

## Code of conduct and integrity policy for the Medicines Evaluation Board (MEB)

Adopted on 4 May 2016  
Version 4.0

Code of conduct and integrity policy for the Medicines Evaluation Board (MEB) .....	1
Code of Conduct of the Medicines Evaluation Board .....	2
Section 1: Correct administrative conduct .....	3
Section 2: Conflicts of Interest.....	7
Table 1: Interests with associated restrictions for Board members and staff .....	10
Table 2b: Interests with associated restrictions for Young MEB members and external experts.....	13
Definitions.....	14
Declaration of interests .....	18
Section 3: Confidentiality and discretion.....	20
Statement of confidentiality .....	21
Section 4: Invitations and gifts .....	22
Section 5: Use of facilities and resources.....	25
Appendix 1: External activities by members of the Board (and staff) that are <i>not carried out on behalf of the MEB</i> .....	26

## Code of Conduct of the Medicines Evaluation Board

The Medicines Evaluation Board (MEB) feels it important that Board members, employees and external experts are ethical, impartial and independent. The Code of Conduct has been drawn up to help achieve this. The Code of Conduct was formulated so as to tie in with the policy of the Ministry of Health, Welfare and Sport (VWS) and the policy of the European registration authority – the European Medicines Agency (EMA) – but different choices have been made in certain areas.

The aim of the policy is to remind the MEB and its staff that they must continually maintain and reinforce their integrity, impartiality and independence in order to safeguard the quality of the work and decision-making. The MEB and its staff can be held to account for this policy by stakeholders and the general public.

The Code of Conduct consists of five components: correct administrative conduct; how to deal with conflicts of interest; the duty of confidentiality and discretion; the policy concerning invitations and gifts; and rules relating to communication and the use of facilities.

The Code of Conduct is applicable to all staff at the MEB, including members of the Board and external experts, and including the Veterinary Medicinal Products Unit and the Novel Foods Unit insofar as activities for the MEB are involved.

The manager should preferably be the first port of call in the event of abuses. In addition, the MEB has appointed a confidential counsellor to whom abuses can be reported.<sup>1</sup> Other incidents can also be reported to this individual, such as (sexual) harassment and discrimination. All MEB staff can report incidents to the confidential counsellor, regardless of the nature of their employment contract. The MEB's Board<sup>2</sup> guarantees that all reports to the confidential counsellor will be treated with the utmost care.

MEB staff who are civil servants can also report abuses to the confidential counsellor at the Ministry of Health, Welfare and Sport (VWS) with the protection of its whistle-blower scheme. This government scheme is not applicable to MEB staff who are not civil servants. [Information about the whistle-blower scheme and reporting abuses](#) can be found on the website of the Ministry of Health, Welfare and Sport.

---

<sup>1</sup> For more information, please see the VWS procedure for reporting integrity violations in the [brochure 'Kan dit?'](#) (Is this OK?).

<sup>2</sup> The MEB Board consists of the MEB Agency directors and the chairman and deputy chairman of the MEB.

## **Section 1: Correct administrative conduct**

This section of the Code of Conduct sets the standards to be observed by the MEB staff, including Board members and external experts, when carrying out work for the MEB.

### **General provisions**

MEB staff should observe the principles laid down in this section of the Code of Conduct in their contacts with the public, including stakeholders.

### **Legality**

MEB staff should act according to the law and apply the rules and procedures that are laid down in Community Law and national law. Staff should ensure that decisions concerning the rights or interests of individual persons have a legal basis and that their content is in accordance with the law.

### **Equal treatment**

MEB staff should ensure that the principle of equal treatment is observed. This principle states that members of the public who are in the same situation must be treated in the same manner. If the manner of treatment differs, the MEB staff member should ensure that this is justified on the grounds of the relevant objective characteristics of the case concerned. In particular, MEB staff should avoid all forms of unjustified discrimination between members of the public based for example on nationality, gender, race or ethnic origin, religion or beliefs, disability, age or sexual orientation.

### **Proportionality**

When taking decisions, MEB staff should ensure that the measures are in proportion to the objective being pursued. There should be a reasonable balance between the general public interest and the individual interests of specific persons. Staff should avoid restricting the rights of citizens or imposing obligations on them if this is not in proportion to the intended objective of the measure.

### **Avoiding the abuse of power**

The powers invested by law should only be used for the objectives for which they are assigned in the relevant provisions. MEB staff should avoid using these powers for objectives that have no legal basis or that do not arise from a public interest.

### **Impartiality and independence**

MEB staff should be impartial and independent. Staff should refrain from any action that could damage the general public, and from any preferential treatment. MEB staff should not let themselves be guided by external influences, including political influences, or personal interests. Staff members should avoid involvement in decision-making on a matter in which their own interests or the interests of their immediate family, relatives, friends and acquaintances are involved.

### **Objectivity**

When taking decisions, staff should take all the relevant factors into account.

**Justified expectations and consistent actions**

Staff should be consistent in the performance of their job and in the application of MEB administrative measures. Staff should follow the normal administrative practices of the MEB, unless there are legitimate reasons for deviating from them in an individual case. Staff should satisfy the legitimate and reasonable expectations that members of the public have in the light of previous MEB conduct.

**Justice**

MEB staff should act fairly and reasonably.

**Politeness**

MEB staff should act dutifully, correctly and courteously and should be customer-friendly in their contacts with the public. In their contacts with the public, MEB staff should act in a way that prevents or limits escalations. When answering correspondence, telephone calls and electronic mail, staff should seek to be as helpful as possible and to answer the questions asked. If the staff member is not responsible for the case concerned, he/she should refer the member of the public to the authorised staff member. Staff should offer their apologies for any errors made that have negative consequences for the rights or interests of the general public. Staff should also point to the MEB complaints procedure.

**Obligation to pass case on to the correct government body**

If a letter or complaint is sent to the MEB that appears to be subject to the authority of another government body, the letter or complaint should be passed on immediately to the correct person or service. The person who receives the letter or complaint in the first instance should inform the person concerned of this referral and state the name and the telephone number of the member of staff handling the case. If it is not easy to determine which government body is authorised, the documents should be returned to the sender.

**Right to be heard and to give statements**

In cases in which the rights or interests of persons are involved, staff should ensure that the rights of the defence are observed at all stages during the decision-making procedure. In cases in which a decision must be taken in which the rights or interests of a member of the public are involved, he/she has the right to respond in writing and if necessary to give oral statements before the decision is taken.

**Reasonable term for making decisions**

Staff should ensure that a decision is made regarding requests or complaints to the MEB within a reasonable term, without unnecessary delay and in any case within the statutory period. This rule also applies to answering letters from members of the public.

**Obligation to provide reasons**

Any decision of the MEB that could damage the rights or interests of a person must be supported with reasons, listing the relevant facts and the legal basis of the decision. Staff should avoid making decisions that are based on limited or unclear grounds or that do not contain specific reasons. If it is not possible to provide supporting reasons for the decision

comprehensively due to the large number of persons to whom equivalent decisions apply, so that standard answers must be provided, the staff member should guarantee that he/she will provide any member of the public who explicitly requests this with an answer giving specific reasons.

### **Specifying the appeal options**

A decision by the MEB that might damage the rights or interests of a person must specify the options for lodging an objection or appeal that are available for appealing against the decision. The decision should state the nature of the appeal, the bodies where the appeal can be lodged and the term within which the appeal should be lodged, in accordance with the General Administrative Law Act.

### **Notification of the decision**

Staff should ensure that in the event of decisions involving the rights or interests of persons, the person or persons concerned are informed in writing as soon as the decision has been taken. Staff should avoid informing others of the decision until the person or persons concerned have been informed.

### **Data protection**

Staff who deal with the personal data of members of the public should observe the principles that are laid down in legislation and regulations concerning the protection of natural persons in relation to the processing of personal data and concerning the free movement of data.

Staff should refrain from processing personal data for unlawful purposes or passing on such data to unauthorised persons.

### **Requests for information**

The staff member responsible for a particular case should provide information to members of the public on request. The staff member should ensure that the information provided is clear and comprehensible.

If an oral request for information is too complicated or detailed, the staff member should advise the person involved to submit this request in writing. If a member of staff is not permitted to disclose the requested information due to its confidential character, he/she should inform the person involved why the information cannot be provided.

With regard to requests for information on matters for which the staff member is not responsible, he/she should refer the applicant to the authorised person, giving the name and telephone number. With regard to requests for information on another government institution or body, the staff member should refer the applicant to the institution or body in question.

Depending on the subject of the request, if necessary the staff member should refer the person requesting the information to the MEB departments that are charged with providing

information to the public, namely the Policy, Regulatory and International Affairs (PRI) department and the Communications department.

#### **Requests for access to documents**

With regard to requests for access to MEB documents, staff should refer the person concerned to the MEB department charged with providing information to the public. This department grants access to these documents in accordance with the procedures of the MEB and also with due observance of the Government Information (Public Access) Act.

If the staff member cannot comply with an oral request for access to documents, the member of the public should be advised to submit this request in writing.

#### **Keeping a record**

The MEB departments should keep a record of incoming and outgoing post, the documents that they receive and the measures that they take.

#### **Public access to the Code of Conduct**

The MEB will take the necessary measures to ensure maximum awareness among the members of the public of this code. The MEB provides access to the code via its internet site and will provide all members of the public with a copy on request.

#### **The right to file a complaint**

If a member of staff fails in any way to observe the principles laid down in this code, a complaint can be filed with the MEB in accordance with the complaints procedure and subsequently with the National Ombudsman, all this in accordance with the provisions in the General Administrative Law Act.

#### **New members of staff**

Any individuals who are going to carry out work at the MEB will be referred to the digital version of the Code of Conduct on the MEB website.

## Section 2: Conflicts of Interest

MEB staff, including Board members, members of Jong CBG (Young MEB) and external experts, must not have any interests that could affect their independence. This rule is based on Section 8, subsection 2 of the Medicines Act and Article 126 of the Directive 2001/83/EC. Whether the person in question is actually influenced by an interest is irrelevant. Every interest is assumed to lead potentially to a conflict of interest or create the impression of such a conflict of interest. This does not alter the fact that when evaluating interests, it is sometimes necessary to weigh up the requirement for independence against the need to engage the best experts for the work of the MEB.

MEB staff, including Board members, members of Young MEB and external experts must submit a declaration of their interests in the past five years, doing so before joining the MEB or being appointed and thereafter once a year. Interests from before that period can be declared on a voluntary basis. Members of staff and Board members should also report the current interests of their partner, children aged under 18 and other persons living at the same address.

In addition to the Declaration of Interests, interests that become known during work for the MEB must be reported immediately to the head of department or the chairman of the MEB. To encourage the reporting of interests, the chairman will ask those present at the start of each meeting of the Board whether they have any conflicts of interest to declare. Those present at Board meetings also have to sign a declaration that they have no interests. If an interest becomes known during the preparation for a Board meeting, for example when examining the meeting documents, this interest must be reported to the Board secretary before the Board meeting. The PRI department advises the chairman concerning any restrictions related to the declared interests. The chairman will take a decision regarding interests declared in the meeting. A deputy chairman will decide on any interests declared by the chairman.

Everyone is personally responsible for the accuracy of the declaration of interests.

### Policy for staff and Board members

The policy on conflicts of interest of staff and Board members is based on the EMA code of conduct that applies to members of the Committee for Medicinal Products for Human Use (CHMP). However, different choices have been made in some areas regarding the policy implementation.

The basic principle is that direct interests are never allowed in companies that have an interest in the activities of the MEB, such as pharmaceutical companies, manufacturers of medical aids with supporting pharmaceutical components and manufacturers of novel foods. Indirect interests are permitted, but they must be declared. Indirect interests also lead to restrictions in the activities for the MEB, such as not being allowed to evaluate certain products.

Table 1 on pages 8 and 9 shows which interests are permitted and which are prohibited. This table should be read in conjunction with the definitions on page 11 et seq. If a member of staff or Board member has interests that are prohibited, that person must dispose of those interests.

### **Policy for Young MEB and external experts**

The policy that applies to Young MEB and external experts is based on the EMA code of conduct that applies to members of a Scientific Advisory Group, as shown in Table 2 on page 10. This table should be read in conjunction with the definitions on page 11 et seq. If a member of Young MEB or an external expert has interests that are prohibited, they must dispose of those interests or the external expert cannot be consulted. The reason why a different integrity regimen has been adopted is that Young MEB and external experts do not take decisions and are not responsible for the legally defined tasks of the MEB. Members of Young MEB and external experts do have to notify the same things as members of staff or Board members, but these result less quickly in consequences or restrictions being imposed.

### **Assessment**

The MEB Board will evaluate whether the declared interests are compatible with the work for the MEB. The MEB Board will assess this on the basis of the Code of Conduct, drawing on advice from the PRI department. The MEB Board will take a decision on all declarations of interests in which an interest is declared, unless what has been declared is clearly not an interest according to the Code of Conduct, in the judgement of the PRI department, or unless the interest has already been declared and evaluated previously in accordance with the applicable policy. The MEB Board always takes a decision on Declarations of Interests or changes in such declarations made by members of the Board.

In its evaluation of the interests, the MEB Board may deviate from the policy in the Code of Conduct, giving reasons. This could be necessary, for instance, if a restriction would block the use of expertise that is essential to the activities of the MEB. When evaluating interests, the MEB Board looks in particular to see whether the interest results in direct personal financial benefits. In making its evaluation, the MEB Board may also take into account the nature of the interest and the type of work the person carries out, for example the extent to which the interest is related to a specific company or product and the extent to which the work transcends particular products and marketing authorisation holders. If there is a deviation from the policy, this must be documented.

The PRI department and the HRM department jointly ensure the evaluation of the declarations of interests is documented and that the person concerned and their department head (if appropriate) receive feedback. The declarations of interests are kept on file by the HRM department. The Declarations of Interest forms completed by the Board members are published on the MEB's website.

The policy can never cover all the interests that might influence a person. If employees, Board members, members of Young MEB or external experts feel they are unable to carry out certain activities in an independent way, they should refrain from carrying out those activities. This includes non-financial interests as a result of which someone has a strong link

to a certain product. The person in question should consult with his/her head of department or the chairman about refraining from certain activities.

MEB staff, including members of the Board, members of Young MEB and external experts, should take care to ensure that personal preferences never play a part in any of their decisions and activities for the MEB – see Section 1 of the Code of Conduct, concerning good administrative conduct.

In addition to the restrictions in the tables mentioned, there is a general rule that employees and external experts are never allowed to assess research or requests that they have worked on themselves. Board members and members of Young MEB may never take part in discussions (and where applicable the voting or final deliberations) about research or requests that they have worked on themselves.

The policy concerning conflicts of interest is evaluated at least once every five years on the initiative of the PRI department.

**Table 1: Interests with associated restrictions for Board members and staff**

<b>Direct interest</b>	<p><b>Prohibited:</b></p> <ul style="list-style-type: none"> <li>• Employee</li> <li>• Consultancy (general and specific)</li> <li>• Strategic advice (general and specific)</li> <li>• Financial interest (types 1 and 2)</li> <li>• Patent ownership</li> </ul>	During membership of the MEB or while working for the MEB.
	<p><b>Allowed with restrictions:</b></p> <ul style="list-style-type: none"> <li>• Employee</li> </ul>	Allowed if between now and three years ago, with the restriction that the person in question must not be involved in activities relating to products of the company in question and specific rival products (e.g. must not take part in discussions, the final deliberation and voting). <sup>1</sup> Allowed if between three and five years ago, with the restriction that only participation in discussions is allowed; participation in the final deliberation and voting relating to products of the company in question and specific rival products is prohibited. <sup>2</sup>
	<ul style="list-style-type: none"> <li>• Consultancy and strategic advice (general)</li> </ul>	Allowed if between now and three years ago, with the restriction that the person in question must not be involved in activities relating to products of the company in question (e.g. must not take part in discussions, the final deliberation and voting). Allowed if between three and five years ago, with the restriction that only participation in discussions is allowed; participation in the final deliberation and voting relating to products of the company in question is prohibited. <sup>2</sup>
	<ul style="list-style-type: none"> <li>• Consultancy and strategic advice (specific)</li> </ul>	Allowed if between now and three years ago with the restriction that the person must not be involved in activities relating to the product and specific rival products (e.g. must not take part in discussions, the final deliberation and voting). Allowed if between three and five years ago, with the restriction that only participation in discussions is allowed; participation in the final deliberation and voting relating to product and specific rival products is prohibited. <sup>2</sup>

<b>Indirect interest</b>	<p><b>Allowed with restrictions:</b></p> <ul style="list-style-type: none"> <li>Principal investigator</li> </ul>	<p>Allowed if between now and three years ago with the restriction that the person must not be involved in activities relating to the product and specific rival products (e.g. must not take part in discussions, the final deliberation and voting).<sup>1</sup></p> <p>Allowed if between three and five years ago, with the restriction that only participation in discussions is allowed; participation in the final deliberation and voting relating to the product or specific rival products is prohibited.<sup>2</sup></p>
	<ul style="list-style-type: none"> <li>Investigator</li> </ul>	<p>Allowed if between now and three years ago, with the restriction that only participation in discussions is allowed; participation in the final deliberation and voting relating to the product and specific rival products is prohibited.<sup>2</sup></p> <p>Allowed without restrictions if between three and five years ago.</p>
	<ul style="list-style-type: none"> <li>Grants or other forms of funding for an institute</li> </ul>	<p><b>Product-related grants or other forms of funding</b></p> <p>Allowed if between now and three years ago, with the restriction that the person must not be involved in activities relating to products of the company that provided the grant or other form of funding, or specific rival products.<sup>1</sup></p> <p>Allowed if between three and five years ago, with the restriction that only participation in discussions is allowed. Participation is prohibited in the final deliberation and voting relating to products of the company that provided the grant or other form of funding, or specific rival products.<sup>2</sup></p> <p><b>Non-product-related grants or other forms of funding</b></p> <p>Allowed if between now and three years ago, with the restriction that the person must not be involved in activities relating to products of the company that provided the grant or other form of funding.<sup>1</sup></p> <p>Allowed if between three and five years ago, with the restriction that only participation in discussions is allowed. Participation is prohibited in the final deliberation and voting relating to products of the company that provided the grant or other form of funding.<sup>2</sup></p>

<b>Partner, children aged under 18 and other persons living at the same address</b>	<b>Prohibited:</b> <ul style="list-style-type: none"> <li>• Financial interest of type 1</li> <li>• Patent ownership</li> </ul>	During membership of the MEB or while working for the MEB.
	<b>Allowed with restrictions:</b> <ul style="list-style-type: none"> <li>• Financial interest of type 2</li> <li>• Employee</li> <li>• Consultancy (general and specific)</li> <li>• Strategic advice (general and specific)</li> <li>• Principal investigator</li> <li>• Investigator</li> <li>• Grant or other form of funding</li> </ul>	If the interest generates 'direct personal financial rewards', the Board member, employee or external expert must not be involved in procedures concerning products of the company in question or in specific products.

### General rule

Staff may never assess research or requests that they have worked on themselves. Board members may never take part in discussions, voting or final deliberations about research or requests that they have worked on themselves.

<sup>1</sup> No participation of any kind in procedures relating to the product is permitted, including as a result of mandated decisions. Exceptions to this are mandated decisions without discretionary authority. 'Without discretionary authority' means the staff member is not able to weigh up options and merely checks the formal requirements.

<sup>2</sup> Only members of the Board take part in the final deliberation and voting as defined in the Code of Conduct. This restriction does not apply to mandated decisions. This restriction is therefore not applicable to MEB employees and external experts.

**Table 2b: Interests with associated restrictions for Young MEB members and external experts**

<b>Direct interest</b>	<b>Prohibited</b> <ul style="list-style-type: none"> <li>- Employee</li> <li>- Consultancy: general or for multiple products</li> <li>- Strategic advice: general or for multiple products</li> <li>- Financial interest (types 1 and 2)</li> <li>- Patent ownership</li> </ul>	<b>During</b> the membership period of Young MEB/the work carried out for the MEB.
	<b>Allowed with restrictions:</b> <ul style="list-style-type: none"> <li>- Employee</li> <li>- Consultancy: general, for multiple products</li> <li>- Strategic advice: general, for multiple products or product-specific</li> </ul>	Allowed if between <b>now and five years ago</b> , with the restriction that only participation in discussions is allowed; participation in the final deliberation and voting relating to products of the company in question is prohibited.
	<b>Allowed with restrictions:</b> <ul style="list-style-type: none"> <li>- Consultancy: product-specific</li> <li>- Strategic advice: product-specific</li> </ul>	<b>During</b> the period of membership of Young MEB/the work carried out for the MEB, this results in the following restriction: the person may not be involved in activities relating to the product in question.
<b>Indirect interest</b>	<b>Permitted:</b> <ul style="list-style-type: none"> <li>- Investigator</li> <li>- Grants or other forms of funding for an institute</li> </ul>	Permitted <b>during</b> the membership period of Young MEB/the work carried out for the MEB; does not result in restrictions.
	<b>Allowed with restrictions:</b> <ul style="list-style-type: none"> <li>- Principal investigator</li> </ul>	<b>During</b> the period of membership of Young MEB/the work carried out for the MEB, this results in the following restriction: the person may take part in discussions, but may not be involved in the final deliberations and voting relating to the product.
<b>Partner, children aged under 18 and other persons living at the same address</b>	<b>Permitted</b> <ul style="list-style-type: none"> <li>- Financial interest of type 1</li> <li>- Patent ownership</li> <li>- Financial interest of type 2</li> <li>- Employee</li> <li>- Consultancy</li> <li>- Strategic advice</li> <li>- Principal investigator</li> <li>- Investigator</li> <li>- Grant or other form of funding</li> </ul>	Permitted <b>during</b> the membership period of Young MEB/the work carried out for the MEB; does not result in restrictions.

**General rule**

External experts may never assess research or requests that they have worked on themselves.

Young MEB members may never take part in discussions, voting or final deliberations about research or requests that they have worked on themselves.

## Definitions

### Direct interests:

- Employee of a company
- Consultancy (general and specific)
- Strategic advice activities (general and specific)
- Financial interests
- Patent ownership

### Indirect interests:

- Principal investigator
- Investigator
- Grant or other form of funding

**Employee:** Any person who has an employment relationship with a company (as defined below), regardless of the remuneration. There is an employment relationship if the company has authority over the activities of the person in question.

**Company:** a company that has an interest in the activities of the MEB, such as pharmaceutical companies, manufacturers of medical aids with supporting pharmaceutical components, manufacturers of novel foods, contract manufacturing organisations, parallel importers and Contract Research Organisations (CROs)<sup>3</sup>.

**Consultancy (general and specific):** an activity in which the person in question provides the company with advice or services regardless of the contractual relationship or whether there is any form of remuneration. This does not include scientific advice given in the course of performing a task for the MEB.

#### Consultancy (general):

This is not directly related to individual products or it is related to multiple products in one or more therapeutic fields.

#### Consultancy (specific):

This is related to individual products within one or more therapeutic fields (even if the development of the product was discontinued and did not result in a commercialised product).

A position as employee of a company that carries out consultancy work, such as consultancy firms, medical writing agencies and contract research organisations, should be reported as an employee of a company.

---

<sup>3</sup> The policy for CROs is that CROs can be a company as defined in the Code of Conduct. The deciding factor for determining whether a CRO is a company is whether it carries out research for a specific pharmaceutical company and whether the staff member is closely involved in work for a specific company.

**Strategic advice activities:** This should be interpreted as the participation by the person in question (with the right to vote or able to influence the outcome) in a scientific or other advisory committee or advisory council with the aim of providing advice or opinions concerning the current or future strategy, direction and development of a company's operations in terms of the general or product-related strategy, regardless of the contractual relationship or remuneration.

Strategic advice (general):

The advice is not directly related to individual products.

Strategic advice (specific):

The advice is related to individual products.

It should be noted that:

- Data monitoring committees (made up of independent external experts who evaluate non-blinded clinical trial data independently of the sponsor) are not covered by this definition. Participation in such committees is treated in the same way as being a principal investigator.
- Involvement in research by companies is considered as an indirect interest, in the same way as being a principal investigator or investigator.

### Financial interest

There are two different types:

- Type 1: possession of shares in or ownership of a company, except for independently managed investment funds and pension funds that are not exclusively based on these companies or a combination of these companies.
- Type 2: bonuses, remuneration, fees and salaries that are paid by companies directly to the person in question other than payments in connection with expenditure on research or the reimbursement of reasonable costs incurred in attending conferences or seminars (for example, travel and accommodation expenses). Financial interests of type 2 include patents owned by the institution for which the person in question works, such as a university, if that patent generates direct personal financial rewards.

**Patent ownership:** This relates to patents for medicines, or products or techniques related to medicines, which are currently owned by the person in question. See the definition of a type 2 financial interest for patents owned by the institution for which the person in question works, such as a university.

**Principal investigator:** This is a person with responsibility for the coordination of investigators in different centres participating in a multicentre trial, or a person who is the

leading investigator in a *mono-centre* trial, or a person signing the clinical trial research report.\*

**Investigator:** This is a person involved at a clinical trial at a specific trial site. This could be the responsible investigator for a trial at a specific trial site or a member of a research team who performs important trial-related procedures or tasks and takes important trial-related decisions.\*

\* The restrictions in Table 1 regarding an interest as a principal investigator or investigator only apply to research that is sponsored by a company (see the definition of a company). This does not alter the fact that all positions as principal investigator or investigator should be declared for the purpose of transparency.

### Grant or other form of funding

There are two possibilities:

- An organisation for which the person works (e.g. a university) receives a grant or other form of funding (e.g. sponsorship of a chair) from a company for research and the person in question does not receive any personal benefits.
- An organisation (e.g. a patient organisation) receives a grant or other form of funding from a company for work other than research and the person in question does not receive any personal benefits (regardless of whether the person has been hired by the organisation or does voluntary work and represents the organisation).

Both possible kinds of grant only apply to grants or other forms of funding that are made under the authority or responsibility of the person and to grants or other forms of funding that generate some kind of benefit, such as funding for his/her doctoral research or research equipment required by him/her.

Table 1 shows the restrictions to which grants and other forms of funding are subject. An explanation of these restrictions is given below:

Product-related grants or other forms of funding are subject to the restriction that the person must not be involved in activities relating to products of the company that provided the grant or funding, or activities relating to rival products to the product to which the grant or funding applies.

In the case of grants or other forms of funding that are not related to a product, the person must not be involved in activities relating to products of the company that provided the grant or funding but is allowed to be involved in activities relating to products of the company's competitors.

One of the standard sentences below can be used and adapted to the individual situation in the case of the interests of an organisation the person in question works for:

- In my capacity of director/head of an institute/institution/department/faculty, i.e. [institute name etc.], I am responsible for a large number of staff. The

institute/institution/department/faculty collaborates in various fields with a variety of companies that have an interest in the tasks of the MEB, but we are not dependent on a limited number of companies for our funding. Staff at the institute/institution/department/faculty receive grants or other forms of funding from companies that have an interest in the tasks of the MEB. I do not receive any personal benefits from these companies. If I should become more closely involved in specific funding than simply in my capacity as director/head of an institute/institution/department/faculty, for example as principal investigator, I will declare such involvement in this declaration form.

**Novel foods:** foodstuffs or food ingredients that were not used for human consumption to a significant degree in the European Community before 15 May 1997 and that fall within the following categories: 1) foodstuffs and food ingredients with a new or intentionally modified primary molecular structure; 2) foodstuffs and food ingredients consisting of or isolated from micro-organisms, fungi or algae; 3) foodstuffs and food ingredients consisting of or isolated from plants, and food ingredients isolated from animals, except for foodstuffs and food ingredients obtained by traditional propagating or breeding practices and having a long history of food use; 4) foodstuffs and food ingredients that have undergone a rarely used production process, if this process gives rise to changes in the composition or structure of the foodstuffs and food ingredients that significantly affect their nutritional value, their metabolism or their level of undesirable substances. Products used as additives or flavourings in foodstuffs, or as an extraction solvent in the production, are not considered novel foods. Foodstuffs consisting of or produced with genetically modified organisms were originally included under the Novel Foods Regulation, but a separate regulation (1829/2003/EC) has applied since September 2003. This is the [definition to be found on the MEB website](#).

**Specific rival product:** This is a product that competes with a product for which the person in question was responsible or in which the person had an involvement. There is deemed to be competition if the product is used for the same medical indication and target group (e.g. treatment, prevention or diagnosis of a certain condition) and therefore constitutes a potential commercial rival product.

**Partner:** This is at any rate the spouse, the individual with whom the person in question has a cohabitation contract or the individual with whom the person in question has a long-term relationship, but can also include other individuals who could be considered analogous to the aforementioned people.

**Discussion, final deliberation and voting:** Three possible stages can be distinguished in the decision-making process: the discussion, the final deliberation and the voting. The discussion is followed by a final deliberation when the chairman asks the Board members to clarify their position one last time, before, where applicable, taking a vote. A restriction regarding the discussion and/or final deliberation and voting does not mean the person in question has to leave the room; he/she simply does not take part in the discussion and/or final deliberation and voting, where applicable.

## Declaration of interests

This is an example of a Declaration of Interests. In practice, the form is filled in electronically. The questions and sections in this example are the same as the questions and sections in the digital form.

Verklaring van belangen	
<p>Op de Verklaring van belangen zijn de definities uit de Gedragscode van het CBG van toepassing. De Gedragscode is gepubliceerd op de website van het CBG: <a href="http://www.cbg-meb.nl/over-cbg/inhoud/onafhankelijkheid-en-integriteit">http://www.cbg-meb.nl/over-cbg/inhoud/onafhankelijkheid-en-integriteit</a></p> <p>Algemene vragen over de Verklaring van belangen kunt u sturen aan <a href="mailto:DienstpostbushRM@cbg-meb.nl">DienstpostbushRM@cbg-meb.nl</a>. Inhoudelijke vragen over de Verklaring van belangen of de Gedragscode kunt u sturen aan <a href="mailto:BBR@cbg-meb.nl">BBR@cbg-meb.nl</a>.</p> <p>Het formulier kan tussentijds worden opgeslagen om het invullen op een ander moment te hervatten. Onderaan de vragenlijst kunt u via de knop "tussentijds opstaan" uw formulier bewaren. Als u vervolgens uw e-mailadres invult, ontvangt u per mail instructies hoe u uw formulier weer kunt openen.</p>	
<b>Reden voor invulling van dit formulier</b>	
Maak uw keuze	<input checked="" type="radio"/> Ik werk reeds voor het CBG en vul de Verklaring van belangen opnieuw in <input type="radio"/> Ik ben sollicitant <input type="radio"/> Ik ben externe expert
<b>Algemeen</b>	
Titel(s)	<input type="radio"/> Dhr. <input type="radio"/> Mevr.
Voornaam *	<input type="text"/>
Tussenvoegsels	<input type="text"/>
Achternaam *	<input type="text"/>
Afdeling (Voor externe experts, wilt u aangeven voor welke afdeling van het CBG u werkt) *	<input type="text"/>
Functienaam *	<input type="text"/>
Bekleedt u andere posities die relevant zijn voor het CBG en die niet vallen onder hetgeen u hieronder moet melden?	<input type="text"/>
<b>Melding van belangen op farmaceutisch gebied</b>	
<b>WERKNEEMER</b>	
Bent u momenteel, of was u in de laatste 5 jaar, werknemer van een bedrijf dat belang heeft bij de taken van het CBG?	<input checked="" type="radio"/> Ja <input type="radio"/> Nee
<p>Met werknemer wordt bedoeld: elke persoon die een arbeidsverhouding heeft met een bedrijf ongeacht de vergoeding. Een arbeidsverhouding bestaat als het bedrijf gezag heeft over de activiteiten van de persoon.</p> <p>Met bedrijf wordt bedoeld: een bedrijf dat belang heeft bij de taken van het CBG, zoals farmaceutische bedrijven, producenten van medische hulpmiddelen met ondersteunende farmaceutische stof, nieuwe voedingsmiddelen industrie, loonfabrikanten, parallelimporteurs en Contract Research Organisations (CRO's). *</p> <p><i>U wordt verzocht om hieronder een specificatie te geven. U kunt meerdere activiteiten melden door 'volgende' aan te vinken. Begint u met de met de recentste.</i></p> <p>Bij welk bedrijf bent of was u werkzaam?</p> <p>Welke periode betreft dit? Van <input type="text"/> dd-mm-jjjj Tot <input type="text"/> dd-mm-jjjj</p> <p>Wat voor werkzaamheden verricht of verrichtte u voor dit bedrijf? Indien uw functienaam uw werkzaamheden voldoende omschrijft, geef dan uw functie.</p> <p>Bij welke producten bent of was u betrokken?</p> <p>Wat zijn de indicaties van deze producten?</p> <p>Volgende..... <input type="radio"/> Ja <input type="radio"/> Nee</p>	
<b>CONSULTANCY</b>	
Verricht of verrichtte u consultancy, of heeft u de laatste 5 jaar consultancy verricht, voor bedrijven die belang hebben bij de taken van het CBG?	<input checked="" type="radio"/> Ja <input type="radio"/> Nee
<p>Met consultancy wordt bedoeld elke activiteit waarbij de persoon een bedrijf voorziet van diensten ongeacht de contractuele relatie of enige vorm van vergoeding. Dit heeft geen betrekking op wetenschappelijk advies dat is gegeven in de uitoefening van een taak voor het CBG.</p> <p>Met bedrijf wordt bedoeld: een bedrijf dat belang heeft bij de taken van het CBG, zoals farmaceutische bedrijven, producenten van medische hulpmiddelen met ondersteunende farmaceutische stof, nieuwe voedingsmiddelen industrie, loonfabrikanten en parallelimporteurs. *</p> <p><i>U wordt verzocht om hieronder een specificatie te geven. U kunt meerdere activiteiten melden door 'volgende' aan te vinken. Begint u met de met de recentste.</i></p> <p>Voor welk bedrijf verricht of verrichtte u consultancy?</p> <p>Welke periode betreft dit? Van <input type="text"/> dd-mm-jjjj Tot <input type="text"/> dd-mm-jjjj</p> <p>Welke werkzaamheden verricht of verrichtte u?</p> <p>Is of was de consultancy product gerelateerd? <input checked="" type="radio"/> Ja <input type="radio"/> Nee</p> <p>Welke producten zijn dit?</p> <p>Wat zijn de indicaties van deze producten?</p> <p>Indien een vergoeding wordt of werd verstrekt voor de consultancy, ten behoeve van wie komt of kwam die vergoeding? Bijvoorbeeld ontvangst of ontving u de vergoeding persoonlijk of werd de vergoeding verstrekt aan een instituut waaraan u verbonden bent of was.</p> <p>Volgende..... <input type="radio"/> Ja <input type="radio"/> Nee</p>	
<b>KLINISCH ONDERZOEK</b>	
<b>Hoofdonderzoeker</b>	
Bent u momenteel, of was u in de laatste 5 jaar, als hoofdonderzoeker betrokken bij één of meer klinische studies?	<input checked="" type="radio"/> Ja <input type="radio"/> Nee
<p>Met hoofdonderzoek wordt bedoeld de persoon met de verantwoordelijkheid voor de coördinatie van onderzoekers in andere centra die participeren in een multicenter studie of</p>	

<input type="radio"/> Nee	
Hierboven is gevraagd naar werkzaamheden en financiering van de laatste 5 jaar. Zijn er vergelijkbare belangen die langer dan 5 jaar geleden zijn geëindigd, maar die uw werkzaamheden voor het CBG nog steeds kunnen beïnvloeden? Kunt u dit toelichten?	<input type="radio"/> Ja <input type="radio"/> Nee
<b>Heeft u een financieel belang in een bedrijf?</b> Met financieel belang wordt bedoeld: Financieel belang type 1: bezit van aandelen in of eigendom van een bedrijf, uitgezonderd onafhankelijk bestuurd beleggings- en pensioenfondsen die niet exclusief gebaseerd zijn op deze bedrijven of een combinatie van deze bedrijven. Financieel belang type 2: beloningen, vergoedingen, honoraria, salarissen, die door bedrijven direct worden betaald aan de persoon anders dan betalingen in verband met uitgaven voor onderzoekswerk of vergoeding van redelijke kosten in verband met het bijwonen van conferenties of seminars (bijv. reis- en verblijfkosten). Onder financieel belang type 2 wordt begrepen een patent in eigendom van de instelling waaraan de persoon verbonden is, zoals een universiteit, indien het patent direct persoonlijk financieel gewin oplevert. U hoeft alleen financiële belangen te melden die u momenteel heeft, of gedurende uw werkzaamheden voor het CBG heeft/had. Met een bedrijf wordt bedoeld een bedrijf dat belang heeft bij de taken van het CBG, zoals farmaceutische bedrijven, producenten van medische hulpmiddelen met ondersteunende farmaceutische stof, nieuwe voedingsmiddelen industrie, loonfabrikanten en parallelimporteurs. * Wat voor belang betreft dit en welk bedrijf is daarbij betrokken?	<input type="radio"/> Ja <input type="radio"/> Nee
Bent u, of is een instelling (afdeling) waaraan u verbonden bent, eigenaar van een octrooi (patent) waarbij u enigermate persoonlijk voordeel heeft? *	<input type="radio"/> Ja <input type="radio"/> Nee
Welk product betreft dit?	 
<b>Overige</b>	
Heeft een van de volgende personen • uw partner • kinderen <18 jaar • personen die op hetzelfde adres wonen als u huidige 'belangen' vergelijkbaar met hetgeen hierboven aan u is gevraagd? *	<input type="radio"/> Ja <input type="radio"/> Nee
Toelichting	 
Heeft u andere mogelijke belangen waardoor uw onafhankelijkheid wordt beïnvloed, of zijn er andere gegevens waarvan het CBG en het publiek naar uw mening op de hoogte moeten zijn? Bijvoorbeeld heeft u lezingen verzorgd waarvoor aan u, of aan het instituut waaraan u verbonden bent, een vergoeding is verstrekt? *	<input type="radio"/> Ja <input type="radio"/> Nee
Toelichting	 
Bent u ambtenaar van het ministerie van Volksgezondheid, Welzijn en Sport? *	<input type="radio"/> Ja <input type="radio"/> Nee
Ik verklaar dit formulier naar eer en geweten te hebben ingevuld. Ik zal wijzigingen ten aanzien van mijn belangen direct melden aan het CBG. Ook ben ik bekend met de Gedragscode van het CBG. [7]	<input type="checkbox"/> Ja
Naam: *	<input type="text"/>
E-mail *	<input type="text"/>
Plaats en datum: *	<input type="text"/>

\* = Invoer verplicht

### **Section 3: Confidentiality and discretion**

The MEB may have to deal with conflicting duties. On the one hand there is the duty to make documents accessible to the public and on the other hand there is the duty to respect the confidentiality of the information that the MEB has under its management in its function as an administrative body. The access to information is subject to limits set by national and European legislation for the protection of commercially and privacy sensitive data.

#### **Duty of confidentiality**

Confidentiality is an essential aspect of the relations between the MEB, the EU, other government bodies and companies. The Board members, the members of Young MEB and some other committees, employees and external experts have access to commercially confidential information and sign a statement of confidentiality. They are required in all cases to observe their duty of confidentiality, both at work and elsewhere.

Everyone should observe caution when answering questions so that they do not provide information that is not publicly known. Confidentiality also applies when discussing professional activities with third parties, including family and friends, and with colleagues or third parties in a public setting such as public transport. Before giving information, these people must first ascertain the identity of the person requesting the information. Questions should be submitted in writing where possible. Everyone should be on the alert for indirect questions that are being used to obtain information.

If anyone has any doubts about whether information can be provided, advice should be sought from an MEB manager, chairman or contact.

Everyone is required to act with integrity and observe confidentiality after leaving the MEB. People who leave the MEB are free to use the skills acquired during their work for the MEB as long as this does not violate their obligation to uphold confidentiality. This is meant in particular to prevent a breach of confidentiality that could damage the interests of the MEB, the EU, other government bodies, and applicants or holders of marketing authorisations for launching products on the market. People who leave the MEB will be reminded of the statement of confidentiality they signed.

#### **The public's right to access information**

The public has access to documents pursuant to the Government Information (Public Access) Act. According to the rules laid down in this and other legislation, requests for information can only be refused if that information concerns personal policy views or is confidential because the information can be traced to an individual or because of purely commercial interests.

Once a document or information has been made public, the duty of confidentiality ceases, but only for the information that has been released into the public domain.

## Statement of confidentiality

The MEB is charged with assessing medicines, novel foods and medical aids with supporting pharmaceutical components. In doing this, the MEB acquires confidential information.

Persons who work for the MEB, such as employees, Board members and external experts, must treat this information with the utmost care and confidentiality. This follows from Article 2:5 of the General Administrative Law Act. To safeguard this confidentiality, persons who could acquire confidential information through the MEB must sign the statement of confidentiality once.

The undersigned hereby declares that:

1. the undersigned accepts the general duty to uphold the confidentiality of the information. That information can consist of data, documents, written materials, notes, computer files, photographs, conversations, work instructions, visual observations, etc. Third parties will not be given the opportunity to learn of this information. There is no duty of confidentiality for the documents and information that are in, or have come into, the public domain;
2. information that is no longer being used will be archived or destroyed in a careful manner so that the confidentiality is safeguarded;
3. the undersigned will take care when answering questions. The undersigned will ensure that requests for information are submitted in writing where possible and will ascertain the identity of the applicant before providing information. If there is any doubt about whether information can be provided, the line manager will be asked for advice and they will if necessary consult the integrity coordinators at the MEB itself. If there is no manager at the MEB, advice will be requested from the contact at the MEB. This contact will at least raise the question with the departmental head responsible, who will if necessary consult the integrity coordinators at the MEB itself.
4. information acquired through work for the MEB will not be used for purposes other than work for the MEB unless the MEB has given permission for this;
5. the undersigned knows that non-compliance with this statement can result in measures in terms of legal status or other measures;
6. the undersigned will uphold the duties arising from this statement of confidentiality, including after the termination of the work for the MEB, with the exception of information for which it can be proved that the undersigned was aware of it before signing this statement or previous versions of this statement.

The undersigned,

Name:

Position:

Signature:

Town/city:

Date:

## Section 4: Invitations and gifts

MEB staff, including Board members, Young MEB members and external experts, must be impartial and independent. Accepting invitations and gifts could affect that impartiality and independence. It is also important to prevent giving the impression of being open to influence. That is why MEB staff are required to comply with the MEB Code of Conduct.

Three aspects are important in this section of the Code of Conduct.

Firstly, this section of the Code of Conduct only applies to invitations and gifts offered in the context of work for the MEB.<sup>4</sup>

Secondly, in principle this section of the Code of Conduct only applies to invitations and gifts offered to the MEB staff member and not to invitations and gifts offered to his/her partner, etc. However, if an invitation or gift is offered to the partner etc. because of their relationship to the MEB member of staff, then the acceptance of this invitation or gift is also prohibited.

Thirdly, this section of the Code of Conduct distinguishes on the one hand between invitations to events together with gifts and on the other hand invitations to external activities for the MEB.

Violations of the Code of Conduct can be reported to the MEB manager or confidential counsellor or the confidential counsellor at the Ministry of Health, Welfare and Sport; see page 2 of the Code of Conduct.

### Gifts and invitations to events

'Gifts' include all presents, gratuities and favours. 'Invitations to events' are invitations to events that are primarily recreational in character (e.g. sporting events).

Gifts or invitations to events must not be accepted. This includes gifts 'in thanks' for giving speeches, talks, etc. It does not matter who is offering the gift or invitation. The prohibition applies to all gifts or invitations from all companies, institutions, organisations, etc., regardless of whether they have an interest in the tasks of the MEB. To prevent a gift being offered, staff can indicate beforehand that gifts cannot be accepted.

In the unlikely event of any gift or invitation being accepted (for example, because to refuse the gift on site would be impolite), it must be reported to the head of department; Board members should report the gift or invitation to the chairman. The head of department or chairman will decide what should be done with the invitation or gift. The guideline here is the policy of the Ministry of Health, Welfare and Sport.

---

<sup>4</sup>Activities associated with the gift may need to be reported under the conflicts of interest rules in the relevant section of the Code of Conduct.

When carrying out work for the MEB, it is forbidden to use objects carrying the logo of a company that has an interest in the tasks of the MEB (such as pharmaceutical companies, manufacturers of medical aids with supporting pharmaceutical components, manufacturers of novel foods, consultancy firms and umbrella organisations).

The occasional refreshment or meal is allowed.

It is appropriate in some situations to offer a gift on behalf of the MEB, for example for external speakers at meetings organised by the MEB or for interns who have completed their internship with the MEB. The gifts must not exceed 50 euros in value and must be given for a clear reason, such as a talk or internship. Management support staff in the PGR department must be notified by e-mail of any gift that is to be given, with specification of the person giving the gift, the recipient, the value and the reason for the gift.

### **Accepting invitations for external activities**

'External activities' refers to activities that cover the same area as the tasks of the MEB but take place outside the confines of the MEB, such as publications, lectures, attending conferences, meetings and talks on subjects that the MEB is involved with.

#### *Acceptability*

The origin of the invitation is a determining factor in whether or not it can be accepted. Every invitation must be raised with the head of department and if necessary with the PRI department. Invitations from national governmental authorities, governmental authorities in the European Union and non-profit institutions and organisations can generally be accepted. Invitations from commercial organisations and pharmaceutical companies must not be accepted in general, unless this external activity is a suitable forum for communicating the policy and/or objectives of the MEB or the Ministry of Health, Welfare and Sport. Permission is required from the chairman, director or head of department before an invitation from such organisations may be accepted.

If a topic arises during an external activity that relates to the MEB, the staff member must avoid acting in contravention of the interests of the MEB and the government.

### **Reimbursement of expenses**

The Medicines Evaluation Board (hereinafter the "Board") has adopted the VWS Bestuurskostenbeleid (Administrative Costs Policy of the Ministry of Health, Welfare and Sport, as determined in December 2014).<sup>5</sup> As a result of that policy, the Board covers the costs of certain external activities.

The VWS Policy Memorandum is used for the reimbursement of the costs of congresses and working visits. Working visits, work conferences, expert meetings etc. are deemed to be 'normal work' and are not covered by the VWS Policy Memorandum. The costs for this can be reimbursed via the organiser.

---

<sup>5</sup> For more information, please see the VWS procedure for reporting integrity violations in the [brochure 'Kan dit?'](#) (Is this OK?).

With the exception of invitations from European governmental bodies or international cooperative links in an EU context or otherwise where the costs are already covered (via the EU Commission or jointly), the Board always pays the costs of congresses, symposia and the like, irrespective of whether someone attends the whole event or only part of it and irrespective of whether they are giving an introduction (which can be interpreted as stating a message).

If the costs of the external activity can be reimbursed by the organising party, the remuneration for any costs that may have been paid in advance must always be repaid directly to the Board. Payments must never be made directly to the staff member.

Payments for external activities must always be made to the MEB, regardless of whether these activities take place during or outside of working hours. The remuneration should be paid to the MEB via the Finance, Quality and Control department.

The chairman, director or head of department must be consulted beforehand concerning all aspects of an external activity where there are doubts, for example regarding the payment or what statements are permissible.

#### **Accolades and honours**

If a staff member is offered an accolade or honour by an organisation or company that has an interest in the tasks of the MEB, prior permission must be obtained from the MEB Board. If permission cannot be obtained in advance and the accolade or honour cannot be rejected (for example, because this would be impolite), the accolade or honour must be reported to the MEB management afterwards. It will decide what should be done with the accolade or honour.

#### **External activities that are not carried out on behalf of the MEB**

For external activities that are not on behalf of the MEB, please refer to Appendix 1 of this Code of Conduct.

#### **Evaluating the policy**

The policy concerning invitations and gifts is evaluated at least once every five years on the initiative of the PRI department.

## Section 5: Use of facilities and resources

MEB staff are expected to treat facilities and resources such as computers or phones with due care. These resources may only be used for the purposes for which they have been made available. This also covers using financial resources with due care – economically and efficiently.

In line with the “Kan dit?” brochure from VWS, the following basic rules apply to personal use of operational resources:<sup>6</sup>

- MEB staff may not use business resources for personal ends, except on an incidental basis;
- The work must not suffer as a result.

The business resources may be used on occasion for personal matters if there are no alternatives. It is however forbidden to use the Internet to enter personal commitments (such as booking a trip).

If a member of staff has any doubts, they should discuss it with their colleagues and/or manager.

---

<sup>6</sup> For more information, please see the VWS procedure for reporting integrity violations in the [brochure ‘Kan dit?’](#) (Is this OK?).

## **Appendix 1: External activities by members of the Board (and staff) that are *not carried out on behalf of the MEB***

### **1. Introduction**

The MEB Code of Conduct and Integrity Policy covers activities that are carried out *on behalf of the MEB* in the following sections:

- Section 1 (correct administrative conduct),
- Section 3 (confidentiality and discretion),
- Section 4 (invitations and gifts) and
- Section 5 (use of facilities and resources).

Section 2 (conflicts of interest), however, applies in *all* cases, i.e. both for work that is done on behalf of the MEB and work that is not.

Members of the Board and MEB staff may also be invited to give presentations etc. other than in their capacity as a Board member or MEB Agency staff member, for example as a professor or physician. They are then **not acting on behalf of** the MEB and Section 4 of the Code of Conduct does not therefore apply. Such invitations may be issued by inter alia pharmaceutical companies, congress offices and further education organisations, with or without sponsoring by pharmaceutical companies. There is no policy for this yet. Experience shows that there is a need for clear agreements, with the aim of allowing issues to be weighed up properly without imposing too many restrictions on the activities that people carry out other than on behalf of the MEB.

This memorandum is an addendum to Section 4 of the Code of Conduct, applicable to situations where there is an external activity that the Board member or member of staff is not involved in on behalf of the MEB.

It must remain clear that Section 2 of the Code of Conduct will continue to apply at all times and under all circumstances: if the activity results in an interest in the sense of the Code of Conduct, for example a type 2 financial interest (whereby the member of staff or Board member receives payment, remuneration, fees or a salary that is paid directly to them by a company as defined in the Code of Conduct), then this may entail restrictions.

### **2. Points for attention and a decision tree for activities that are not on behalf of the MEB**

The present Code of Conduct is limited to invitations to external activities that are carried out *on behalf of* the MEB. The following points focus on activities that are carried out *other than in the capacity of Board member or MEB Agency staff member*.

In a way that is partly analogous to the Code of Conduct for Advertising Medicines issued by the Medicines Advertising Code Foundation ([Stichting Code Geneesmiddelenreclame](#)), members of the Board and MEB Agency staff are recommended to take the following into account when accepting invitations to activities (e.g. giving presentations):

1. the services provided and the rewards for them are defined in writing in an agreement (e.g. by e-mail, but not solely verbally) that clearly describes the objectives and the execution of the service that is to be provided,
2. the remuneration – irrespective of whether it is monetary or in kind – must be reasonably proportionate to the work carried out,
3. the event must take place at a suitable location, and
4. the expenses paid should ideally benefit the institution – e.g. a university, hospital or society – for which the Board member or MEB staff member works (in addition to the MEB). If the reimbursement of expenses is nevertheless assigned to the individual, Section 2 of the Code of Conduct applies and the activity must be notified (as it may potentially lead to restrictions).

It is the responsibility of the Board member or staff member to implement these aspects. There are no checks by the MEB either beforehand or afterwards.

With an eye on transparency, Board members and staff are encouraged to report all activities in the annual Declaration of Interests, including the activities they carry out that are not on behalf of the MEB. Given that it is not feasible to notify *all* activities carried out that are not on behalf of the MEB, determining whether something should or should not be notified can be done using the following decision tree.

**Decision tree for whether activities that are not carried out on behalf of the MEB should be notified**

Definitions:

- Activity: an activity in the public arena related to medicinal products (e.g. giving a lecture, presentation or interview or taking part in a panel) other than in the capacity of Board member or MEB staff member.
- Company: a company that has an interest in the activities of the MEB, such as pharmaceutical companies, manufacturers of medical aids with supporting pharmaceutical components, manufacturers of novel foods, contract manufacturing organisations and parallel importers (the same as the definition from the Code of Conduct).

1. Is it an activity according to the definition given above?  
*Yes:* continue with Section 2.  
*No:* no action needed.
  
2. Is the activity on the initiative of and/or directly financed by a company (as defined above)?  
*Yes:* state it on the Declaration of Interests in the section for activities that are not carried out on behalf of the MEB.  
*No:* no action needed.

If activities need to be notified at any interim point or if there are any questions, the PRI department can be contacted at any time.