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**Annexes**
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*Address correspondence only to the return address stating the date and reference of this letter.*

Date 12 May 2023
Subject
Parliamentary
questions

Dear Chairman,

I hereby send you the answers to the questions by members Ellemeet and Westerveld (both GroenLinks) on the lawsuit filed by Stichting Farma ter Verantwoording against pharmaceutical company AbbVie (2023Z03341).

Sincerely,

Minister of Health, Welfare and Sport,

Ernst Kuipers

Answers to Parliamentary questions by members Ellemeet and Westerveld (both GroenLinks) on the lawsuit by the Pharma in Accountability Foundation against pharmaceutical company AbbVie (2023Z03341, submitted 23 February 2023).

Question 1.
Are you familiar with the article 'Lawsuit against pharmacist of lucrative drug: 'High price violates human rights'? 1)

Answer 1. Yes.

Question 2.
Do you share the concerns of the Pharma to Accountability Foundation that excessive profits in patented drugs may crowd out other care?

Answer 2.
I am concerned about the ever-increasing spending on medicines. These are partly caused by high prices and put a great strain on our solidarity.
These drugs are increasingly associated with uncertainty about their effectiveness and their proper place in treatment. Therefore, the coalition agreement agreed to tighten the existing policy for expensive drugs and ensure that they enter the market at a fair price.

Question 3.
Do you share the view that excessive profits in the pharmaceutical industry are ultimately at the expense of the affordability of healthcare?

Answer 3.
High drug prices come at the expense of the affordability of care. It is not for me to rate the profits companies make. But I do think companies have a moral duty to keep the balance between public efforts to develop drugs and get them to patients, and prices companies charge for drugs.

Last year, I shared a study with the House of Representatives on the ecosystem around drug research funding[1]. It showed that there is a relationship between the investment behaviour of financiers on the one hand and their expectations of the willingness of governments and insurers to pay for a new drug now and in the future on the other. Due to sophisticated investment strategies, the drug sector is still one of the most lucrative sectors in the world. However, it is also in the interest of companies to contribute to the sustainability of healthcare systems. In my view, this does not happen enough now.

[1] Parliamentary paper 29 477, no 765

Question 4.
Do you share the insights provided by Farma ter Verantwoording on the excessive profits for the period 2004-2018 for AbbVie's drug Adalimumab (Humira) in the Netherlands?

Question 5.
Do you believe that the ministry has enough tools at its disposal to prevent excessive profits? If so, what instruments are they and what went wrong in AbbVie's pricing of Humira? If no, why not?

Answer questions 4 and 5.
On the individual case of AbbVie and the drug Humira, I am not going to comment because the case is sub judice. I do know the life cycle of Humira and await the judge's ruling with interest.

The price of a medicine is determined by the company itself. Apart from setting a Dutch maximum price based on prices in neighbouring countries, I have no influence on this. Nor is it up to me whether or not to limit companies' profits. Nor can I control companies' profits, once more because it concerns medicines in a global market with international companies.

Nationally, I focus on controlling *spending* on medicines. Here, the cost-effectiveness of a medicine is decisive. Instruments to control the costs of new drugs are partly embedded in European laws and regulations and in national reimbursement policies. For expensive new medicines with a high cost impact, the medicine sluice is at my disposal. I have recently tightened the conditions for the lock, which is expected to lead to more price negotiations (and thus expenditure control).

It is disappointing that companies are now using the protection periods established in Europe to allow innovative products to enter the market to maximise their profits. For example, by continuing to charge undiminished prices for medicines for which all protection periods have already expired, because there will be no competition in the form of a generic or biosimilar.

Another example is to make small changes to already existing drugs with limited research costs, starting a new period of protection, e.g. for orphan drugs. This makes it possible to keep prices high. This is done, for example, by registering a new indication for an existing drug before the expiry of the protection period, or by introducing a different form of administration of the drug.

I call on firms to take their social responsibility to reduce the price after all protection periods end.

Question 6.
Do you share the view that a lawsuit like this can be avoided if the government takes more direction and sets limits on what the maximum profit percentages can be?

Answer 6.
It is not for me to judge profit rates. What is important, however, is to state clearly what medicines society needs and what we are willing to determine for them: more of a supply-driven to a demand-driven situation.

This requires two important and complex steps: first, we need to determine what our 'unmet medical needs', our greatest unmet medical needs, are. Second, a widely supported social framework for determining the level of drug prices and -expenditure[2]. This can be used to determine what we consider acceptable spending on medicines. Both require a broader societal discussion.

As I indicated in the aforementioned letter around ecosystem research, I foresee two routes with these two instruments in hand. On the one hand, it is important to send a clearer signal to researchers and investors which medicines are socially needed.
Possibly also with a defined financial reward in prospect. On the other hand, the government, whether or not in cooperation with private or European funds, could exert more influence on drug development through the targeted deployment of research funds. In this way, the government could take more control of drug development both at the front and at the back.

Question 7.
Do you think the public interest of health should always take precedence over commercial interests of pharmaceutical companies?

Answer 7.
As Minister of Health, Welfare and Sport (VWS), my responsibility is always to patients. In doing so, I seek a responsible balance between access to medicines on the one hand and long-term sustainability of care on the other. This is in the public interest: without profit or low fees, hardly any medicines are developed, while high profits threaten access to them.

In a capital-intensive sector with significant business risks like this, commercial interests and profit motives inevitably come into play. However, this should never undermine the sustainability of our healthcare system.

2 https://www.rijksoverheid.nl/documenten/publicaties/2023/02/23/werkagenda-nza-zinl-acm

Question 8.
Do you think it is the government's job to protect the public interest of health and ensure fair prices of medicines?

Answer 8.
It is the government's job to achieve responsible spending on medicines so that care remains accessible and affordable in the longer term.

Question 9.
Can you give an estimate of what the average financial share of publicly funded scientific research is in the total cost of the research and development of a contemporary, patented drug?

Answer 9.
The study[3] I commissioned from SiRM, L.E.K. and Rand Corporation on the financial ecosystem of drug research indicates that $300 billion is spent on R&D annually worldwide. Of this, about 195 billion comes from biopharma companies, more than half of which come from the 10 largest companies worldwide. About $65 billion comes from the public sector and about $10 billion from non-profits. About $30 billion comes from venture investors. So the publicly funded part is just over 20% (65/300). This represents amounts actually spent ('out-of-pocket costs'), without taking into account the cost of capital required ('cost of capital').
The same study (para 2.3.2, p. 17) indicates that developing a drug costs the system between $1.2 billion and $1.7 billion. Public money is mainly used for basic research. As a result, the direct relationship with the relative contribution to a developed drug is not easy to indicate.

Question 10.
Do you think you could have negotiated better if pharmacists are required to include a reasonable price calculation in the reimbursement dossier they submit to the Health Care Institute?

Answer 10.
For me, the advice of the Healthcare Institute is leading. In it, an opinion is given on the cost-effectiveness of a medicine. If a medicine is judged not to be cost-effective, an advice on the necessary price reduction follows. Because my goal is to achieve cost-effective and therefore socially acceptable reimbursement, the firm's asking price is not my starting point in negotiations.

[3] The financial ecosystem of pharmaceutical RD | Report | Rijksoverheid.nl.

Question 11.
Do you share the opinion that the Dutch Health Care Institute can give a better advice on inclusion in the basic package if, in addition to the current information it receives from pharmaceutical companies, it also receives information on the R&D and production and marketing costs of the individual drug?

Answer 11.
While I am in favour of increasing insight into the price structure of medicines, the cost-effectiveness of a medicine is central to the Care Institute. This is independent of the actual price or price structure. The costs mentioned are irrelevant in this respect.

Question 12.
How will you legally implement WHO resolution at national level
72.8 "Improving the transparency of markets for medicines, vaccines, and other health products", which urges WHO member states to make public the net prices of pharmaceutical products? 2) And when can the Chamber see concrete results of this?

Answer 12.
I promised you in the Commission debate on drug policy on 22 March to elaborate on this.
Transparency is not an end in itself. It is a means to better understand the mechanisms of the cost of drug development and the price at which the drug is eventually marketed. It makes it possible to deploy targeted policies where possible.
In my negotiations for a financial arrangement, I always strive for a transparent outcome and publication of net prices. Unfortunately, firms categorically refuse to do so. The firm will eventually have to go along with the desire for more transparency.

In my view, the WHO resolution therefore aims to improve understanding of the sector and support countries to make choices about the medicines they need and set the prices they are willing to pay for them.

This is precisely where I have been working in recent times. Examples of my efforts include:

- Co-founding the International Horizon Scanning Initiative (IHSI) in which early identification of resources coming onto the market. This will allow much better preparation for the value and expenditure of these resources;
- Conducting a study on the financial ecosystem of drug research and development and subsequent follow-up studies;
- Exchange with other countries on opportunities around identifying unmet medical needs and 'willingness to pay', society's willingness to pay a certain price;

- Partly in response to the den Haan motion[4] , the Health Care Institute, the Dutch Healthcare Authority and the Consumer and Market Authority are, at my request, working on a joint working agenda entitled 'towards socially acceptable prices'[5], which should lead to a policy advice. I expect this in about one year's time.

Question 13.
Are you aware that Intravacc's chairman of the board, Mr Groen, thinks he can make Intravacc a big "commercial success" after privatisation because of promising OMV technology? Are you aware that Intravacc holds the vast majority of patents for this new technology? Are you aware that the development of this technology has been paid for with public money and after the sale it will apparently end up in the hands of a big pharmaceutical company, which will then charge commercial prices for the purchase of this technology, paid for by the same taxpayers who have already paid for the development? Now that you have decided to sell Intravacc, how do you prevent this technology from leading to extortionate prices?

Answer 13.
I have taken note of the statements made by Mr Groen in the Financieel Dagblad dated 20 February 2023. My predecessor informed your Chamber earlier that when Intravacc B.V. is sold, it will be contractually stipulated that as soon as Intravacc transfers a vaccine, which was (partly) created by using public funds, to a producer, Intravacc will make agreements with the producer about the price the producer will charge the State.

Question 14.
Suppose the corona nasal spray vaccine Avacc10 becomes a resounding success for Intravacc - and they no longer freely share its patent with C-TAP/WHO because they will be owned by a large commercial pharmaceutical company - how do you prevent the new owner of Intravacc from being able to charge extortionate prices for the Avacc10 vaccine?

Answer 14.
This candidate product is currently still in development and in the autumn of 2022 entered the pre-clinical research phase. My predecessor previously informed your Chamber that when Intravacc B.V. is sold, it will be contractually stipulated that as soon as Intravacc transfers a vaccine, which was (partly) created by using public funds, to a producer, Intravacc will make agreements with the producer about the price the producer will charge the State.

[4] Parliamentary paper 29477 no. 722
[5] https://www.rijksoverheid.nl/documenten/publicaties/2023/02/23/werkagenda-nza-zinl-acm

Question 15.
Do you think the revenue model of the pharmaceutical industry is still tenable and explainable? Even now that your ministry itself has found that not public health but drug profitability is leading in this industry?

Answer 15.
See my answer to question 7.

Question 16.
Do you consider it desirable for pharmacists to have a legally enforceable duty of care, as Farma to Accountability argues? 3)

Answer 16.
For now, I see no added value in imposing a duty of care. Imposing a duty of care on drug manufacturers is a far-reaching measure that bears some resemblance to the instrument of compulsory licensing. The question is to what extent it is actually enforceable and provides a long-term solution for access.

Question 17.
Can you answer the above questions one by one?

Answer 17.
Insofar as that did not cause duplication, I did.

1) https://www.volkskrant.nl/nieuws-achtergrond/aanklacht-tegen-farmaceut-van-het- lucrative-medicine-the-high-price-shucks-human-rights~b6932e7e/
2) https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf
3) https://www.pharmaceuticalaccountability.org/2023/02/06/new-policy-brief-time-to-legislate-realisingaccess-to-medicines-through-states-obligation-to-protect-the-human-right-to-health/