained for the same budget. It is important that the Dutch government sets limits on maximum societally acceptable prices. In the Netherlands, it is up to the National Health Care Institute to issue price recommendations. Additionally, it is important that the Minister of Health promotes these guiding principles in the public debate and, above all, adopts the recommendations.

Defining these guiding principles does not mean that the assessment framework is now complete. The next step is to quantify the aforementioned guiding principles where possible. The National Health Care Institute will do this in collaboration with experts from the WAR and the ACP, among others. The process will start straight away, aiming to produce an evolved and updated assessment framework during the course of 2026. The National Health Care Institute will then use the updated assessment framework in its recommendations to the Minister of Health for the inclusion of medicines in the basic healthcare package. Parties such as health insurance companies and hospitals can also use the assessment framework for determining what a societally acceptable price for medicines is.

Our recommendation to the Minister of Health

- Express these guiding principles in the public debate and support the National Health Care Institute in its endeavour to update the assessment framework. Adopt future recommendations based on the updated framework. Provide more transparency of considerations underlying a reimbursement decision.

How can competition between medicines be strengthened?

Competition between medicines

Competition between companies is crucial to keep medicines affordable and encourage innovation. Competition drives down prices. It is therefore important that competition occurs in a timely and effective way. In this section, we present proposals to strengthen competition between pharmaceutical companies.

4.1 The importance of competition

Competition arises when prescribers or purchasers can choose between different available alternatives. This means that a company, when setting the asking price for its medicine, has to take into account that a prescriber or purchaser can also choose another medicine, which may be offered at a lower price. This is how competition drives down prices. Competition is therefore important for the affordability of medicines and for sustainable spending within the given healthcare budget. It also spurs companies to develop better medicines because they know that they may otherwise be surpassed by competing companies with better alternatives.

The fact that competition leads to lower prices can be seen most clearly when the period of market protection ends and alternatives with the same active ingredient come onto the market (*generic competition*, see 1.3). There can also be competition during the period when a medicine has market protection, namely when medicines with different active ingredients, or non-medicinal technologies, become available for largely the same patient population (*therapeutic competition*, see 1.3).

Bottlenecks

Companies benefit from maintaining market protection for their medicines for as long as possible by avoiding or delaying generic competition. To this end, they can employ various strategies, such as evergreening (see inset in 3.3). We find this strategic behaviour undesirable, because the longer a medicine's market protection lasts, the longer society pays a higher price. Purchasers play an important role here: within their procurement procedures they can provide a counterbalance. For example, they might decide not to purchase a slightly modified medicine in light of the arrival of generic competition. Health insurance companies can also provide an incentive for this through their reimbursement policies.

Strategies to prevent or delay generic competition may raise the question of whether there has been a violation of the Competition Law, in which case the ACM can take action.

Market protection by the government
Patent strategies such as evergreening are primarily possible because of medicines' market protection. How market protection is regulated by governments nationally and in Europe (patents, supplementary protection certificates, data exclusivity, and market exclusivity) can potentially influence the extent to which these strategies can be avoided. To provide specific recommendations on this complex issue, further in-depth work is needed. In this report, we focus on ways competition can be enhanced, given current market protections, and on how the government can prevent high prices in the absence of proper competition.

With therapeutic alternatives, it is less obvious than is the case with generic competition when medicines can be considered equivalent alternatives. For therapeutic competition to be as effective as possible, it is important to understand which medicines can be considered interchangeable and that there is a level playing field.

Interchangeability means that there are no clinically relevant differences for most patients with a given condition in terms of efficacy or safety between two (or more) medicines. For some individuals, there may be a preference for a specific medicinal product, but at the group level, the medicines can be seen as equivalent alternatives to each other. For most patients, which one medicine is given, will therapeutically not make a difference.

From the results of a company's clinical and registration studies, it is often not apparent to which degree medicines are interchangeable. When a company claims added value for its medicine in a particular patient group compared to the standard of care, it is up to the company to prove that this is the case. If the added value cannot be proven these medicines can, in principle, be considered interchangeable. Moreover, it is also important for patients and practitioners that medicines are properly compared so that it is clear which treatment is best for which patient. This helps to prevent patients from unnecessarily being exposed to adverse effects of treatments, especially if these treatments eventually prove to be ineffective or have less effect than expected.

It is important that the system in the Netherlands is set up so that purchasers can actually let existing alternatives that are therapeutically interchangeable (with the same active ingredient or a different one) compete with each other on price in purchasing decisions. At present, we note that this is not always the case. In this section we examine some of the factors that can hinder competition:

1. Studies are mostly not set up to investigate interchangeability (see 4.2).

2. Interchangeable alternatives are not always reimbursed from the same budget and/or incentives for good procurement are sub-optimal (see 4.3).

3. Interchangeable alternatives are sometimes procured at different levels (see 4.4).

4.2 More competition through a better understanding of mutual interchangeability

As indicated above, studies are often not designed to compare medicines with their potential alternatives. In particular, we see:

- **No proper comparison with existing medicines** – Lack of clarity about the interchangeability of medicines is largely due to companies' clinical studies being primarily designed to ensure that they can get market authorisation for their medicines. To obtain this market authorisation, there is no requirement to study the extent to which the medicine works better than another medicine(s). In clinical trials, medicines are often compared with the treatment that was standard at the time of the study, but may not be now, or against a treatment that is not the standard in the Netherlands. As a result, evidence is not always useful with regards to how a new medicinal product compares with other pre-existing treatments in the Netherlands.

- **No proper comparison of patient groups** – Companies are not incentivised to design clinical studies in a way that allows for comparing medicines and determining if there is an alternative medicine for the same patient group, thus generating competitive pressure. For example, companies may conduct their research with a slightly different patient group. The patient populations may differ, for example in the choice of a different cut-off point for a biomarker, or different inclusion criteria based on patient characteristics, or by defining subgroups. The net effect is that the results of different medicines cannot be properly compared and clarity about their possible interchangeability is lacking.

What could be done better?
Recent European regulations stipulate that European reimbursement assessment bodies can advise pharmaceutical companies about study design (Joint Scientific Consultations, JSC). These recommendations may help to improve the understanding of therapeutic interchangeability. JSCs are however only done at the request of the company, the results of the advisory reports are confidential, and it is not obligatory for the companies to adhere to the advice.

Our recommendation to the Minister of Health

We offer two recommendations below that are needed for a better understanding of medicine interchangeability.

1. Make the case at the European Commission that recommendations resulting from Joint Scientific Consultations are made public.
2. Explore (at the European level) how to make Joint Scientific Consultations more binding, addressing both the requests for such advice and the follow-up.

4.3 More competition through the right incentives and the same budget reimbursement

For similar medicines to compete properly with each other, they should be reimbursed from the same budget. At present, medicines in the Netherlands can be reimbursed from the budget that covers outpatient medicines and a different budget covering inpatient medicines.

- **The budget for inpatient care (in Dutch: "geneeskundige zorg")** – These include medicines administered in the hospital or in certain cases under the responsibility of a medical specialist in the home setting (e.g. oncological treatments). These medicines are reimbursed through the budget for inpatient care. Declarations by the hospital for expensive medicines are made using special codes, called add-on codes in Dutch. This refers to medicines which are not included in diagnosis treatment combinations which are reimbursed using set rates. The NzA is responsible for both these rates and the so-called add-on declarations. The health insurances companies reimburse the hospitals for these medicines from the inpatient medicine budget, but in doing so they have some leeway in negotiating with the hospitals about the amount they reimburse.

- **The budget for outpatient care (in Dutch: "farmaceutische zorg")** – These include medicines dispensed by public pharmacies which are used outside the hospital, such as tablets, capsules and sometimes injections. These medicines are reimbursed through the budget for outpatient care. In the Netherlands, health insurance companies cover these costs from their budget for outpatient medicines.

The location where the medicine is used (inside or outside the hospital) determines under which budget they are reimbursed. There are exceptions: some groups of medicines are always reimbursed through the inpatient care budget, despite the location of treatment. These medicines, which include all cancer medicines, are referred to as 'transferred medicines'.

In hospital pharmacies, prices of medicines can be determined through competition with each other. Hospitals have budget responsibility for inpatient medicines and thus they have an incentive to negotiate prices. They can make agreements with their prescribers about the actual or preferred positioning of certain medicines.

What could be done better?

Price pressure through competition between therapeutically interchangeable medicines only works well if all the alternatives are considered part of the inpatient care pathway. This is not always the case.

While health insurance companies can exert price pressure on inpatient medicines, the price pressure they can exert on outpatient medicines is limited. This is because hospital purchasing groups can negotiate discounts on a medicine. Health insurance companies can therefore reimburse hospitals for lower prices. Public pharmacies can do this to a lesser extent, as they usually have less influence over (hospital) prescribers. Consequently, the price pressure that health insurance companies can exert on outpatient medicines is limited.

Generating price pressure through competition also fails to work well when there is no level playing field due to medicines being covered through different budgets, i.e. inpatient and outpatient. The hospital may have a financial incentive to prescribe outpatient medicines, since it has no effect whatsoever on the hospital's budget. Thus, hospital may negotiate well for inpatient interchangeable medicines, but outpatient medicines will be excluded from that pool.

This situation occurs when, for example, a company introduces a new variant of their medicine whereby the old medicine is used intravenously (IV) and the new variant is administered subcutaneously (SC). This is a well-known practice that can be regarded as an evergreening strategy, since the company can obtain a new patent for the new mode of administration. When the IV-variant of the medicine goes off-patent, biosimilars can enter the market; these biosimilars will be also be used intravenously. IV use of medicines falls under the inpatient care budget. However, it is possible that the SC-variant is covered through the outpatient care budget and therefore does not fall under the budget responsibility of the hospital. The price of the new SC-variant may however be more expensive compared to the IV-variant, but there may still be an incentive to dispense the SC-variant, since the hospital does not bear the costs. This distorts efficient prescribing and leads to higher expenditure. It is appropriate that competition between all variants and suppliers should create price pressure that reduces society's expenditure on the medicine.

Our recommendation to the Minister of Health

1. Ensure that for inpatient medicines new forms of administration and interchangeable medicines are covered through the same budget, in order to create a level playing field. This avoids undesirable incentives and is necessary to support and enhance the bargaining position.

2. Explore how to provide incentives for competitive price negotiation in the outpatient setting. It is desirable to also create sufficient opportunities and incentives for competition between therapeutically interchangeable medicines in the outpatient setting.

4.4 More competition through better purchasing processes

There are various organisations in the Netherlands which may negotiate prices with pharmaceutical companies: the Ministry of Health, health insurance companies, and healthcare providers (i.e. via their purchasing organisations). It depends on the type of medicine, as well as at which stage of the lifecycle a medicine is, as to which party is the appropriate negotiator. Is it a new medicine without any competition? Or has it been on the market long enough for there to be therapeutic or generic competition?

Discounts negotiated by the Ministry of Health and health insurers with pharmaceutical companies lead directly to lower expenditure on medicines for society. Discounts negotiated by hospital buyers might indirectly lead to lower expenditure on medicines for society, dependent on the price agreement between health insurers and hospital buyers.

What could be done better?
Negotiations about medicines that might compete with each other are not always conducted by the same party. These parties do not always work with the same timing, strategy and information, which leads to their negotiating power being fragmented. On top of that, price agreements often remain confidential: the Managed entry agreements team at the Ministry of Health, health insurers and hospitals do not know the agreed price the others have negotiated. This creates an information asymmetry, which deteriorates the buyers' negotiating positions compared to the pharmaceutical companies.

Our recommendation to the Minister of Health

- Better align price negotiations. Anticipate the arrival of new medicines. Decide jointly in good time which party is best equipped to negotiate, i.e. who has the best bargaining position to reach agreements with a company. Make sure that interchangeable medicines are all included in the same procurement process. Also ensure that sufficient information can be exchanged between the buyer parties. This strengthens the parties' bargaining positions. The 'Programma Toekomstbestendig Stelsel Geneesmiddelen' (future proof system for medicines programme) is studying how to improve the process of assessment and inclusion for new medicines. This can also incorporate the coordination of price negotiations.

How can rate regulation and market oversight help create societally acceptable medicine prices?

Rate regulation and market oversight

Competition helps keep medicine prices down and thus helps to keep expenditures societally acceptable. However, new medicines often have no competition, either because of their market protection against generic competition or because there are no therapeutically interchangeable alternatives. And even after market exclusivity ends, generic competition does not always arise in a timely manner. If the market – through the absence of proper competition – fails to generate acceptable pricing itself, the government can implement policies and instruments to keep the prices of expensive medicines (and thereby the expenditure on them) societally acceptable. In chapter 3 we described how the National Health Care Institute's assessment framework plays a part in this. This chapter contains a discussion of the roles that the NZa (subsection 5.1) and ACM (subsection 5.2) can play in this regard.

5.1 NZa rate regulation

The NZa sets separate declaration titles for medicines in hospitals (inpatient medicines) that cost more than an average of €1,000 per patient per year. These declaration titles are called add-on medicines ('add-ons') and are declared separately from the rest of the treatment (care products for a diagnosis-treatment combination). The medicines covered by this report cost much more than the NZa's limit of €1,000 per patient per year. So, the NZa can set add-on declaration titles for these medicines, as long as they are intramural medicines. For outpatient medicines (both expensive and inexpensive), the NZa does not set declaration titles, nor rates.

To prevent an absence of market forces from leading to unacceptably high prices, the NZa sets maximum rates for certain parts of healthcare. This also applies to expensive medicines in hospital settings (add-ons). The NZa's maximum rate is the maximum amount that hospitals can claim for that medicine.

What could be done better?

At present, the NZa sets the maximum rate per medicine as being equal to the companies asking price. This means that the maximum rate for hospitals and health insurance companies at least covers their costs. However, the NZa does not take lower purchasing prices for hospitals (agreed purchasing discounts) into account when setting these rates. This is different from how the NZa sets rates in other sectors, where the rates are based on costs incurred by healthcare providers (such as hospitals, dentists and GPs). In those cases, healthcare providers are obliged to submit cost prices to the NZa. What is more, under this current policy, a societally unacceptably high company's asking price thus results in a societally unacceptably high NZa maximum rate. This is inconsistent with the purpose of the NZa's maximum rates and raises the question of whether the NZa should start setting its maximum rates for expensive inpatient medicines in a different way.

An important caveat here is that the NZa maximum rates, unlike the maximum prices set by the ministry of Health under the Medicines Pricing Act, do not directly affect the maximum price that a pharmaceutical company can charge a hospital. The NZa maximum rates relate to the claims between the healthcare provider and the health insurance companies. The way that the NZa maximum rates affect pharmaceutical companies is thus indirect.

Ideally, maximum rates match with what is societally acceptable. Is it possible, for instance, to link the updated assessment framework to NZa maximum rates? The NZa will explore whether it is possible to set the maximum rates for add-ons in a way that keeps them aligned with what we consider to be the societally acceptable maximum and, if so, how and in what situations this is necessary. And whether this would provide added value compared to other measures that will be taken.

The NZa will discuss the initial results of this exploration with the parties concerned by 1 April 2026.

5.2 The ACM's power to stimulate competition

The ACM oversees and ensures fair competition. Companies must comply with the rules and regulations on competition as laid down in competition law. The ACM checks that any mergers and acquisitions do not lead to excessive concentration of power. Cartel agreements are prohibited, and a pharmaceutical company may not abuse its economic dominance.

Cartel agreements
Companies may not enter into agreements that distort competition. For example, they are prohibited from making agreements on prices and offers or exchanging information about them. Companies are also not allowed to make agreements about who supplies which customer or who works in which area. They are also not allowed to make agreements not to enter a market.

Economic dominance
A company is said to be economically dominant if it has little or nothing to worry about from consumers or competitors. Economic dominance is not prohibited; in fact, market protection granted by the government contributes to the economically dominant positions of pharmaceutical companies. However, a company may not abuse its economic dominance. The company has a responsibility not to diminish the remaining competition or prevent new competition in ways that go beyond normal competition. Excessive prices due to economic dominance are also not allowed.

If a company violates competition rules, the ACM can intervene. Strategies that reduce or delay the impact of generic competition or therapeutic competition may, for example, be violations of competition law. Other companies will then not get a fair chance to compete.

What could be done better?

An investigation to prove that there are cartel agreements or that a dominant economic position is being abused requires a lot of time and capacity, and the burden of proof is high. Such investigations are often about one particular medicine and do not offer a comprehensive solution for similar situations. Competition law is thus not suited to prevent all undesirable strategies that, for instance, impede the development of generic medicinal products or biosimilars. It is therefore important to prevent such strategies rather than to rely mainly on retrospective monitoring and oversight.

The ACM's powers for supervising competition are evolving. This may also be relevant for its oversight of the medicines sector. A legislative proposal was made in June 2025 to give the ACM what is known as a 'call-in power'.[18] This means that the ACM can also assess mergers and acquisitions for which there is no notification requirement (as they do not meet the turnover thresholds) if there are valid reasons to believe that competition problems may arise. This may be the case if a merger or acquisition could enhance the market power of the party or parties involved. In the medicines sector, this could be the case for what are known as 'killer acquisitions', where an acquisition is made in order to remove specific competition (actual or potential) from the market, for instance in the case of a startup that has developed a promising innovative medicine, but has not yet generated any revenue from it. If the ACM or the European Commission can prohibit damaging takeovers, it could help improve market efficiency and competition.

The proposed call-in power is not unique to the Netherlands. Forms of such powers already exist in several European countries (including Denmark, Italy and Sweden) or are under consideration (including Belgium, France and Finland).

In addition, the possibility of what is known as a 'new competition tool' is being examined. Even without a violation of competition law, certain behaviour combined with a given market structure can lead to faltering competition or even to a market being effectively locked. The new competition tool lets the ACM impose competition-enhancing regulations on specific companies after the market has been studied, without the ACM having to find competition law violations. This power could also give the ACM more opportunity within the pharmaceutical sector to help find appropriate and efficient solutions to market problems. Using the new competition tool could, for example, allow the ACM to terminate market-wide anti-competitive discounts, even when the company does not have economic dominance. Alternatively, the ACM could impose supply obligations if problems with the supply of raw materials cause production chains to work poorly and little or no competition can arise. A new competition tool is useful in the joint international oversight with European partners of the pharmaceutical industry. The new competition tool already exists in countries such as the United Kingdom, Germany and Italy and is currently being developed in several countries in the European Union.

Our recommendation to the Minister of Health

1. Call on the Minister of Economic Affairs, Agriculture and Innovation to give the ACM the call-in power.
2. Call on the Minister of Economic Affairs, Agriculture and Innovation to give the ACM the new competition tool.

18 Wetsvoorstel Wet inroepbevoegdheid ACM (2025), kamerstuk 36774 *(Legislative proposal on a power of invocation for the ACM (2025), parliamentary paper 36774)*

Review and follow-up

Review and follow-up

In this report, we have described recommendations and actions aimed at creating an updated assessment framework, removing barriers to competition, and opportunities for rate regulation and market oversight. The aim is to achieve acceptable pricing for medicines from a societal perspective, so that we can achieve greater health gains with the available budget.

Availability of medicines

We are willing (and will remain so) to pay high prices for medicines that lead to large health gains and benefit society as a whole. We want to encourage and reward genuine innovation. This does not mean that all new medicines should be reimbursed, but rather that good medicines should become available. At an acceptable price.

We realise that imposing limits on pricing in reimbursement decisions about a specific medicine may affect the availability of that medicine. After all, a company could decide not to make their medicine available in the Netherlands at the maximum societally acceptable price or may only do so at a later date. There are already some medicines that do not get included in the Dutch basic healthcare package because the price is too high. This can be frustrating for patients. The Netherlands has a high willingness to pay for medicines; our maximum reference values are high. However, it would be undesirable to have the overall health of the Netherlands as a whole decline rather than improve due to high medicine prices. Difficult decisions are therefore necessary. The public consultation has shown that the public at large understands this.

Understanding the minister's considerations

For many expensive medicines, the Minister of Health makes a decision on whether to reimburse that medicine at a certain price. The minister does this using the recommendations of the National Health Care Institute about what maximum societally acceptable price is appropriate for the medicine in question. It is important that the minister takes the recommendation on board and provides a clear picture of the considerations underlying a reimbursement decision, especially in the event of a decision to deviate from the National Health Care Institute's recommendation. Understanding the minister's choice and the arguments underpinning it is important for the societal legitimacy of the choice. It lets the Lower House of the Dutch Parliament assess those choices on behalf of society.

International context

The Netherlands is one player in the global market. In our assessment framework we describe what we consider to be societally acceptable in the Netherlands. Our willingness to pay does not depend on the willingness of other countries (such as the United States) to pay. We know that the problems we have outlined in this report are also in play in other countries and that those countries are also looking critically at the prices of medicines in relation to the health gains. We call on the Minister of Health to cooperate with other European countries where necessary. We also actively seek cooperation with our international partners ourselves. Examples include collaboration under the European HTA (Health Technology Assessment) regulation, including the Joint Scientific Consultations (see 4.3), and the Beneluxa initiative. These various collaborations could also explore possible benefits of centralizing the procurement of medicines.

Continuation

As a follow-up to this report, we will undertake the following actions:

1. Defining the guiding principles does not mean that the assessment framework is now completely and fully developed. The next step is to quantify the guiding principles in this report. The National Health Care Institute will do this in conjunction with among others the experts from the WAR and the ACP. This process will start straight away, the intention being to get a more mature and updated assessment framework ready in the course of 2026.

2. The NZa will explore whether it is possible to set the maximum rates for add-ons in a way that keeps them aligned with what we consider to be the societally acceptable maximum. It will discuss the initial results of this exploration with the parties concerned by 1 April 2026.

We are convinced that measures are and will remain necessary for the viability of healthcare and its accessibility and affordability for future generations. We will continue our collaboration as governmental organisations, following up on the actions listed in this report and identifying new actions that are needed. As overseers of the basic healthcare package, regulators and supervisory competition authorities, we call on the minister to support us in this endeavour.

Annexes

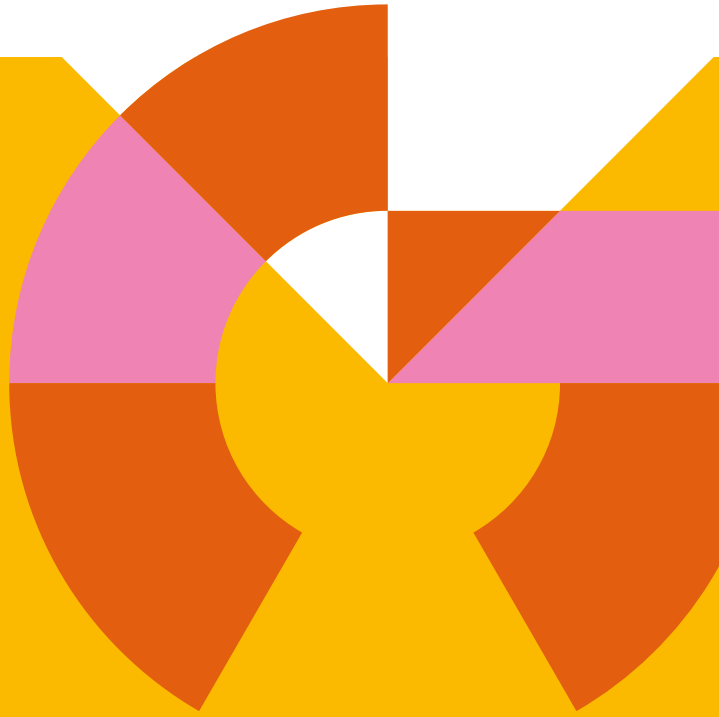
Annex 1 Rapport 'Niet tegen elke prijs', Burgerraadpleging Dure Geneesmiddelen, Radboudumc, juni 2025 *(Report 'Not at any price', Public Consultation on Expensive Medicines, Radboudumc, June 2025)*

Annex 2 Burgerstandpunt van het Burgerforum 'Dure Geneesmiddelen' *(Public's Point of View from the Public Forum on 'Expensive Medicines')*

Annex 3 Resultaten interviews over elementen voor maatschappelijk aanvaardbare prijzen van en uitgaven aan geneesmiddelen *(Results of Interviews about Elements for Societally Acceptable Prices of Expenditure on Medicines)*

Annex 4 Reactie op consultatiereacties partijen *(Reaction to the Parties' Responses to the Consultation)*

maatschappelijk
aanvaardbare
uitgaven
geneesmiddelen



Autoriteit
Consument & Markt

NZa

Zorginstituut Nederland