Dutch Association
Innovative
Medicines

# Code

Dutch Association
Innovative Medicines

# Integrity, Transparency, Quality & Social responsibility

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Innovative Medicines

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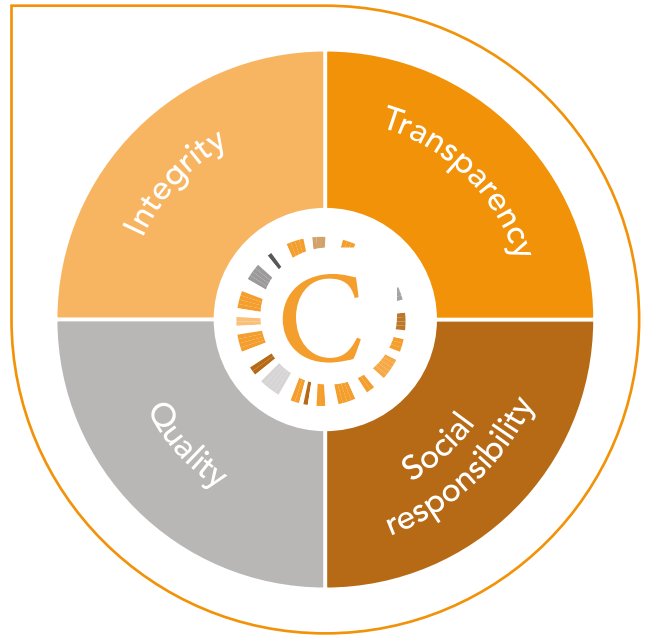


# 1 INTRODUCTION

The Association Innovative Medicines stands for a healthy future. We represent pharmaceutical companies that are fully committed to research and development of new medicines. Together we work on solutions to make people better and to improve quality of life. We are making the medicines for tomorrow, for the treatment of diseases that are difficult to treat or are as yet untreatable.

Dutch healthcare is among the best in the world. We maintain our lead and strengthen this unique position by making agreements and working with all partners in the healthcare sector. Together with doctors, researchers and patients, amongst others, we are committed to the availability of safe and high-quality medicines.

The Netherlands wants te be a global leader in Life Sciences & Health. We share this ambition and contribute to it every day. By investing in innovations and a favourable research climate. In doing so, we seek the right balance between social interests and business results. We strive for added value for all parties in the healthcare chain.

As a result, the Association's members also have a great social responsibility.
It is our responsibility to continue to develop innovative treatments and to make them available to patients. We emphasise this by means of this Code.

We are obligated to comply with existing legislation and regulations and are committed to the sector's further self-regulation. This Code complements this legislation and is in line with international guidelines. The Code provides our core values: integrity, transparency, social responsibility and quality.

The Code is a guideline for all Dutch branches of companies that are members of the Association Innovative Medicines. It is part of the learning culture in our sector, a foundation for setting boundaries, identifying dilemmas and conducting a dialogue. The new Code is a growth model; it will be further shaped on the basis of experiences and societal developments.

With this Code, we show what we stand for and where we want to go, but also where we draw the line. Because we want to ensure that the Dutch healthcare remains sustainable accessible and affordable, it is important to agree on what we can hold each other accountable for. The Code is the basis from which we commit ourselves to optimal cooperation with all parties involved in healthcare.

An independent Advisory Board monitors compliance with the Code. In this way, the Association Innovative Medicines can call individual members to account for their actions and, as the ultimate consequence if they fail to comply timely, can also expel them. The Advisory Board issues an annual report and advices on how to work on further development and improvement of the Code.

This is how we are working towards a better Dutch healthcare system and a healthy future for all of us.

*Dutch Association Innovative Medicines*

'The new Code is a growth model. It will be further shaped on the basis of experiences and societal developments.'

# 2
# 'APPLY OR EXPLAIN'

## General

The Code was adopted as a member-binding decision by the General Assembly of the Association. This means that every member company is obliged towards the Association to adhere to the Code and that only the Association can ensure that its members comply with the Code. The Association is assisted in this by the independent Advisory Board.

The 'apply or explain' principle applies to the Code. A member of the Association in principle applies the standards of the Code. The application of the standards partly depends on the activities and other specific characteristics of the company and the group to which it may belong.

The members of the Association to which the Code applies differ in many respects. For example, they have different corporate governance structures, they operate in different markets or parts of these, and they can be nationally or internationally oriented.

Differences in the interpretation and application of the standards may be justified, provided that this can be properly justified on the basis of the specific circumstances.

## Self-assessment

Each member company conducts an annual self-assessment to determine whether the Code is being properly adhered to. The way in which this self-assessment is carried out is determined by the company itself. The changes and adjustments, the learning and improvement points that emerge from this are included in the self-assessment that accompanies the declaration.

## Apply or explain

The interpretation and implementation of the Code is carried out in accordance with the 'apply or explain' principle. This principle means that the company itself provides a motivated answer to the following questions:

- Does each standard apply?
- If the answer is yes, how is each standard of the Code adhered to?
- Does this interpretation meet the scope and explanation of the standard from the Code? A standard can also be adhered to because the company belongs to an international group that has adopted this standard.
- Is the degree to which the Code is broadly and deeply rooted (implemented, known and complied with) in the company sufficient?

## Declaration

Each year, by means of a signed declaration, the company confirms that it complies with the Code. With the declaration, the company sends its self-evaluation that demonstrates how it implements each standard. In this self-evaluation the company states:

- whether a standard applies;
- whether a different interpretation is given to a standard and/or explanation as described in the Code;
- in which documents the application of the standards is described;
- the action plan and implementation period for standards that are not (yet) met (completely).

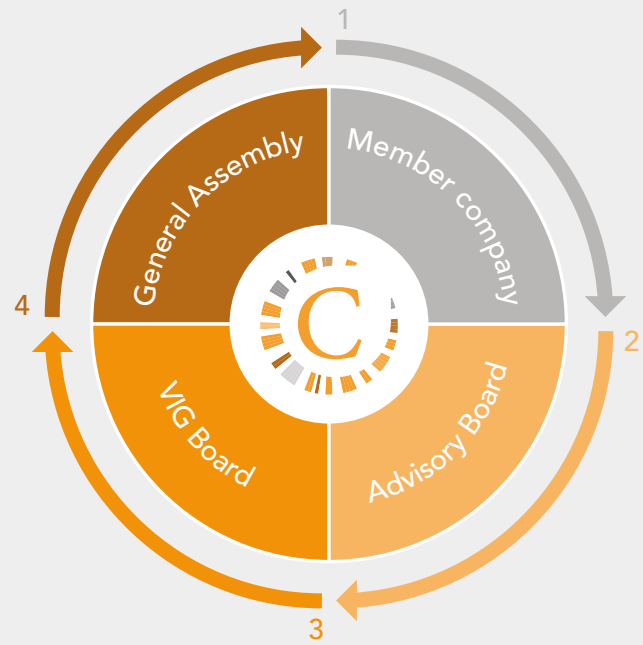
The signed declaration and self-evaluation is reviewed and approved by the independent Advisory Board. The Advisory Board assesses whether any deviation from the Code (based on the 'explain' principle) is justified. The secretariat of the Advisory Board administers the declarations.





# THE CODE : GROWTH MODEL

ANNUAL CYCLE




The Code has a growth model that requires our members to annually report on their compliance with the Code. The independent Advisory Board that supervises the Code evaluates these reports and issues a report on their findings to the Board of the Association for Innovative Medicines. In its report, the Advisory Board includes recommendations about possible improvements to the Code. The Board can transform these recommendations into modifications to the Code, following approval by the General Meeting of Members. The new standards are then incorporated into the member self-evaluations. As such the Code is constantly developing.

‘Only if all partners can trust each other, we can jointly provide the best care to patients.’

# 3
# CODE VALUES AND STANDARDS

## 1. Integrity

### Introduction

As pharmaceutical companies, and particularly as developers of innovative medicines, we are important allies of doctors and patients in the fight against diseases. After all, we are the pharmaceutical companies that develop new resources to fight these diseases.

As members of the Association Innovative Medicines, we realise that we are partners in a broader alliance of healthcare professionals, institutions, patient organisations, insurers and government. Only if all partners can trust each other, we can jointly provide the best care to patients.

That trust begins with integrity of conduct. Hence, in this section, we describe the principles of our conduct. These principles are about responsibility, provision of information and fair dealings with healthcare professionals and the public. They are also about the way in which we have organised ourselves to consistently adhere to these principles.

The Platform on Transparency and Ethics has established a list of principles to which we are committed.

In order to specify the core value of integrity, we consider the following:

## Responsible conduct

1.1 Our conduct is transparent, responsible and consistent with the interests of patients and public health in general. We are committed to the List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector of the Platform on Transparency and Ethics[1].

***Explanation***
This Code provides for the standards of the List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector, dealing with amongst others responsible behavior, transparency of relationships, information, promotion and benefits or inducements.

## Responsible information provision

1.2 We provide healthcare professionals with timely, qualitatively good and complete medical information for independent judgement.

***Explanation***
The choice to prescribe a medicine should only be made by a qualified healthcare professional based on a professional assessment of the patient's interests. We will therefore inform healthcare professionals objectively

[1] http://www.eu-patient.eu/globalassets/news/list-guiding-principles_nov2012.pdf





about the medicines we provide and do nothing to induce these persons or institutions to prescribe or dispense these medicine to patients other than for medical reasons. The healthcare professional must be able to make decisions on the basis of sound and complete information (see also Article 91, par. 3 Dutch Medicines Act and Article 5.2.2.4 Code of Conduct for Pharmaceutical Advertising CGR).

Our advertising of our medicines is therefore only aimed at ensuring that healthcare professionals are aware of their existence and have the information necessary to make a balanced decision in prescribing them to patients. The principles that our advertising satisfies are described in the Code of Conduct for Pharmaceutical Advertising (Gedragscode Geneesmiddelenreclame, CGR), with which our members comply.

## Fair lobby

1.3 We promote our interests based on relevant and reliable information

***Explanation***
In lobbying activities, we provide fair and reliable information. Our (internal and external) Public Affairs associates are trusted partners in the public debate, who check their information for accuracy before disseminating it.

## Responsible relationships

1.4 We do not compromise the professional independence, reliability or integrity of healthcare professionals. We refrain from undesired influencing of healthcare professionals, institutions, patient organisations, patients and other stakeholders

in prescribing, dispensing or using medicines. We comply with the Code of Conduct for Pharmaceutical Advertising (CGR).

***Explanation***
The standards with regard to responsible relationships and information provision have been further elaborated in the Code of Conduct for Pharmaceutical Advertising (CGR).

## Scientific department

1.5 We have a scientific department that is under qualified leadership. This department reviews all our promotional materials and medical information to be provided for accuracy.

***Explanation***
We guarantee that all of our promotional materials and advertising give a fair representation of the facts and do not make false promises concerning what can be expected of our medicines. Therefore, we have a scientific medical department, which is led by a qualified manager with medical expertise. This department reviews all promotional materials and advertising for appropriate scientific substantiation.

## Compliance programme

1.6 To ensure that all employees comply with existing legislation and self-regulation and with the additional integrity standards (including this Code) of the organisation, we have a compliance programme.





***Explanation***
We are professional organisations with good internal processes that ensure that our employees are aware of existing legislation and self-regulation and other integrity standards (such as this Code) and adhere to it in our activities. We therefore have a healthcare compliance programme that meets the following characteristics:

a. It has the unconditional support of management, as evidenced in the description of the compliance governance and roles within the organisation;
b. It provides clarity to employees as to which practices are or are not permitted, how to monitor these and the sanctions imposed for violations;
c. A (risk) analysis is conducted periodically to identify integrity risks in the organisation;
d. Based on this analysis, an audit will be conducted within the organisation to ensure compliance with the integrity rules;
e. Employees are trained periodically in applying the relevant laws and the additional integrity rules (such as this Code) of the organisation;
f. Each employee signs an integrity declaration in which he/she commits to the integrity standards of the organisation.
g. A reporting protocol enables employees to report violations of integrity standards without personal consequences after which these are followed up.
h. Periodically, management checks whether the compliance programme is still up to date.

# 2. Transparency

## Introduction

Openness is an important condition for trust. With regard to our societal mandate as pharmaceutical companies, open and clear communication is needed on how the (societal) interests of those involved are taken into account.
We may be expected to be transparent about our studies conducted during the (further) development of medicinal products, as well as their results and our financial relationships with healthcare professionals and patient organisations.
Furthermore, we play a role in predictability of the availability and affordability of medicines in the Dutch market, as well as the expected healthcare outcomes. A core value for us is to contribute to this transparency and predictability.

In the interpretation of the core value transparency, we consider the following:

## Safety information

2.1 We are open about all information that impinges on patient safety, such as new information about side effects.

***Explanation***
As pharmaceutical companies, we are responsible for monitoring the safety and quality of our medicines.
We research and test our medicines for side effects. Medications that we are already marketing are closely monitored, and all reports of suspected adverse reactions are registered.





Reports of suspected adverse reactions or product complaints are closely investigated and promptly communicated to the authorities. Should information need to be provided to the public on the safety and quality of medicinal products, we shall do this in consultation with the authorities.

## Recognisability

2.2 In their communications, our employees immediately disclose that they work for a pharmaceutical company.

***Explanation***
Our employees and contractors are required to be recognised as such when meeting with other stakeholders. For example, in professional contacts through social media, employees should disclose that they work for, or act on behalf of, a pharmaceutical company.

## Clinical studies

2.3 We register our clinical studies initiated in the Netherlands in public trial registers.

***Explanation***
Before we start a clinical study for a new medicine in the Netherlands, we register this in the Netherlands Trial Register and for international studies, in another public trial register. This register is completely public and searchable. It contains all clinical studies that will be or are being conducted in the Netherlands or that involve Dutch researchers. See also Article 4.5.

## Clinical research collaboration

2.4 If we collaborate with third parties in clinical research and provide remuneration for this, we prepare a contract with them in advance, taking into account the model agreement of the Dutch Clinical Research Foundation.

***Explanation***
In many cases, we work with researchers from universities or other research institutions. In order to properly arrange in advance how this research is to be done and what happens to the results, we always prepare an agreement in which this is jointly established. For this, we take the model agreement of the Dutch Clinical Research Foundation into account. This foundation is a partnership of university medical centres, research organisations, pharmaceutical companies, medical ethics committees, patient organisations and the government.

## Publication of research results

2.5 We publish the results of the pharmaceutical research we are conducting or initiated for, regardless of the results.

***Explanation***
Scientific research benefits from openness and publicly available outcomes. This allows researchers to build on each other's results and align their research. It is important that not only positive results be shared but also the results of research that did not have a successful outcome, for example because it has not been able to confirm the action of a remedy.
We are committed to disclosing the results of a study at all times, regardless





of the outcome. This applies both to research we have conducted ourselves and to research that we have initiated and paid for, directly or indirectly. We record the research results in the available databases.

## Financial relationships

2.6 We report financial relationships with healthcare professionals, healthcare institutions and patient organisations in the Healthcare Transparency Register.

***Explanation***
To provide insight into the reimbursements paid (according to the criteria of the Code of Conduct for Pharmaceutical Advertising), our members use the Healthcare Transparency Register. This central registry is publicly accessible. An overview of financial reimbursements among pharmaceutical companies, healthcare professionals, institutions and patient organisations is published annually. This data is rendered publicly accessible through the Healthcare Transparency Register.

## R&D expenditure

2.7 We publish annually how much we have spent on research and development of (new) medicines in the Netherlands.

***Explanation***
We report how much we paid in total for pharmaceutical research in the Netherlands. In this way, it is clear which pharmaceutical companies invest in finding new medicines or improving methods of treatment, and the extent

of such investment The structure of this reporting has been prepared by the European Federation of Pharmaceutical Industries and Associations and has been documented in the EFPIA HCP/HCO Disclosure Code. This data is accessible via the Dutch Association Innovative Medicines website.

## Harmonisation of registers

2.8 We are committed to harmonising the different registers that track the outcome of treatments.

***Explanation***

After the introduction of a medicinal product, it still is important to record the results of the treatments. This contributes to deeper insight that is important in the further development of, and information concerning, the medicine. Central registers documenting the effects of medicines help in this.
Currently, several registers are kept side by side. One central register or an automated link between these decentralised registers is missing at the moment. As an Association, we are committed to achieve this in collaboration with other stakeholders.

## Government spending predictability

2.9 We support the government and other parties in making good predictions of pharmaceutical expenses.





***Explanation***

Both for government and for insurance and healthcare organisations, it is important to be able to make a good prediction of pharmaceutical costs. It is important for the government to know how many patients use each medicinal product. It is also relevant to know for which new medicines and indications market expansion may be expected.
We are well positioned to collect this information. As an Association, we work closely with the government and involved parties to increase insight into pharmaceutical expenditure.

## Procurement procedures

2.10 We work with healthcare organisations, healthcare professionals, and healthcare insurers to ensure a fair and transparent purchasing process when purchasing medicines.

***Explanation***

An open and honest purchasing process is in the best interests of the purchasing healthcare institutions and the insurers as well as the pharmaceutical companies themselves. A good process defines the conditions of purchase in advance. As an Association, we strive to improve the purchasing process by formulating together with healthcare insurers, healthcare institutions and other purchasing parties the basic principles for a prudent and clear purchasing procedure, thus ensuring a fair and transparent process.

# 3. Social responsibility

## Introduction

We wish to be honest and reliable partners for those with whom we deal directly and wish to have a role in society as a whole. This means, among other things, defending the interests of patients, contributing to the improvement of the environment, providing resources for social projects, and providing a safe and pleasant working environment for employees.

Corporate social responsibility is a broad concept which is interpreted in different ways. International standards exist (incorporated in the ISO 26000) which describe what should be understood under good governance, respect for human rights, provision of good working conditions, environmental responsibility, fair business practices, consumer interests and involvement in the development of the community. As internationally operating pharmaceutical companies, we embrace and implement these international standards.

In order to implement the core value of Social Responsibility, we consider the following:

## Mission and vision

3.1 We have established and published a mission and policy vision with regard to social responsibility.

***Explanation***

We have described our social responsibility as part of our company's mission. We publish this mission and vision so that these are clear to everyone.





## Social dialogue

3.2 We are in constant dialogue with stakeholders on the interpretation of our social policies and the implementation of social activities.

***Explanation***

Social accountability begins with knowing the stakeholders and conducting dialogue with them. This allows them to communicate their wishes and expectations to us, and we understand what is happening in society and how it values the role of the pharmaceutical companies.

In this, we focus on external stakeholders, such as our patients, scientific institutions, governments, suppliers and society as a whole, but also on internal stakeholders, such as employees and directors.

## Social interests

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.

***Explanation***

We know and recognise our role in society and behave accordingly. When making important decisions which impact internal or external stakeholders, we weigh their wishes and expectations and can explain how final decisions have been made.

## Accountability

3.4 We give account of the results of our corporate policies in our annual report or in specific social reports.

***Explanation***
We periodically report on how our company's actions affect people, the environment and the economy. In this way, it is clear how we have specifically interpreted our vision regarding social responsibility.

## Availability of medicines

3.5 Our policy is aimed at a sustainable availability of medicines and to avoid shortages of medicines.

***Explanation***
Many patients' lives or quality of life are dependent on the medicines we produce. Ensuring that these medications are adequately available for patients is therefore crucial. That is why we work closely with distributors, pharmacies and healthcare institutions.
We monitor production and stocks constantly and accurately. If we foresee shortages due to manufacturing issues, we report this ahead of time to the Medicine Shortages and Defects Notification Centre. We also look at how to prevent future shortages.

## Working conditions

3.6 We ensure an inspiring, motivating and safe working environment for our employees and our partners.

***Explanation***
We ensure inspiring and innovative work. Pharmaceutical companies are practising good employer practice. Importantly, there is attention for





personal development (training) and a safe working environment (preventing discrimination, bullying, sexual harassment, etc.). The establishment of an internal code, diversity policy, whistle-blower scheme, confidential adviser, or internal complaint system contributes to a responsible working environment.

## Environment

3.7 We are committed to increasing the sustainability of the pharmaceutical sector. This is achieved by resource-efficient and circular use of raw materials, contributing to clean water, a healthy living environment and $CO_2$ reduction.

***Explanation***
In the sector's packaging sustainability plan, we have formulated concrete objectives for 2022 with regard to prevention of wastage of medicines and for sustainable and circular sourcing of packaging. In addition, we are working together in the chain to prevent medicinal residues from reaching groundwater and surface water and how to reduce the risks of environmental damage with quality of healthcare being paramount.
We are committed to contributing to these themes at a European/international level.

## Privacy

3.8 We safeguard a careful processing of sensitive personal data.

***Explanation***
We collect, manage, protect and destroy personal data in accordance with

applicable legislation (General Data Protection Regulation (GDPR)). We work with sensitive personal data (of patients, consumers, healthcare professionals) only in relation to the development and use of medicines and if necessary in connection with reported adverse events, medical or product complaints or requests for further information by those concerned.

## Support

3.9 We support projects with the goal improvement in the innovation of medicines or science and thereby in the quality of healthcare.

***Explanation***
We support quality-improvement and innovative projects. In doing so, we ensure that this support does not lead to an obligation to prescribe, dispense or use particular medicines (in accordance with Article 6.5.3 CGR).

## Participation and charitable causes

3.10 We participate in social projects and support good causes.

***Explanation***
As pharmaceutical companies, we support numerous NGOs and other good causes whose activities are related to our core business, worldwide. In example in which we participate is the project caregiver-friendly organisation.





# 4. Quality

## Introduction

As pharmaceutical companies we aim at achieving a high quality of our products and services. Pharmaceutical research and development is subject to strict quality standards and requirements. The requirements set our products, production and services is guaranteed by quality systems. Once a medicine is marketed, we closely monitor its safety. We continuously monitor the various aspects of quality provided and allocate sufficient resources to improve the product and the process. In addition, we work with supply-chain partners to counteract counterfeit medicines.

In order to contribute to the quality core value, we consider the following:

## Requirements

4.1 We set high requirements with respect to the quality of our products and services, and ensure that our employees are well informed about these.

***Explanation***
The quality requirements with which our products and services have to comply are governed by legislation, international standards of practice, regulations and other arrangements. Achieving these requirements is documented in quality manuals and is controlled by internal and external audits.

## Patient central

4.2 We focus on the quality of our products and services in the best interests of the patient.

***Explanation***

The safety and effectiveness of patients' medicines are paramount for us. The proper deployment and use of medicines contribute to the optimal value of patient care. We strive for the right resource at the right time for the right patient. We endorse the principles of value-based healthcare (result–focussed care for the patient).

## Patient(organisation) involvement

4.3 We involve patients and patient organisations in improving the quality of products and services.

***Explanation***

Patients have and keep control over their own health. We provide education about diseases and the optimal treatment of these. In addition to providing information and education on disease states, medicines and use and treatment, we inventory what patients want and expect. Taking into account the integrity standards, we involve patients (organisations) in development, use and education.





## Treatment guidelines

4.4 We contribute to keeping professional organisations' treatment guidelines up-to-date through the provision and availability of scientific data.

***Explanation***

Professional organisations' treatment guidelines continuously evolve through research and renewed knowledge and insights. In collaboration with professional organisations of physicians, pharmacists, healthcare professionals and patient organisations, we provide scientific data for updating treatment guidelines.

## Good Clinical Practices

4.5 Our pharmaceutical research is based on international standards.

***Explanation***

Pharmaceutical research is internationally regulated, as in the European Legislation on Clinical Research and the Declaration of Helsinki. We comply with national legislation and regulations.
In the design, conduct and reporting of clinical research, we adhere to the rules of Good Clinical Practices and for non-clinical studies, the Good Laboratory Practices. For NWMO studies (research not covered by the Wet Medisch-wetenschappelijk onderzoek met mensen [Medical Research involving Human Subjects Act]), we take the guidelines and agreements of the Dutch Clinical Trial Foundation into account. See also Article 2.4.

## Good Manufacturing Practice

4.6 We produce our medicines according to Good Manufacturing Practices and under the control of a qualified person who fulfils the legal requirements governing training and work experience.

***Explanation***
Medicinal products must be manufactured from raw material to finished product in accordance with the norms of international standards (Good Manufacturing Practices), under the responsibility of a Qualified Person. This forms part of the manufacturing licence and is audited by the authorities. Even if production takes place outside the EU, a screening – based on the same norms and standards – must be carried out by the authorities of one of the member states of the European Union.

## Good Distribution Practices

4.7 We distribute our products according to Good Distribution Practices.

***Explanation***
The distribution of medicinal products must, throughout the distribution chain, be in accordance with the Good Distribution Practices. Good Distribution Practices form part of the terms of a manufacturing licence and wholesale licence and ensure, amongst other things, the quality of storage, transport and destruction.





## Good Pharmacovigilance Practices

4.8 We control the use of our medicines by closely monitoring and following up reports and complaints about them.

***Explanation***
We take responsibility for the quality, safety and efficacy of our products. That is why we carefully monitor our products and follow up on reports on the effects of our products in collaboration with the authorities.
We follow the Good Pharmacovigilance Practices.

## Complaints

4.9 Complaints, suggestions and reports are recorded and resolutely pursued, and a reaction is given.

***Explanation***
Complaints from customers and other stakeholders are taken and treated seriously. Complaints are recorded and analysed, and provide input for improvements. Our companies have a procedure to record complaints.

## Good use

4.10 We support programmes for the good use of medicines. We promote compliance and combat counterfeiting.

***Explanation***
As an Association, we participate, along with other healthcare parties, in the ZonMw-initiated Good Use of Medicines programme. This initiative encourages the addressing of questions concerning, for example, compliance. This involves research, practical projects, presentations, congresses and bringing together relevant parties. In addition, we contribute to good use of medicines by (further) developing diagnostic methods that support healthcare professionals in the treatment. Furthermore, we participate in the NMVO (Stichting Nederlandse Medicijnen Verificatie Organisatie [Netherlands Medicines Verification Organisation Foundation]), in which, in cooperation with other parties (KNMP, Bogin, BG Pharma), is worked on a comprehensive chain approach that can be used to ensure that patients receive only genuine high-quality medicines.

## Monitoring results

4.11 We invest in professional operations and continuously monitor progress and achievement of our goals.

***Explanation***
We have translated our objectives into KPIs and standards and our Management Information Systems provides insight into progress and results with regard to these KPIs. This insight enables us to respond adequately to (unexpected and unforeseen) developments and to adapt and improve business operations. In this way, we ensure the continuity of the organisation.





## Improvement

4.12 We continue to invest in improving and innovating treatments with our products, processes and services.

***Explanation***
Responsibilities for implementing improvements are documented and known to us. Results of improvements are measured and communicated in the organisation.

# THE CODE: KEY VALUES

## Integrity

- Our conduct is open, reliable and responsible
- High-quality information for patients and stakeholders
- We represent interests with honest and reliable information
- We refrain from exercising undesirable influence
- All of our medical information is checked by an academic institution
- We have access to compliance programmes

## Transparency

- Open about information that touches on patient safety
- Employees always divulge that they are working for a pharmaceutical company
- We register clinical studies initiated by us in the Netherlands in a public trial register
- When we collaborate with third parties in clinical research we enter into an agreement in advance
- Publication of research results
- Transparency in financial relationships
- Annual publication of R&D expenditures
- Insight into the outcome of treatments (harmonisation of data registers)
- Support the predictability of expenditures on medicines
- Meticulous and open procurement process

## Social Responsibility

- Mission and vision for social responsibility
- Constant dialogue with stakeholders
- We provide due consideration to social interests
- We account for our social policy
- Sustainable availability of medicines
- We see to it that there is an inspiring, challenging and safe working environment
- We devote efforts to making the pharmaceutical sector sustainable
- Respect for the right to privacy
- Support projects designed to improve healthcare
- Participate in social projects

## Quality

- High quality and safety criteria
- Patient-oriented care
- We involve patients for the purpose of improving the quality of our medicines
- We contribute to keeping the treatment guidelines of professional organisations current
- Research into medicines based on international standards
- We produce our medicines in accordance with ‘Good Production Practices’
- We distribute our products in accordance with ‘Good Distribution Practices’
- Promote the monitoring and reporting of side effects of medicines
- Our companies have a complaints handling procedure
- We promote the proper use of medicines and combat falsification
- We invest in professional business operations
- Continuously invest in treatment improvement and innovation

‘An independent Advisory Board monitors compliance with the Code and advices on how to work on further development and improvement of the Code.’

# 4 MONITORING AND ENFORCEMENT OF THE CODE

The Code concerns a member-binding resolution to which the members of the Association (by means of a declaration and self-assessment) conform towards the Association. The Code does not have any external function to which third parties can appeal. It is up to the members themselves to be accountable (according to the ‘apply or explain’ principle).

The monitoring of compliance with the Code has been assigned to an independent Advisory Board that reports to the General Assembly. The members of the Advisory Board are independent and experts and judge as good people in reasonableness and fairness in compliance with the Code and the goals of the Association. In doing so, thy adhere to strict confidentiality. The members of the Advisory Board are appointed by the General Assembly. They are entitled to a subsistence allowance. The Advisory Board has its own secretary/secretariat.

The Advisory Board has the following tasks:

- reviewing and approving the declarations and self-assessments of the members that they comply with the Code and enquiring further as necessary (admissibility assessment);
- monitoring the progress of implementation of the Code by members;
- issuing of a recommendation concerning the behaviour of one or more members, based on a (forwarded) request by one of the bodies of the Association ;
- noting complaints against one or more members of the Association, which have been submitted by one or more members or bodies of the Association, in accordance with the provisions of the Articles of Association and the General Rules of Procedure of the Association, and the issuing of a recommendation in this regard;
- provision of solicited or unsolicited policy guidance on a particular theme or development in relation to the Code. This may include consulting Advisory Board experts or forming an expert board and requesting input;
- provision of solicited or unsolicited advice regarding any concrete changes to the Code;
- writing an Annual Report which describes the findings with regard to Code compliance, and with regard to the recommendations issued, recommendations on the further development of the Code and accountability of the performance of the Board's tasks in the preceding year. The Annual Report will be issued to the General Assembly and will be published.

Due to the annual cycle of self-assessment and reports, the Code is constantly evolving. Based on findings, the Advisory Board may propose changes to the Code that can be adopted by the General Assembly and thus become part of the annual self-assessment.





The Advisory Board will review complaints about violations of this Code to the extent that no specific body is designated, as well as any questions concerning compliance with statements of self-regulatory bodies recognised by the Association (such as the CGR). This means that the Advisory Board does not duplicate the work of the CGR, for example, but acts if the complaint means that a ruling of the CGR is not adhered to. For standards for which no other self-regulatory assessment exists, the Advisory Board itself issues a substantive judgement.

It is common practice within the Association that members first try to reach an agreement in case of an alleged infringement of the Code, before submitting a complaint to the Advisory Board. The members are also asked that whenever possible signals about a correct compliance with the Code can arise, they will inform the board as soon as possible and preferably in advance In case a complaints or signal is submitted to the Advisory Board, it will in the handling thereof hear both sides of the argument. The Advisory Board may be assisted by experts or external expert advice (such as the Code Commission of the CGR) in its investigation of the complaint and/or signal.
The Advisory Board provides a recommendation to the Association (the Board of Directors), which may propose taking one or more measures. The recommendation may entail:

- declaration that the complaint or the signal is unfounded;
- incentive measure with regard to the member against whom the complaint was addressed, to improve compliance with the Code;
- internal reprimand;

- public distancing of the member's behaviour by publication in:
  - internal documents of the Association;
  - the Association's website;
  - one or more industry trade journals, etc.;
  - regional media;
  - national media.
- recommendation to cancel member's membership at the end of the year;
- recommendation to suspend membership with immediate effect;
- recommendation to expel the member from the Association with immediate effect.

The person who submitted the complaint and the member against whom the complaint or signal was directed may appeal against the decision of the Advisory Board at the General Assembly.

The composition, powers and practices of the Advisory Board have been further elaborated in a Regulation.





# MEMBERS OF THE ADVISORY BOARD

Chairman Mr A. (André) Rouvoet, LLM, studied law at VU University Amsterdam. He occupied a wide range of political positions since 1985. For example, he worked for a political party, was director of the Reformational Political Federation (RPF), member of the Dutch House of Representatives, party chairman and party leader of the ChristianUnion, and from 2007 to 2010, he was Minister for Youth and Families, and deputy Prime Minister in the Balkenende IV cabinet. In 2011, he left the political arena. In 2012, he became chairman of the Association of Dutch Health Insurers (ZN), a position that expires on 1 February 2020. Since 2017, he also was ambassador for the 'Divorce without Damage' programme and chairman of the Platform with the same name. In addition, he occupies various supervisory and advisory positions in social organisations (including in the youth care and educational sectors) and is in high demand as a speaker and day's chairman.

Ms C. (Cathy) van Beek, MCM, is a nurse, public administration expert and change management expert, and for 20 years served as administrator in the healthcare sector. She served in this capacity at the Sint Maartens Clinic where the first polyclinical pharmacy was opened; at the Dutch Healthcare Authority (NZa) where as vice-chairman she was responsible for the pharmaceutical sector for a period of two years; and finally at Radboud UMC where for 6 years she was responsible for patient participation, quality, safety, medication safety and sustainability. Effective from 2018, she has her own company 'Leading Sustainable Health Care'. She has various assignments, for example from the Ministry of Health, Welfare and Sport (VWS) and of Infrastructure and Water as Coordinator Sustainable Health to increase administrative and professional awareness and to develop perspectives for action, for example on the basis of the Green Deal Sustainable Health. In addition, she is independent chairman of the management board of Akwa GGZ [mental healthcare alliance] and fulfils various coordination, advisory and supervisory roles.

Prof. dr. ir. J.J.M. (Koos) van der Hoeven, internist oncologist, is professor emeritus Medical Oncology at the LUMC and Radboud UMC. He was chairman of a committee of the Dutch Cancer Society (KWF) that wrote two reports about the accessibility of new expensive medicines against cancer. Currently he is a member of the management board of the Hartwig Medical Foundation, member of the KWF Advisory Board and member of the Board of the Dutch Institute for Clinical Auditing (DICA).

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