SPECIFICATION OF COLLABORATION SITUATIONS

APPENDIX TO AGREEMENT ON COLLABORATION REGULATIONS FOR THE PUBLICLY FINANCED HEALTHCARE, THE PHARMACEUTICAL INDUSTRY, THE MEDICAL DEVICES INDUSTRY AND THE LABORATORY DEVICES INDUSTRY

The agreement on collaboration regulations is a policy signed by the parties with guiding principles and regulations of a long-term nature, which make up the basic conditions for the collaboration.

As support for more ongoing collaboration the parties have developed this appendix with specific collaboration situations, which the parties update continuously for the greatest possible relevance. The present version is published on the websites of the respective parties and is integrated where necessary in their own ethical regulatory frameworks.

Both the agreement and appendix govern the collaboration between healthcare and industry.

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1) Specific information and actions with the purpose of ensuring correct use and function

a) Service information for medical devices and IVD companies

By Service information the parties refer to the statutory obligation under the EU's regulations for medical devices (MDR, 2017/745) and in vitro diagnostic medical devices (IVDR, 2017/746), to provide information where a product specialist instructs on patient safety and correct use of the product, and follow up of the product's use. The information is provided for products that have already been procured or purchased in some other way by healthcare and also apply to product updates and replacement products.

Service information refers to instructions and advice about daily operation and management of medical device products, and follow up on the use of these, on the unit where they are used or will be used.

The information must be given to the employees that need it for safety or for use. The information is given during working hours and at the workplace and must be based on legal requirements as well as the needs and demands of healthcare. Deviations from this must be well motivated and be possible to record, for example equipment that is too heavy to be moved, simulator operations or training at special training centres or similar situations that make adequate training in the normal work place impossible.

The service information and its follow up must benefit healthcare employees in their daily work. Companies must not designate information or visit service information with the aim of marketing products other than those already purchased. Neither may they be used to allow financing of other collaborations or meetings. This is especially important to observe if the service information is given outside the workplace.

In addition to what is stated in the procurement contract, whoever provides the service information is responsible for all relevant costs so that the service information can be implemented. In such cases this must be in line with overall principles of the collaboration regulations.

Provision of service information is not affected by ongoing purchasing processes.

b) Risk minimising information (RMI) for pharmaceutical companies

Risk minimizing information (RMI) refers to the information that holders of marketing permission are liable to communicate to healthcare employees (or patients via healthcare employees) according to conditions of the product's approval (2001/83/EG) or those imposed after approval because of safety signals that have arisen.

RMI is intended to ensure correct and safe use of a medicine and is described in the product's risk management plan.

RMI is based on patient safety aspects and is given to the employees that for safety and usage reasons need to use it. The information is given during working time and in the workplace. Deviations from this must be well motivated and be noted.

Companies may not market affected products and/or other products in conjunction with visits or meetings titled as RMI. Neither does RMI mean financing of other collaborations or meetings. This is especially important to observe if the information is given outside the workplace.

In addition to what is stated in any procurement contracts the company may bear all relevant costs for the RMI to be implemented, however in line with the guiding principles of these regulations.

Provision of RMI is not affected by ongoing purchasing processes.

2) Product information

A meeting regarding product information must give participants current and relevant information about characteristics, functions and use of specific medicines or medical and laboratory devices. For medical and laboratory devices, product information is provided when it refers to products that have not been procured or are used in a medicinal capacity and that have not yet been used in healthcare, that is to say an activity with the purpose of marketing.

The invitation is sent to relevant employees, the main target group for the meeting, with a copy to the Operations manager or their representative.

The invitation must state the content, duration and, if possible, time and place. The title must state that it regards product information. The design of the invitation must make it clear that the information is not product neutral.

Product information should preferably be provided to groups of employees at their workplace and during working hours.

3) Other meetings

Other meetings refer to different forms of competence development, for example therapy-oriented training, seminars, scientific meetings, congresses and symposia.

The employer has the responsibility for the continued training and competence development of employees and must bear the cost of participation in such activities.

The different main types of meetings are described below (a, b, c) after which more detailed regulations for them are specified.

Contents: industry may only offer meetings and sponsorship of events that have a connection to the company's own area of operations. The scientific and vocational program must make up the dominant part and the purpose of the relevant meeting.

Costs: industry may contribute to costs for premises, lecturers, study material, modest meals and similar that are necessary for the implementation of the meeting.

Travel and accommodation: may not be paid for by industry or requested by individual participants. Booking of Travel and accommodation may be arranged by industry. If booking and payment is carried out by industry the participants must be invoiced by the company for the full amount. For meetings in accordance with c) below neither booking of hotels nor travel may be done.

Remuneration: participants in meetings must not be offered remuneration by the company and the participants do not have the right to accept or request remuneration for their participation.

a) Meetings arranged by industry

Type example: a therapy meeting that industry finances itself or by participant fees, healthcare participants pay for their own travel and accommodation.

Industry can arrange, pay for and act as consignor of meetings aimed primarily at healthcare employees.

Invitation: the invitation is sent to relevant employees, the main target group for the meeting, with a copy to the Operations manager.

Pharmaceutical companies shall also send a copy of the invitation for information to the relevant Pharmaceutical committees. Medical device companies must, if relevant, send a copy to the affected medical device managers.

In event of open advertising of physical meetings in print or online media directed at a larger target group, the invitation procedure above need not be followed. The same applies for remote participation in such meetings or remote participation in other meetings that are aimed at larger target groups. Type example: A large training event, congress or symposium that is advertised in medical trade journals or the online versions and that all affected employees can be assumed to have access to.

The invitation should contain the purpose and content, the duration of the planned meeting, the location, the costs that the company may stand for and any side arrangements.

If there will be product information it must be clearly stated in the invitation.

Meeting place: the meeting will normally be arranged at the participant's workplace or in the same place that the participant's workplace is situated, or as a close to that location as possible, unless special reasons motivate otherwise.

b) Meetings co-arranged by healthcare and industry

Type example: meeting arranged by healthcare, including its professions, and industry where the parties share the cost and responsibility.

Industry can in collaborations with healthcare part pay for and stand as consignor of meetings aimed primarily at healthcare employees.

No sponsorship situation is present because all parties are arrangers.

Meeting place, invitation procedure and content: Same regulations as 3a) above.

Both parties are expected to contribute to the implementation of the meeting. Common costs that are necessary for implementing the meeting are split between the parties, that is premises, lecturer, study material, modest meals and similar. Healthcare stands for the costs for their own employees, such as for example internal lecturer, course secretary and similar.

c) Meetings arranged by healthcare or third parties

Type example: meeting arranged by or on behalf of healthcare or a professional body that organises employees within healthcare.

Income from sponsorship may only cover actual, documented, reasonable and direct costs. Who is sponsoring must be communicated in good time before the meeting.

Sponsorship of meetings where the meal is the only actual cost may not be requested or offered.

Sponsorship of internal healthcare activities may not occur, for example a single operation's training, planning conference or employees party. Neither should such sponsorship be offered or requested.

Healthcare stands for the costs for their own employees, such as for example internal lecturer, course secretary and similar.

At a request for sponsorship the arranger must provide a complete budget for the activity as decision making documentation, where all costs are specified. Within three months of the completed activity the budget must be followed up and the financial results reported for the affected sponsors, including exhibitors. When the sponsorship income is equal to the costs, a simple written communication stating that this is the case is sufficient. If the sponsorship income generates a surplus there should be repayment to the sponsors.

4) Consultation and assignment for industry

Employees and management within healthcare often make important contributions to different activities, for example research, training, conferences, product development and advisory boards.

Collaboration is normally a work assignment. If the assignment is a consultancy it should be regarded as a secondary occupation. In those circumstances the secondary occupation regulations shall be applied.

The assignment must be agreed in writing between the employee, the employee's employer and the company. At a public sector employer the agreement is a public document. Remuneration for work carried out must be in reasonable proportion to the work carried out and the time spent. In addition to covering the cost of travel, food and accommodation no other remuneration, benefits or gifts should occur. Remuneration for assignments within work must be paid to the employer.

In the agreement the consultant must, in relevant situations such as for assignments for the authorities or expert bodies, be encouraged to be transparent about the assignment and include it in the relevant declaration of interest.

Participating in an advisory board is an assignment where industry engages and remunerates employees in healthcare to give independent advice and contribute knowledge within a specific area where the knowledge cannot be obtained within the company and the company intends to take action from the information obtained.

An advisory board thereby makes up a small group with a few participants and the number of employees appointed shall not be larger than is necessary to achieve the identified objective. The selection criteria when choosing employees must be based on the identified need and responsible persons from industry must have the experience required to be able to evaluate whether a particular person within healthcare meets the requirements.

An advisory board is an activity that must not be intended to influence participants.

5) Scholarships

Industry may finance scholarships that are intended for healthcare. A scholarship is awarded after nomination to a person or persons to promote a certain objective. Companies shall only give scholarships within an area that has a connection to the company's own operations.

The scholarship shall be professionally developmental in nature, for example future training and research or similar and must give added value to healthcare. Selection criteria, purpose,

scholarship committee, reason for selection of the scholarship and scholarship donor must be public and transparent.

The donor of the scholarship must obtain the approval of the scholarship recipient's employer. The scholarship must not be remuneration for work on the behalf of the employer.

Scholarships in the form of travel or participation in a congress must not be given to healthcare employees to get around the intentions of these collaboration regulations.

6) Donations

Donations may not be given to internal healthcare activities or normal operations. Industry donations must never be requested or offered to finance social activities.

Industry donations to healthcare may only be given to Research and Development (R&D) and on the conditions that the donation is transparent, well documented, and in accordance with this agreement and its intentions.

However, donations may not in any way be connected to earlier, present, or potential future use, recommendation, sales or order of the donor's products or services.

7) Development projects where healthcare and pharmaceutical companies collaborate

The collaboration between healthcare and pharmaceutical companies can have different appearances and different purposes.

Development projects refer to collaborations in project form around areas and subjects with a natural connection to the operations areas of the parties involved. Development projects may not be started with the purpose of financing or in any other way supporting the normal operations of healthcare.

Project proposals regarding the development project must be sent to the Operations manager who informs any relevant agencies. An agreement that regulates the project's contents and scope must always be signed. A development project must not be a personal assignment with a single person, the agreement must be made between the pharmaceutical company and a unit within healthcare.

The agreement may not mean exclusivity for the pharmaceutical company to make agreements about collaborations with one or more units within healthcare. The agreement must make the respective roles and responsibilities of healthcare and industry clear (for example regarding management of personal data, patient responsibility and how the results of a development project may be used).

Both healthcare and the company must contribute to the project with resources such as financial support, materials and/or working hours. The division between the parties' contributions must be balanced. Healthcare must always bear the costs of its own administration associated with the project, for example employees' time or travel within the framework of the development project.

There must be a detailed project plan that can also regulate how the project is to be evaluated and how the experiences are to be collated and distributed/made public. A budget must always be set.

The project must be time limited (as a rule max. 1 year) and not be longer or more extensive than is necessary to achieve the purpose of the project. The project must be completed after the project time.

The collaboration must be recorded openly, for pharmaceutical companies that means that it must be entered in the Läkemedelsindustriföreningen's collaboration database.

Activities that are not defined as development projects in these regulations are:

- collaborations to develop commercial products for companies. Such projects must be carried out within the framework of a consultancy agreement,
- offers of treatment connected to a company's medicine through agreements or procurement are regulated within the framework of normal business operations, at central regional or national level to maintain fair competition. Examples of areas are arranged introduction and examples of products and services that can be covered are tests, diagnostics or advanced patient support programs.

8) Reference customer

A reference customer is a unit within healthcare where medical devices, services and treatment methods are available to customers and interested parties with the purpose of developing and spreading knowledge about products or service's function in daily operation.

In order for a company to be able to give a unit as a reference customer, an agreement that regulates all parts of the relationship must be drawn up between the parties. The agreement must state in what way the company may use the reference customer for marketing purposes.

9) Market research

Market research are surveys, interviews and focus groups with different objectives and arrangements and may only have the purpose of obtaining information, opinions and attitudes. The research may not be aimed at affecting the respondent or creating sales contacts. When companies covered by these collaboration regulations carry out market research, the person carrying out the research must follow the ethical guidelines for market research in accordance with ICC/ESOMAR.

Requests to participate in market research may only be made via e-mail or letter unless otherwise agreed in individual cases.

The proportion of respondents may not exceed the number necessary to achieve reasonable safety in the results. The respondents' responses must be handled with strict confidentiality and in accordance with applicable data protection legislation.

Remuneration for participants must not exceed what is reasonable in relation to the time expended. For rapidly executed market research via telephone or surveys no or only symbolic remuneration should be paid. For more time demanding market research, for example with in-depth interviews, remuneration corresponding to the loss of time may be paid, although at a maximum of 2.5 percent of the applicable price base amount/KPI.

The respondent is responsible for obtaining their employer's approval. For financial remuneration for participation in market research that is related to their work, the employer's approval must always be obtained.