

Dutch association Innovative Medicines

PER EMAIL Vereniging Innovatieve Geneesmiddelen (VIG) Attn to the Board

Den Haag, 30 May 2024

Interim advice from the Advisory Board of the VIG Code in response to the advisory request from the VIG board regarding the societal dialogue

Dear board,

On October 19, 2023, we received your request for advice regarding the societal dialogue. The request for advice arose from the results of a study conducted by the Netherlands School of Public Administration (NSOB) on the positioning of the VIG (Association of Innovative Medicines) and the sector. The study reveals that stakeholders, on the one hand, appreciate the innovation brought by the pharmaceutical sector, but on the other hand, they do not trust the VIG and its members. They perceive them as elusive multinationals that prioritize shareholders over society. This perception is reinforced by signals received by the VIG itself from stakeholders regarding aggressive lobbying and communication by companies related to access of medicines in the insured package.

This stakeholder perception does not align with the values that the sector aims to uphold according to the Code. Therefore, your request seeks advice on how the Code could contribute to changing this perception. Specifically, you inquire whether the Code should be tightened or if governance around the Code should be improved to enhance compliance. In general, you ask us to advise on potential proposals to improve the sector's societal dialogue with its stakeholders and whether the Advisory Board can play a role in this process

The Advisory Board has received your request for advice with appreciation. The fact that the VIG asked the NSOB to conduct research on the positioning of the VIG and subsequently engages with the confronting results of this study, demonstrates that the VIG takes its position and the sector's societal responsibility seriously. The topic of the advisory request is significant, and the Advisory Board does not harbor the illusion that it can easily provide a solution for establishing a balanced societal dialogue between the pharmaceutical sector and its key stakeholders. The solution does not solely lie in further strengthening the Code. The creation of a dialogue must involve multiple perspectives. And here, the saying holds true: "Trust is hard to gain but easy to lose."

You requested to hear from us in the spring. Given the complexity of the matter, we have chosen to provide you with an interim advice, during which we are willing to continue thinking and conducting research in the coming time to propose further recommendations and advice.

In this interim advice, we first describe the approach we adopted when we received your advisory request. Subsequently, we provide an analysis of our preliminary findings and our initial thoughts on proposals that could potentially contribute to improving the societal dialogue.

Approach

The Advisory Board has initiated its orientation on the subject of the advisory request. It engaged in further discussions with the NSOB regarding the findings of its research. Additionally, the Advisory Board conducted a study on potential behavioral rules that align with the values of the Code and provide further concretization.

To gain more insight into the vision and experiences of companies, the Advisory Board framed the 2023/2024 self-assessment in the context of the advisory request. The self-assessment focused on values related to the societal dialogue. Specifically, it addressed three values where the sector considers stakeholders' interests:

- Government spending predictability (clause 2.9) We support the government and other parties in making good predictions of pharmaceutical expenditures.
- 2. Societal dialogue (clause 3.2) We are in constant dialogue with stakeholders on the interpretation of our societal policies and the implementation of social activities.
- 3. Societal interests (clause 3.3) In the development of our policies and in the day-to-day implementation of these, we consider the interests of others who rely on us.

Through specific inquiries related to these three values, the Advisory Board assessed the extent of responsibility felt by companies. Additionally, the Advisory Board conducted three company visits, thoroughly discussing the NSOB's findings and gathering insights from companies regarding their relationships with stakeholders

Finally, the Advisory Board has reached out to several key stakeholders for direct consultations. This round of discussions is still ongoing. The Advisory Board considers these conversations crucial because, as previously indicated, improving the dialogue will require cooperation from various angles.

Analysis of preliminary findings

The Advisory Board's research thus far confirms the picture painted by the NSOB. Based on the self-evaluation and company visits conducted with VIG member companies, it appears that the pharmaceutical companies recognize the NSOB's findings. The dialogue with stakeholders faces challenges at multiple levels, particularly concerning the procedures for access of medicines to the insured package. Companies find these procedures insufficiently predictable in terms of timelines and assessment criteria. It is often noted that direct negotiations between the parties have become scarce, and the entire process now primarily occurs in written form. Several companies express openness to exploring steps that could enhance mutual trust and shorten procedure timelines. However, they expect similar cooperative efforts from their negotiation partners.

External stakeholders confirm their mistrust of pharmaceutical companies' intentions. The signal that certain companies engage in aggressive lobbying practices and assertive communication methods was illustrated with concrete examples. However, the NSOB's portrayal of its own role of external stakeholders in the disrupted collaboration with the sector is less recognized here. Different signals emitted by pharmaceutical companies are met with contradictions.

Prisoner's dilemma

The Advisory Board observes that there appears to be a prisoner's dilemma concerning the admission of new innovative medicines to the insured package and the predictability of procedures and costs associated with it. The prisoner's dilemma is a thought experiment from game theory involving two rational parties. Each party can either cooperate for mutual benefit or betray the other for individual gain. This dilemma can be applied to situations where two parties could achieve significant benefits by collaborating or suffer if they fail to do so, but coordinating their actions proves challenging. The Advisory Board elaborates this further.

An increasing number of innovative medicines are being developed for smaller patient groups. These medicines often come with high prices and there also seems to be an upward trend in those high prices. Besides improving healthcare and providing prospects for the relevant patient populations to access innovative medicines, stakeholders also prioritize predictability of expenditures and cost control. Consequently, most of these new medicines undergo evaluation based on therapeutic value and cost-effectiveness.¹ Once it is established, following the procedure (including potential price negotiations), that providing a medicine is cost-effective, it is admitted to the insured package. During the procedure, patients do not have access to the new medicines unless pharmaceutical companies provide them free of charge during this period. A significant number of companies announced in early 2024 that they would cease this practice unless the negotiation timeline for admitting new medicines in the Netherlands is significantly reduced. They have become more cautious because, according to them, predicting whether a drug will be reimbursed in the Netherlands is challenging.²

The Minister of Health, Welfare, and Sport (VWS) paints the picture that admission procedures and negotiations are necessary because companies charge socially irresponsible prices. However, the following dilemmas come into play:

- 1. Lack There is no objective framework to determine when a price is socially responsible.³
- 2. Negotiations and financial arrangements regarding prices are confidential.
- 3. There is no independent procedure at an independent professional body to review the actions of involved parties.

Given these circumstances, the perception persists that pharmaceutical companies act in socially unacceptable ways. This perception leads stakeholders to avoid collaboration with the VIG.⁴ Neither the individual companies nor the VIG can defend against this perception due to the confidentiality of financial arrangements. While providing price transparency could be helpful, it is inherently complex in a highly competitive international market and may have significant implications for existing price reference systems between countries and related pricing laws.

On the other hand, stakeholders find it challenging to justify why innovative medicines are not reimbursed in the Netherlands (within a reasonable timeframe). VWS refutes the notion that the Netherlands negatively distinguishes itself from other European countries. They point

¹ Via the procedures of the medicine reimbursement system (GVS), the lock or decentralized procedures with health insurers (clean team).

² Farmabedrijven beperken gratis verstrekking kankermedicijnen, FD 3 maart 2024.

³ See the joint work agenda "<u>Towards socially acceptable prices and expenditure of medicines in the basic package</u>" of the Netherlands Authority for Consumers and Markets (ACM), the Dutch Healthcare Authority (NZa) and the Dutch Healthcare Institute (ZINL), with the first theme of creating of a framework for socially acceptable prices and expenditure of medicines. On <u>May 24, 2024</u>, the Minister for Medical Care informed the House of Representatives about the progress, accompanied by a letter from the ACM, NZa and ZiNL.

⁴ As an example, the VIG is not represented in the National Consultation on Expensive Medicines (LODG).

out that a large country with a faster admission procedure is looking to the Dutch policy because the consequences of their own policy are deemed unsustainable in the long run. However, others argue that the Netherlands does indeed increasingly differentiate itself negatively from other countries, both in terms of patient access to medicines and the general attitude toward pharmaceutical companies. The extent to which the previously mentioned declining willingness of pharmaceutical companies to continue providing free medicines during lengthy price negotiation procedures puts pressure on stakeholders to expedite the inclusion of medicines in the insured package remains unclear.

It is foreseeable that the problem outlined above will only increase with the development of innovative medicines for increasingly specific and therefore also smaller patient populations (including personalized medicines), where the therapeutic value is still largely unknown. Without clear agreements on costs, expenditures related to these medicines become unpredictable. However, without predictable procedures and assessment frameworks, pharmaceutical companies' willingness to reach favorable agreements will decrease. In a prisoner's dilemma, unilateral action cannot improve the outcome, but cooperation could lead to a better result. Trust and credibility are crucial for achieving this.

Initial Thoughts for Proposals

Although the VIG and its members cannot unilaterally solve the prisoner's dilemma, they can work on building trust and credibility within the sector. This, in turn, will enhance the possibilities for establishing a societal dialogue and collaboration with stakeholders. The Advisory Board identifies at least two paths toward achieving this goal.

First, it is essential for the sector to speak with one voice through the VIG as the industry association that can engage with the government as a dialogue partner. VWS clearly indicates that it does not currently view the VIG as an organization with which meaningful discussions on sector-wide issues can take place. The self-assessments reveal that member companies recognize the importance of speaking with one voice through the VIG. Most companies see a crucial role for the VIG in representing the sector. However, this requires behavioral changes from member companies and trust in the VIG.

The VIG can act on behalf of the sector only if member companies enable it to do so. Appointing an independent chair for the VIG is a positive step. The next step, according to the Advisory Board, should involve providing the VIG with all relevant sector information to allow it to act as an equal dialogue partner with stakeholders. As the VIG's position becomes stronger, so will trust and credibility. The self-assessments indicate that many member companies recognize this, and some envision a role for the VIG in improving horizon scanning to better predict pharmaceutical expenditures. Companies would need to provide the necessary data for this purpose. The Advisory Board recommends that the VIG establish an infrastructure where members can share confidential information with the VIG, adhering to applicable legal conditions (confidentiality agreements, competition rules).

If the VIG will be enabled to act as a full-fledged dialogue partner, it should also receive the mandate to propose and negotiate on behalf of the sector. This pertains to cross-sector agreements—agreements related to policies, procedures, and potentially a macro-pharmaceutical budget in the future. Importantly, this does not involve agreements regarding the admission of individual medicines; that remains the responsibility of individual companies.

The credibility and effectiveness of the VIG as a sector representative depend on the behaviors of member companies. Communication regarding the topics for which the VIG has a mandate and the establishment of sector-wide agreements should flow through the VIG. Furthermore, the VIG—the board, independent chair, director, and bureau—should be better equipped to effectively implement the mandate and act as a dialogue partner toward the

government. The mandate granted to the VIG by its members should not be undermined by individual member companies. This applies not only to the agreements concerning the mandate itself but also to other behaviors expected from an integral party.

Behaviors of individual companies can impact trust for the entire sector. This applies not only to VIG member companies but also to other pharmaceutical companies. It is essential for the VIG to take a clear stance against behaviors that contradict its core values.

The Code provides the framework through which member companies can be held accountable. One of the Code's core values is integrity. The self-assessments indicate that all member companies have their own stringent integrity rules that align with this Code's core value. Another core value of the Code is social responsibility, where the sector acknowledges its social role and considers social interests in its actions. The mandate given to the VIG can further concretize this social responsibility and serve as a basis for additional agreements with the government.

The question is how the VIG acts when a company's behavior does not align with the values of the Code. This brings us to our second point: the role of the Advisory Board itself. In conversations with stakeholders, reports have been made regarding behaviors of member companies that are at odds with the Code's values. In hindsight, it was revealed that the VIG itself had received these signals. However, the Advisory Board was unaware of these signals. The Advisory Board acknowledges that this situation negatively impacts the overall credibility of the Code and, specifically, the VIG and the Advisory Board externally.

The Advisory Board can fulfill its role effectively only if it is involved in signals related to behaviors of companies that may violate (parts of) the Code. If a member company has acted insufficiently with integrity, it is in the VIG's interest to take action. The Advisory Board can ensure a careful procedure and advise the VIG's board. The potential lack of integrity by one member company can significantly affect the reputation of the entire sector.

The Advisory Board is open to further discussions on the possible role it can play in such situations before developing a governance proposal. In this context, consideration will be given to whether the Code can be adjusted, supplemented, and/or strengthened in specific areas.

The Advisory Board is willing to provide further clarification on this interim advice and is prepared to refine and supplement the proposed recommendations.

Kind regards,

Hugo Hurts Chair of the Advisory Board