Coupry lawyers, Hausfeld lawyers
To the attention of Mr. Dr. JJM Sluijs and Mr. Dr. R. Meijer
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Feature
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Subject
Request for position on displacement of care (reference number 14.499)

Date
April 16, 2025

Dear Mr. Sluijs and Mr. Meijer,

On March 10th, you requested the Dutch Healthcare Authority (NZa) to clarify our position on expensive medicines and displacement. To that end, you asked us the following questions:

1. Do the 2016 and 2019 monitors confirm the conclusion that there has been, and could not have been, any displacement of legally insured basic care as a result of expensive medicines?

2. Does the NZa endorse the definition of displacement of care as used by FTV, namely: "the care that could have been provided for the surplus on the fair price of the medicine concerned, given the fact that the demand for care is greater than the available budget." And with the explanation that in our legally insured basic health care system, the excessive share of the total price of a medicine promotes displacement of care and hinders access to other care.

3. What is the NZa's position on the concept of displacement of care used by FTV, and what can the NZa say about this over time, i.e. in the period 2004 to 2018?

In this letter we will answer your questions. In order to answer them properly, we have listed the order of the questions have been adjusted. In the box below you will find a summary of our answers in this adjusted order. Our full answers are described below.

a. *Does the NZa endorse the definition of displacement of care as used by FTV? And: What is the NZa's position on the concept of displacement of care used by FTV?*

The NZa approaches crowding out at a macro level. We do not specifically look at the question of how much health gain is achieved (this information is not structurally available) and whether more health gain could have been achieved for the same money if it had not been spent on the medicine in question, but on something else. Nor whether the price is reasonable. Our approach is as follows: because an increasing share of specialist medical care (MSZ) is spent on medicines and expenditure on MSZ is limited, there is less money left for other MSZ and crowding out occurs. While it is often unclear whether expensive medicines add more value than other specialist medical care. Money that you spend on a medicine cannot be spent on other care or other collective expenditure. Whether this is a problem depends on the question of whether the current expenditure on medicines and, underlying this, the current prices of medicines are socially acceptable in relation to other healthcare expenditure. Expenditure on healthcare and, within that, on specialist medical care is limited by means of outline agreements between the Ministry of Health, Welfare and Sport, hospitals and health insurers. In our publications we show that expenditure on expensive medicines increased faster than expenditure on other specialist medical care (msz).

The share of expensive medicines within the msz expenditure has increased from 6.8% in 2012 to 9.9% in 2018. This leads to crowding out something else. Only in recent years have we come to this insight and we explicitly mention crowding out in our reports.

b. *What can the NZa say about displacement in the period 2004-2018?*

In the period 2012-2018, there was a maximum permitted expenditure on msz per year. This led to hospitals and health insurers having to make choices about spending money, taking into account their duty of care for care that was included in the insured package and increasing healthcare expenditure. Financial space was sought within (stricter purchasing policy) and outside the medicines file. Post-calculation agreements gave expensive medicines a priority position compared to other cost items. Over the entire period 2004-2018, increasing healthcare expenditure displaces other collective expenditure.

c. Do the 2016 and 2019 monitors confirm the conclusion that there has been, and could not have been, any displacement of legally insured basic care as a result of expensive medicines?

No, that is not the case. The monitors show that the increasing expenditure on expensive medicines is putting pressure on the accessibility and affordability of specialist medical care, because there was an annual maximum expenditure on msz. In both monitors, the research focused on the accessibility of *expensive medicines* and not on other msz. We reported that healthcare providers and health insurers were concerned about crowding out of other care. This was also the case in 2016: *'There is also the concern that a (further) increase in the costs of expensive medicines will displace other care.'* And that this displacement is difficult to recognize, but can take the form of cuts in personnel costs, which can lead to waiting lists.

Ad. a. Does the NZa endorse the definition of displacement of care as used by FTV? And: What is the NZa's position on the concept of displacement of care used by FTV?

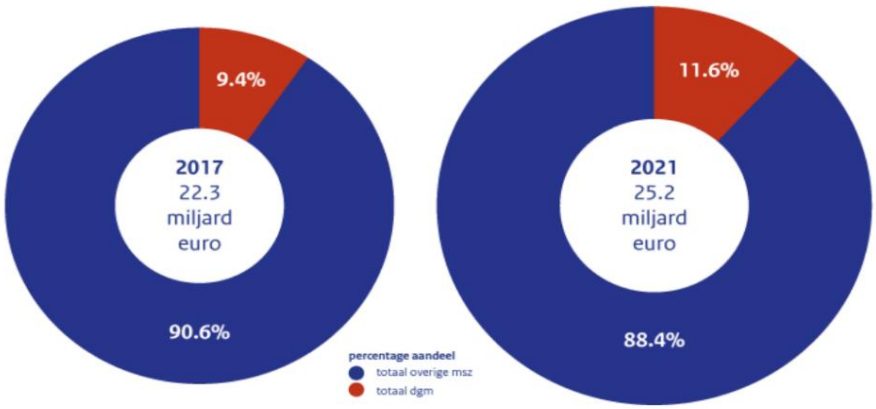
The NZa approaches displacement at a macro level. We do not specifically look at the question of how much health gain is achieved (this information is not structurally available) and whether more health gain could have been achieved for the same money if it had not been spent on the medicine in question, but on something else. Nor whether the price is reasonable.

Expenditure on healthcare and, within that, on specialist medical care (MSZ) is limited by agreements between the Ministry of Health, Welfare and Sport and field parties. In our publications we show that expenditure on expensive medicines increased faster than expenditure on other MSZ. The share of expensive medicines increased from 6.8% in 2012 to 9.9% in 2018.1 This leads to displacement of something else. Only in recent years have we come to this insight and explicitly name the occurrence of displacement. In our 2023 Key Figures report we worded this as follows:

'Because an increasing share of the MSZ is spent on medicines within the MSZ, there is less money left for other MSZ and there is crowding out. While it is often unclear whether expensive medicines add more value than other specialist medical care. To know how big this effect is, we look at the change in the share of expensive medicines within the total expenditure on MSZ. In doing so, we deliberately look at the expenditure before offsetting, among other things, the proceeds between the Ministry of Health, Welfare and Sport and pharmaceutical manufacturers. This money is transferred to health insurers, who then decide for themselves how to spend this money. Our 2022 monitor showed that most health insurers use this money for the premium level of insured persons and do not let it flow back to the MSZ. The practice may now be different. But because health insurers make that choice themselves, the price negotiations of VWS do not necessarily lead directly to a reduction in the crowding out of MSZ by expensive medicines in the hospital. The share of expenditure on expensive medicines compared to total MSZ (after settlement and excluding Covid regulations) will increase from 9.4% in 2017 to 11.6% in 2021. This is a crowding out effect of 2.2 percentage points. This corresponds to approximately €554 million (2021 price level) and is more than 13 thousand times the average gross annual salary of a nurse.'

1 These are the figures from our most recent publications that include the year in question.

Figuur 1 Verdringing van andere msz door dure geneesmiddelen in de ziekenhuizen



Bron: Zorginstituut Nederland (jaar- en kwartaalstaten) en Vektis

From the perspective of health insurers (after settlement and excluding Covid arrangements), the share of expensive medicines will grow from 9.2% in 2017 to 10.5% in 2021. This is a difference of 1.3 percentage points and corresponds to approximately €339 million (2021 price level).

FTV includes the surplus on a fair price in its definition. The NZa does not do this and states in this publication from 2024: ***Are drug prices so high that they crowd out other care? Yes.*** *Hospitals are spending an increasing proportion of their budget on drugs. This money cannot be spent on anything else, which means that other hospital care is being crowded out. Whether that is bad depends on the health gain that can be achieved with the same money in one or the other form of care. We do not know that now.* ***Are we spending too much on drugs? We do not know that well now.*** *Compared to other countries, the Netherlands spends relatively little money on drugs. That is true for generics, but not for monopoly drugs. A comparison based on total expenditure on resources (including generics) says nothing about the high expenditure on monopoly drugs. For the 'customer' (the citizen who pays the premium, patient, doctor, government) it is important that: 1) The price we pay outweighs the actual health gain. 2) We spend our healthcare money as honestly as possible. Is it better to treat one patient with a drug of three hundred thousand or more patients with, for example, elderly care or mental health care? We do not know that well at the moment, because the costs are not transparent, there is often insufficient clarity about the effectiveness of a new monopoly drug in reimbursement decisions and because in practice resources do not always do what they promise.*

In its statements on displacement, the NZa did not specifically look at the question of whether a price is reasonable. Money that you spend on a medicine cannot be spent on other care or other collective expenditure. The NZa notes that expenditure on MSZ is limited and expenditure on add-on medicines is increasing, which means that other expenditure is no longer or less possible. Whether this is a problem depends on the question of whether the current expenditure on medicines and, underlying this, the current prices of medicines are socially acceptable in relation to other healthcare expenditure.

Ad. b. What can the NZa say about displacement in the period 2004-2018?

We will construct the answer to this question chronologically. In the period requested and prior to that, changes were made in the area of entitlement and funding that affect the answer to this question. It is relevant that medicines fall under two entitlements: Pharmaceutical care (public pharmacies, funding of pharmaceutical care) and Medical care (hospitals, funding of msz). Until 2012, adalimumab was provided via the entitlement Pharmaceutical care
care and from 2012 via the Medical care claim. For a good understanding of hospital funding, we also describe the period before 2004.

Period from the end of the previous century to 2012: Description of financing of specialist medical care

Hospitals received a fixed individual budget each year, which was determined by the NZa on the basis of parameters. Hospitals had to provide care for that money.

At the end of the previous century, pharmaceutical manufacturers introduced (hospital) medicines with higher asking prices than the market had been used to until then. The government was not equipped for this budgetary development: for package inclusion in the Medical care claim, the price and (expected) expenditure played no role. Although care and therefore medicines had to meet the package criteria, this was also not assessed. In practice this meant that drugs were 'automatically' reimbursed for the manufacturer's asking price, regardless of effectiveness and budget impact.

This increased the pressure on hospital budgets. There were signals in the news that one hospital (A) was using a certain expensive medicine and another hospital (B) was not. The focus was on the accessibility of medicines: do patients get the medicine they are entitled to? And not on the question of what hospital A would no longer do if the medicine was used.
And also not to the question of whether the manufacturers were asking a reasonable price in relation to, among other things, their investments, health gains in practice and/or other care (deployment of nurses and doctors).

Instead, more money was made available for medicines. In order to guarantee the accessibility of care, the NZa introduced the policy rules 'Expensive medicines' and 'Orphan medicines' in 2002. This was an 'open-ended arrangement' (without a maximum), for which healthcare institutions were reimbursed for the costs afterwards. For medicines with a therapeutic added value and with a macro-cost burden of more than 2.5 million euros, hospitals received in addition to their budget, 80% of their net purchasing costs for these expensive medicines.2 3

Period 2004-2012: description of funding for pharmaceutical care and specialist medical care

AbbVie introduced Humira to the Dutch market in 2004. It was reimbursed through the Pharmaceutical Care entitlement and financed under the Pharmaceutical Care framework until 2011. Although Humira was prescribed by medical specialists, the provision, purchase, declaration and reimbursement were handled by public pharmacies and health insurers. In those years, the expenditure Pharmaceutical care is not limited. This means that expenditure increases due to the arrival of new

[2] https://www.eerstekamer.nl/behandeling/20020402/brief_minister_volksgezondheid
[3] Research report - Accessibility and affordability of medicines in specialist medical care – 2015 https://puc.overheid.nl/nza/doc/PUC_3308_22/

expensive medicines through Pharmaceutical care affected the total expenditure on care. This situation also applies today. The Budgetary Space Study Group indicates that care expenditure displaces other expenditure and depresses disposable income, because care is given priority within the total national budget.4

During this period, hospitals received a budget to cover their costs and the transition period to performance-based funding had begun.

Period 2012-2018: description of financing of specialist medical care

In 2012, adalimumab, together with similar drugs, was excluded from the Pharmaceutical care claim by the Minister of Health, Welfare and Sport. From that moment on, adalimumab fell exclusively under the Medical care claim and could only be declared and reimbursed via specialist medical care. From that moment on, hospitals are financially responsible for prescribing adalimumab.

In 2013, the transition from budgeting to performance-based funding was completed: hospitals became almost entirely dependent on declared production for their income. In general, hospitals' expenditure on expensive inpatient medicines competes with all other cost items, such as personnel costs, material costs, maintenance and energy costs, depreciation of assets and interest. They are paid per care service provided. We call these DBC care products (DBC-ZP). A DBC-ZP is a combination of the diagnosis and performed procedures during a fixed period. The price per DBC-ZP depends on the agreements that hospitals make with health insurers and is usually based on an overarching ceiling agreement or contract price.5 The policy rules for expensive and orphan drugs were abolished. To prevent the high costs of a medicine from becoming a problem or not fitting well into a DBC-ZP, hospitals have been able to charge expensive medicines separately since 2013, via an add-on service in addition to a DBC-ZP. The NZa set this with a rate that is equal to the lowest price per milligram. In the case that there was only one supplier, such as with adalimumab, the NZa maximum rate was equal to the manufacturer's asking price.

The collective expenditure, including care and including specialist medical care, was and is budgeted by the Central Planning Bureau and VWS. The politicians then agree on expenditure ceilings per sector. These are hard. The Minister of Health then agrees with field parties on how the expenditure ceiling for the msz can be realised (main line agreements, hla's). In the years 2012 and 2013, a maximum expenditure growth of 2.5% was agreed. In 2014 this was 1.5% and 2015 to 2017

1%. This growth limit was expressed in the agreements between individual health insurers and individual hospitals, which often agreed on a turnover ceiling; a contractually established prohibition on declaring more than a certain amount in a year. The government can intervene if the expenditure becomes too high. The Ministry of Health, Welfare and Sport then instructs the NZa to remove a portion of the individual turnover from each of the institutions, so that the total turnover drops back to the agreed level. This levy is called 'the macro-control instrument (mbi)'.6

4 16th Study Group Budgetary Space: Setting a Course - Choosing in Times of Budgetary Tightness pdf
5 https://puc.overheid.nl/nza/doc/PUC_3308_22/
6 https://puc.overheid.nl/nza/doc/PUC_3308_22/

In the meantime, medicines were admitted to the insurance package, expenditure on medicines continued to rise and they competed increasingly fiercely with other expenditure within the hospital.
In 2015, we wrote the following about this in the research report Accessibility and affordability of medicines in specialist medical care : *'The figures show that expenditure on MSZ medicines is growing faster than expenditure on other forms of care. Expenditure on medicines is also increasing faster than the available BKZ, which is putting pressure on total expenditure on MSZ. The transfer of medicines to the framework of specialist medical care reinforces this effect; the total growth in MSZ expenditure is increasing as a result.'* And from the perspective of health insurers, we noted: *'The basic insurance package can be expanded (for example by including a new, expensive medicine in the package) without the macro performance amounts (risk equalisation) being increased. In that case, health insurers will have to examine other expenditure and take measures there. There are roughly two options for this: 1. Increase the nominal premium. (Unlike for hospitals, there are no regulations that*

the collective turnover of insurers is limited. Only the risk equalisation has a maximum.) 2. Limiting expenditure (for example on medicines). This can be done, for example: - by setting a turnover ceiling; - by encouraging healthcare providers to adopt certain prescribing behaviour; - by negotiating with manufacturers themselves; - and/or by cutting back on other expenditure. One risk is that disguised risk selection is applied.'

From our 2016 monitor: *'The main reason for the experienced bottlenecks in contracting is stated by both healthcare providers and health insurers as the uncertainty about the total costs of medicines. In addition, the rising costs of medicines, the growth of these costs in relation to the total budget of the healthcare provider and the limited growth opportunities in the administrative framework agreement are a problem. The uncertainty is caused by the arrival of new medicines, indication extensions and the growing application of off-label use (use for an indication for which the medicine is not registered). The costs of medicines are rising because more and more specialized medicines with a more limited indication but with higher prices are being brought onto the market. In addition, many diseases are becoming chronic and patients are being treated for older and longer periods. In order to absorb the rising costs of medicines, there may be displacement of other care.'* And: *'All healthcare providers indicate that the costs of medicines are rising and that this is putting more pressure on affordability and, in the (near) future, possibly also on accessibility.'* And: *'The hospitals interviewed indicate that they have little to no opportunity to obtain purchasing discounts for unique medicines. Many manufacturers hide behind the VWS price arrangements. A number of healthcare providers and health insurers consider the price arrangements to be a good initiative. However, another healthcare provider and health insurer also see disadvantages because there is no transparency regarding the results achieved. A health insurer indicates that the financial bottleneck for medicines for which a price arrangement is concluded is not removed at the time the patient is treated. The healthcare provider must pay the pharmacy purchase price and cannot negotiate a discount. The chance of displacement of other care is therefore not reduced.'*

Because healthcare providers earn money from the purchase and sale of medicines and health insurers wanted to use this financial space to remain within the main points agreement, more friction arose between these parties. Health insurers also sought this space in other forms of care: *'Healthcare providers and health insurers try to minimize cost increases. Health insurers try to do this by, among other things, negotiating lower prices where possible. According to health insurers, lower prices are possible for medicines that are off patent and for which purchase discounts can be obtained or by using*

stimulate biosimilars. In addition, health insurers indicate that this is experienced by healthcare providers as 'cutting' on the medicine budget. Healthcare providers indicate that instead of 'cutting' on the medicine budget, lower prices are also negotiated by health insurers for other care, which the healthcare provider experiences as 'taking a cigar from their own box'.

The hospitals made efforts to have expensive medicines reimbursed by health insurers, or referred patients to other institutions. Some healthcare providers indicated that they had accepted the exceedance of the contractual agreements as a loss for the hospital, because they did not want to refuse care to patients and did not want to refer patients for financial reasons.7 8 Again, despite the latter consequence of the financial pressure within the hospital, attention was focused on the accessibility of *medicines.* The NZa reported on this in 2015 and 2016 and investigated this in 2017: *'Almost all health insurers have ceiling agreements when purchasing medicines. One insurer makes post-calculation agreements. With post-calculation agreements, a fixed price (p) is agreed per medicine, but, unlike with a ceiling agreement, the number of treatments (q) is not limited in advance.'* And *'Our research has not shown that there are patients who ... did not receive their medicines or received them too late.'*

In the following years, health insurers increasingly took over the costs of expensive medicines from hospitals by reimbursing them on the basis of post-calculation within and outside the turnover ceilings. This in exchange for lower contract prices for medicines where there was room for negotiation due to competition, particularly at the substance name level. And agreements on the efficient prescription of expensive medicines where it was not possible to enforce a low purchase price from the manufacturer due to monopoly position.

Post-calculation agreements reduced accessibility risks for expensive medicines, but not of the msz as a whole. Hospitals and health insurers had committed themselves to maximum expenditure growth of msz, which includes medicines. Expenditure on medicines grew faster than the agreed growth space.9 The expenditure growth on add-on medicines compared to the previous year was 5.4% in 2015, 6% in 2016, 9.2% in 2017 and 8.7% in 2018. This leads to crowding out of other expenditure within the hospital. The fact that the minister did not recover excesses of the msz framework via the macro control instrument does not change this. After all, the financial pressure had already occurred and as a result choices had already been made.

In the 2019 monitor we reported: *'Despite the fact that most hospitals have made post-calculation agreements, many hospitals still experience bottlenecks in the contracting process, particularly regarding the growth in the costs of medicines, the level of the rates and uncertainty about the costs. of new medicines and indications. One explanation for this is that hospitals and health insurers have agreed that expenditure on msz may increase by a maximum of 0.8% in 2019, while expenditure on medicines within msz is increasing relatively faster. Despite the post-calculation agreements for medicines, expenditure must still remain within the agreed maximum expenditure growth, which poses a challenge for the contracting process. The risk of crowding out*

[7] https://puc.overheid.nl/nza/doc/PUC_3425_22/
[8] https://puc.overheid.nl/nza/doc/PUC_3511_22/
[9] https://puc.overheid.nl/nza/doc/PUC_3425_22/

other msz is increased by this. In an interview, a hospital indicates that this expenditure growth is a reason that the volume growth for other care is zero and that waiting lists are created in some places.'

And in the 2021 monitor we reported: *'Because the main agreement stipulates that expenditure on medical specialist care may grow to a limited extent (0.8% in 2019), the increase in expenditure on medicines results in a reduction in the permitted expenditure on specialist medical care. This pressure on expenditure increases the need for efficiency, including the 'Right care in the right place' movement. But according to the hospitals, there is no limit to this. It requires a social discussion to determine to what extent the development of healthcare expenditure is a cause for concern. None of the parties interviewed have a concrete example of desired but undelivered care. One hospital interviewed believes that crowding out is more likely to occur in personnel costs.'*

In short, there was crowding out at the macro level in the period 2012-2018, because expenditure on expensive medicines grew faster than other MSZ and ceiling agreements were in force based on the agreed maximum growth space of the total MSZ. This led to hospitals and health insurers having to make choices about spending money, taking into account their duty of care for care that was included in the insured package. As our reports for those years show, financial space was sought within (stricter purchasing policy) and outside the medicines file. Post-calculation agreements gave expensive medicines a priority position compared to other cost items.

Ad. c. Do the 2016 and 2019 monitors confirm the conclusion that there has been, and could not have been, any displacement of legally insured basic care as a result of expensive medicines?

No, that is not the case. The monitors show that the increasing expenditure on expensive medicines is putting pressure on the accessibility and affordability of specialist medical care, because there is an annual maximum expenditure option on msz. In both monitors, the research was specifically focused on the accessibility and therefore possible displacement of *expensive medicines.* We reported that healthcare providers and health insurers were concerned about displacement of other care. This was also *the case in 2016: 'There is also concern that a (further) increase in the costs of expensive medicines will displace other care.'* And that this displacement is difficult to recognize, but can take the form of cuts in personnel costs, which can lead to waiting lists.

From patent to competition

We recently published on the expenditure and use of seven medicines, including adalimumab, from their introduction by AbbVie through the introduction of biosimilars by other manufacturers. This shows that it takes a long time before competition arises for these medicines. When issuing patents for new medicines, the government does not look at the payback period of manufacturers. Prices drop by 80 to sometimes 99 percent after the patent expires. As a result, society pays a high price for these medicines for a long time. The analyses of adalimumab can be found in the appendix.

Finally

We have explained at macro and meso level how we view displacement in the period 2004-2018. At these levels, expenditure was limited, forcing individual hospitals (micro level) to make choices. This also applies today. The rising healthcare expenditure, healthcare premiums and collective government expenditure increase the need for the government, politics and society to make more conscious choices. This also applies to the choice of whether or not to include new medicines with additional budget impact in the insured package. The Study Group Budgetary Space indicates that healthcare expenditure displaces other expenditure and depresses disposable income, because healthcare is given priority within the total national budget.

It is important that good medicines remain available for those who need them, now and in the future. Just as it is important that sufficient money remains available for staff and facilities that are needed for the availability of other care. We must therefore ensure that medicine prices do not rise unnecessarily and thus take too large a bite out of the available healthcare budget. The NZa has addressed this problem since 2015 in sixteen publications. In the programme Socially Acceptable Expenditure and Prices of Medicines (MAUG), the Netherlands Authority for Consumers and Markets, the Dutch Healthcare Institute and the Dutch Healthcare Authority work together to achieve socially acceptable prices and expenditure for medicines.

We trust that we have informed you sufficiently.

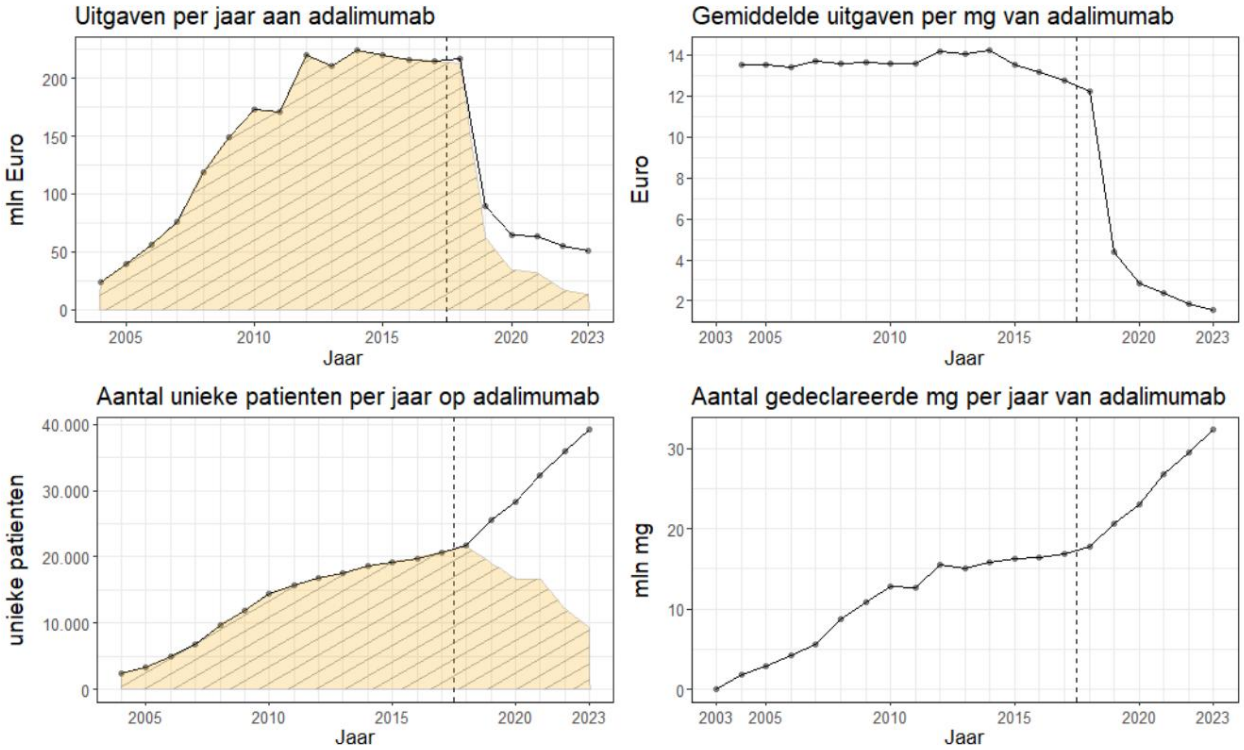
Yours sincerely,
Dutch Healthcare Authority

drs. J. Rijneveld
director Regulation

Attachment

Adalimumab

Brand name	Humira®
Manufacturer	AbbVie
Year of introduction 2004	
Year competition on substance name started 2018	
Mechanism of action	TNF-alpha inhibitor; ATC code L04AB04
Therapeutic area	Rheumatoid arthritis, idiopathic arthritis, enthesitis-related arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, uveitis; Behcet's; IBD; Takayasu; polychondritis; sarcoidosis; fasciitis; JIA; Pyoderma; gangrenosum; checkpoint inhibitor toxicity
Administration	By subcutaneous injection
Financial arrangement VWS	No



What do we see?

Expenditure on adalimumab has increased to approximately €218 since market approval in 2004 million per year between 2012 and 2018. The dip in 2011 and small increase in 2012 may be an effect of the transfer of TNF-alpha inhibitors as of 2012. After the emergence of competition in 2018, expenditure fell sharply to €90 million in 2019. It then falls further to €51 million in 2023. Compared to 2018, expenditure in 2023 will have fallen by more than 77%. After the emergence of competition in 2018, the number of patients increased annually faster than before. The number of milligrams declared shows a somewhat similar pattern,

Average expenditure per mg was around €13.5/mg in 2004-2017. After that, expenditure decreased to €12.2/mg in 2018. After the emergence of competition, expenditure decreased significantly: to €4.4 in 2019 and further to €1.6 in 2023. Compared to 2004, this is a decrease of almost 90%. **Expenditure per patient per year decreased between 2017 and 2023 from approximately €10,400 to approximately €1,300.**

For 14 years, Abbvie experienced no competition on substance name. The yellow area in the figure above left shows how much money health insurers spent on Humira® per year from Abbvie. Since 2019, biosimilars have taken an increasing market share.