



> Return address: PO Box 320, 1110 AH Diemen

Coupry  
To Mr. JK Sluijs, attorney-at-law  
Carnegieplein 5  
2517 KJ The Hague

2025008814

Date April 17, 2025  
Re letter in connection with the FTV v. AbbVie lawsuit regarding Humira®

**Dutch Healthcare Institute**

Concern  
Advice Package and Quality  
Willem Dudokhof 1  
1112 ZA Diemen  
PO Box 320  
1110 AH Diemen  
www.zorginstituutnederland.nl  
info@zinl.nl

T +31 (0)20 797 85 55

**Contact person**

L. Timmers  
T +31612038017

**Our reference**

2025008814

Dear Mr. Sluijs,

The Healthcare Institute has taken note with interest of the case you are pursuing against AbbVie regarding the price of Humira®.

The Healthcare Institute would like to address a number of issues about which you have asked us questions, insofar as they fall within our expertise.

**Assessment of medicines** The Healthcare

Institute assesses the package value of medicines and other care on the basis of the State of Science and Practice<sup>1</sup> and the applicable package criteria (necessity, effectiveness, cost-effectiveness and feasibility).<sup>2</sup> The Healthcare Institute does not assess competition law in this regard.

**Cost-effectiveness** The

cost-effectiveness criterion focuses on the question of whether we as a society get value for our money. We do this by looking at the relationship between the effect of a treatment and the costs. In other words, what value does a treatment add for the patient compared to what it costs. At the end of 2024, we will have provided an update of our cost-effectiveness assessment framework.<sup>3</sup> In our "Assessment framework for the cost-effectiveness of care: weighing effects and costs"

describes the various steps that the Healthcare Institute takes when determining cost-effectiveness. In this way, we explain transparently which considerations are taken into account. In short, we look at:

- What a treatment costs and what the health effect is for a patient.

- The maximum amount we as a society are willing to pay for health benefits.

We also answer other questions for a good decision.

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<sup>1</sup> [Assessment of the state of science and practice 2023 | Publication | Netherlands Institute for Health Care](#)

<sup>2</sup> [Report - Package management in practice 4 | Report | Dutch Healthcare Institute](#)

<sup>3</sup> [Report - Assessment framework for cost-effectiveness of care | Report | Netherlands Institute for Health Care](#)

The Healthcare Institute has set out the method for determining cost-effectiveness in the Guideline for conducting economic evaluations in healthcare.

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When assessing cost-effectiveness, the Healthcare Institute uses three reference values, which depend on the disease burden. 5 The reference values that the Healthcare Institute uses to determine whether or not a medicine is cost-effective are intended as maximum values for a medicine. Cost-effectiveness is always weighed in combination with other criteria during the assessment by the Healthcare Institute. This is described, for example, in our report Weighing and balancing for a fair package (2017).6

In addition to cost-effectiveness, the Healthcare Institute also looks at the budget impact of a medicine, for example. The Package Advisory Committee (ACP)7 – the Healthcare Institute's advisory committee that advises the Board of Directors on package advice – has recorded the arguments that play a role in advice on the reimbursement of expensive medicines in the ACP Argument Framework Expensive Medicines. 8

### **Socially acceptable price**

A cost-effective price is not necessarily the same as a socially acceptable price. The Healthcare Institute has described the relationship between cost-effectiveness and the asking price of a medicine in the cost-effectiveness assessment framework:

#### *"1.5.3. Relationship between cost-effectiveness and asking price of medicines*

The 'costs' component within cost-effectiveness is partly based on the costs that must be incurred in order to be able to offer the treatment. For competitive reasons, the development and production costs of medicines are often not made public, which is why the asking price of the medicine is used as an alternative. This price includes the (unknown) costs that the manufacturer must incur in order to develop, market and produce a medicine, but also an (unknown) profit percentage. The fact that the asking prices are increasing and that society has no insight into this has led to a great deal of discussion about the social acceptability of the asking prices. Although this issue is broader than determining cost-effectiveness, it is important to outline the relationship between the two. The price determines, unlike the costs, how the benefit (the difference between the costs of production and development on the one hand, and the social value; the 'surplus' on the other) of the treatment is divided between society and the manufacturer.

For example, if there is a drug for which a manufacturer is already reimbursed for multiple indications, it seems plausible that the manufacturer has already more than earned back its investment. This also applies if a

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4 [Guideline for conducting economic evaluations in health care | About us | Healthcare Institute](#)

[The Netherlands](#)

5 [Disease Burden in Practice - The Theory and Practice of Calculating Disease Burden in Package Assessments | Report | Dutch Healthcare Institute](#)

6 <https://www.zorginstituutnederland.nl/publicaties/rapport/2017/09/06/rapport-pakketadvies-in-de-praktijk-weighing-up-and-weighing-up-for-a-fair-package>

7 [Advisory Committee Package \(ACP\) | About us | Dutch Healthcare Institute](#)

8 [Argument framework expensive medicines | Publication | Netherlands Healthcare Institute](#)

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patent period has been extended by an adjustment with limited clinical added value (evergreening). In such cases, it may be preferable from a social perspective not to use the current reference values for cost-effectiveness, but to use (an estimate of) the costs incurred by the manufacturer. Discussions on this issue are ongoing in various forums. These have not yet been settled and are therefore not yet part of this assessment framework.

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When developing the cost-effectiveness package criterion given in this report, it is important to realise that a cost-effective price is not necessarily the same as a socially acceptable price.”<sup>9</sup>

The Healthcare Institute notes that most medicines have a much lower price than the reference value. That is a good thing. If all care is paid at the reference value price, only a fraction of the current care can be provided with the available budget.

### **Displacement**

The Healthcare Institute would like to explain the above:

As a society, you want to distribute the available budget for healthcare as fairly and justly as possible. Reimbursing new, sometimes expensive, care from basic insurance means that this can be at the expense of other care. After all, we can only spend the money once. When new, expensive care is at the expense of existing care that would provide better health, we call this crowding out. For example, money that is spent on (expensive) medicines cannot be spent on nursing homes, physiotherapy, other specialist medical care or care for the disabled. One could argue that the available budget should then be increased. But that is then at the expense of available resources for other public goals such as education, safety or social security. So crowding out can also occur outside of healthcare. Incidentally, this principle of crowding out applies to both the so-called “open system” and the “closed system”.

In recent years, there has been much talk about the displacement of specialist medical care in hospitals because expenditure on 'expensive medicines' (in this case: intramural add-on medicines) is increasing. For more information on this, we refer to publications by the Dutch <sup>10</sup> as well as the report *Displacement effects within the Healthcare Authority (NZa), the Dutch healthcare system* (2018).<sup>11</sup>

### **MAUG**

Finally, we would like to note that the Healthcare Institute, together with two other ZBOs, namely the ACM and the NZa, is working on advice on the framework for socially acceptable expenditure on medicines (MAUG).<sup>12</sup> The advice of the MAUG program is expected after the summer of 2025.

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<sup>9</sup> Report - Assessment framework for cost-effectiveness of care

<sup>10</sup> [Specialist medical care and expensive medicines | State of healthcare 2024 | Dutch Healthcare Authority](#)

<sup>11</sup> <https://www.zorginstituutnederland.nl/publicaties/publicatie/2018/04/17/verdringing-binnen-de-ziekenhuiszorg>

<sup>12</sup> [Home - MAUG](#)

**Finally,** above

we have explained how the Healthcare Institute views cost-effectiveness and socially acceptable prices and expenditure for medicines. We hope that this explanation has answered your questions. The Healthcare Institute is of course prepared to provide further explanation.

Yours sincerely,



MJ Janssen  
*Chairman of the Board of Directors*

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