

BY EMAIL Association of Innovative Medicines (VIG) Attention: The Board

January 29, 2025

Subject: Final advice of the Advisory Board on the VIG Code following the VIG Board's request for advice regarding the social dialogue

Dear Board,

On May 30, 2024, we sent you our interim advice as a first response to your request for advice dated October 19, 2023, regarding improving the social dialogue of the VIG and its members with their external stakeholders. In the interim advice, we noted that concerning the admission of new, innovative, and expensive medicines to the insured package, there is a prisoner's dilemma. This dilemma cannot be solved unilaterally by the VIG and its members. However, work can be done on the trust and credibility of the sector, which will increase the possibilities for establishing a social dialogue and cooperation with external stakeholders.

In the interim advice, we made two preliminary proposals. First, it is important that the sector speaks with one voice through the VIG as a trade association that can be approached by external stakeholders as a discussion partner. Second, the VIG must be able to distance itself from the behavior of member companies and/or address member companies on behaviors that are at odds with the values of the Code.

We understand that the first part of our advice has been followed up. The General Assembly has agreed with the principle that the VIG – through the independent chairman and the director – represents the sector when it comes to sectoral matters that transcend individual business interests. Work is being done on a mandate for the VIG to contribute on behalf of the sector to the establishment of a future-proof system for the access of new, innovative medicines to the insured package.

In our interim advice, we indicated that the credibility and effectiveness of the VIG as a sector representative stand or fall with the behavior of the member companies. Communication on the subjects for which the VIG has received a mandate and the making of sector agreements must go through the VIG. The mandate that the VIG has received from the members must not be undermined by individual member companies. This applies to the agreements made about the mandate itself, but also to other behaviors that can be expected from an honest party.

From the conversations we have had since then, it appears that, particularly among the medical profession and hospitals, the distrust in the sector partly stems from a knowledge gap about the actual costs of expensive medicines. The medical profession and hospitals experience an increase in the costs of expensive medicines, while this is not actually the case due to the underlying financial arrangements with the Ministry of Health, Welfare and Sport (VWS). This is evident, among other things, from the recent publication of the NZa on the key figures for intramural expensive medicines (period 2018 to 2022 and preliminary

figures for 2023).¹ The NZa concludes that from the perspective of hospitals, the share of expensive medicines is increasing, while the share of spending on expensive medicines relative to total medical specialist care is actually decreasing. This is because the proceeds from price negotiations with manufacturers by the Ministry of VWS largely do not end up with the hospitals. Better insight into the actual costs of expensive medicines among the medical profession and hospitals could therefore improve trust in the sector. The Advisory Board advises the VIG to consider organizing a conference in collaboration with parties on this topic and investigating how more insight can be provided into the actual costs of expensive medicines. The Advisory Board is willing to contribute to this if desired.

In this final advice, we further elaborate on the governance of the VIG to require member companies to adhere to agreements made and to address them when they do not behave in accordance with these agreements. Our proposal further elaborates on the norm-setting in the Code and the governance for its compliance, specifically the role the Advisory Board can play in assessing the behavior of member companies and the VIG in relation to compliance with the Code.

Norm-setting

We propose to clarify in the norm-setting of the Code what is expected of member companies in representing their interests, and more specifically when it has been agreed that the VIG represents the sector interest (on a specific subject). The VIG will have to organize its governance for obtaining a negotiation mandate on behalf of the members. Once the VIG has obtained a mandate, the member companies must act accordingly.

We advise including the principle that members are bound by VIG decisions regarding representation of interests as a value in the Code. This shows the outside world that the VIG can represent sector interests and that the member companies will commit to this.

With this in mind, we propose the following amendment to Article 1.3 of the Code, highlighted in red, and also propose replacing the title "fair lobby" with "reliable and correct representation of interests."

Reliable and correct representation of interests

1.3 We represent our interests based on relevant and reliable information. We act in accordance with generally accepted social norms of knowledge and skills, integrity, transparency, and confidentiality and commit to the agreements made within the Association of Innovative Medicines (VIG) regarding the representation of sector interests by the VIG.

Explanation

This clause relates to 1) representation of individual business interests and 2) representation of sector interests by the VIG. For representing our individual business interests, we provide honest and reliable information. Our (internal or external) associates are trusted partners who check their information for accuracy before disseminating it. The generally accepted social norms mentioned in this clause are laid down in this Code and in the codes of conduct of the individual member companies. For representing sector interests, we commit to the agreements made by the VIG on this matter.

¹ <u>https://puc.overheid.nl/nza/doc/PUC_775444_22</u> /

Governance for compliance with the Code

The credibility of the Code and the VIG as a sector representative stands or falls with compliance with the agreements made and governance that can oversee this compliance. The Advisory Board has a formal supervisory role and a general advisory role in this regard. We propose to further elaborate on this advisory role to strengthen the formal supervisory role. We explain this further below.

The Advisory Board has the task under the VIG statutes (Article 23) to oversee compliance with the Code and handle complaints against non-compliance with the Code or other binding decisions for members. Complaints can only be submitted by members or the VIG Board and the General Assembly. The Advisory Board provides a fair process and has the possibility to propose sanctions if a complaint is found to be justified. The VIG Board decides on the imposition of sanctions, with the involved member having the possibility to appeal to the General Assembly. The procedure is further elaborated in the Internal Rules (Article 25) and the Advisory Board Regulations.

In addition to this formal task with possible legal consequences for members, the Advisory Board also has a general advisory and signaling role. The Code stipulates that members must conduct an annual self-evaluation, which is assessed by the Advisory Board. Furthermore, the Advisory Board conducts company visits to gain insight into how the values of the Code are being adhered to by the member companies. The Advisory Board reports on this in its annual report. The Advisory Board can also provide advice on matters related to the Code, either upon request or on its own initiative. This can be based on the behavior of member companies that have come to the attention of the Advisory Board or on more policyrelated themes arising from the self-evaluation or company visits. The Advisory Board can conduct its own research and consult experts. The Advisory Board can also advise on amending the Code.

So far, the Advisory Board has carried out its advisory role solely at the request of the VIG Board. It has issued advisory opinions based on requests from the VIG Board. The Advisory Board proposes to further elaborate on its advisory role by strengthening its signaling role concerning societal trends in relation to the values of the Code. For this, it is important for the Advisory Board to receive signals about experienced dilemmas regarding access to innovative medicines at a socially acceptable price. This mainly concerns signals about the behavior of member companies that may conflict with the values of the Code. These signals can be submitted to the Advisory Board to promptly inform the Advisory Board of such signals and to inform external stakeholders that they can report signals. Based on these signals, the Advisory Board can decide to conduct its own research into the trend of the experienced dilemmas and the behavior of the involved parties.

It is explicitly not the intention for the Advisory Board to become a complaints office, with the expectation that submitting a signal will lead to an investigation. The Advisory Board reserves the right to conduct further research into broader themes based on various signals and to consult the involved member companies, stakeholders, external experts, and/or other parties. Based on this, the Advisory Board can provide advice to the VIG Board on these themes and the expected behavior in relation to the values of the Code.

The Advisory Board would like to advocate that all its advice is public in principle (unless the Advisory Board itself indicates that the advice is not public) and that it can share this advice with external parties consulted by the Advisory Board in the context of the advice. Transparency will contribute to the credibility of the supervision. Besides, the advice offered for publication will not be traceable to a specific company; for this, the formal complaints procedure serves.

The Advisory Board proposes to further elaborate on the signaling role mentioned above in the Advisory Board Regulations. Before elaborating on this proposal, the Advisory Board would like to know whether its advice on amending clause 1.3 of the Code and broadening its signaling role is supported by the VIG Board and the members.

We are available for further explanation.

Yours sincerely,

Hugo Hurts Chairman of the Advisory Board