

## Form for disclosure of potential conflicts of interest<sup>1</sup>

for

### collaboration in early benefit assessments of drugs according to §35a Social Code Book V

According to §139b para 3 Social Code Book V, this form covers all connections to **companies, institutions and interest groups** in the health care system, in particular to **pharmaceutical companies, manufacturers of medical devices and industrial interest groups**.

Details on what relevance the information provided has for the Institute, and how this information is dealt with, are explained on the IQWiG website: “Frequently asked questions about the ‘Form for disclosure of potential conflicts of interest’” (see <https://www.iqwig.de/en/participation/conflicts-of-interest/frequently-asked-questions-about-the-form-for-disclosure-of-potential-conflicts-of-interest.3307.html>).

In this form, 7 questions are asked on different types of connections. If you have no such connection, please tick “No”. Otherwise, please provide a full list of connections for each question and – if required by the respective question – the amount of any remuneration. When describing a connection, please fill in all columns in the corresponding table, or if you cannot fill in a field, provide an explanation. If you need additional space, you may add additional pages. If you complete this form on screen as a PDF file, you can add as many lines to the tables as you need.

According to §139b para 3 Social Code Book V, whoever collaborates in the Institute’s projects must disclose ALL connections to the companies, institutions and interest groups named above. **Please therefore disclose ALL connections for the questions, even if in your opinion this connection does not create a conflict of interest (except for question 7, see there).** False or incomplete answers can lead to exclusion from an application process or to the termination of a contract.

The details of your disclosure are confidential. This information is only viewed by employees involved in the inspection and evaluation process. In addition, the disclosure forms part of the contract if a contract is concluded.

If you become involved in the preparation of an early benefit assessment, a summarized form of the details you provide, as well as your name, and, if appropriate, the name of the institution you work for, will be published on the IQWiG website. In this context, for questions 1 to 7 it is merely summarized whether this type of connection exists or not. Specific cooperation partners or the amount of payments are not stated.

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<sup>1</sup> This is the translation of the German document “Formblatt zur Offenlegung potenzieller Interessenkonflikte” (Status: 11/2016). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

**Project (no. and name):**

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**Task (please tick):**

- ☐ Collaboration in an early benefit assessment (as a medical expert)
- ☐ Collaboration in an early benefit assessment (as a patient or other person affected who is involved in discussions about patient-relevant outcomes)

**Contact information:**

Title and name:

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Institution:

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Address:

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E-mail address:

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Telephone number should queries arise:

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**Question 1: Employment / self-employed activities / voluntary activities**

Are you or have you been, within this year and the last three calendar years, employed by or, on a self-employed or voluntary basis, working for

a **company, an institution or an interest group** in the health care system, in particular a **pharmaceutical company, a manufacturer of medical devices or an industrial interest group**

or are you or have you been working on a self-employed basis in an independent practice?

(The institutions named above also include hospitals, self-government bodies, professional societies, contract organizations, for example.)

- ☐ Yes (if yes, please provide details in the following table)  
☐ No

If yes, please add the following details

Company etc.	From (month/year)	To (month/year)	Position	Employed/ self- employed/ voluntary

**Question 2: Consulting relationships**

Are you or have you been, within this year and the last three calendar years, directly or indirectly advising

a **company, an institution or an interest group** in the health care system, in particular a **pharmaceutical company, a manufacturer of medical devices or an industrial interest group**

(e.g. as a reviewer, an expert, a member of an advisory board, of a Data Safety Monitoring Board (DSMB) or of a steering committee)?

- ☐ Yes (if yes, please provide details in the following table)  
☐ No

If yes, please add the following details (separately for each company and consulting topic)

Company etc.	Consulting topic	Period	Total sum of payments

**Supplementary question:**

Have you **ever** directly or indirectly advised the **company affected** by the benefit assessment in connection with the **preclinical or clinical development of the drug to be assessed**?

- ☐ Yes  
☐ No

If yes, please also add details on activities that you were involved in more than three years ago in the table above.

**Question 3: Fees**

Have you, within this year and the last three calendar years, directly or indirectly received fees from

a **company, an institution or an interest group** in the health care system, in particular from a **pharmaceutical company, a manufacturer of medical devices or an industrial interest group**

(e.g. for talks, trainings, comments or articles)?

- ☐ Yes (if yes, please provide details in the following table)  
☐ No

If yes, please add the following details (separately for each company)

Company etc.	Type of activity	Topic	Date/period of activity	Total sum of payments

**Supplementary question:**

Have you **ever** received fees for talks, comments or articles from the **company affected** by the benefit assessment in connection with the **preclinical or clinical development of the product to be assessed**?

- ☐ Yes  
☐ No

If yes, please also add details on activities that you were involved in more than three years ago in the table above.

**Question 4: Third-party funds**

Have you or the institutions you have listed in question 1, within this year and the last three calendar years, received financial support, e.g. for research work, clinical studies, other scientific services or patent applications from

a **company, an institution or an interest group** in the health care system, in particular from a **pharmaceutical company, a manufacturer of medical devices or an industrial interest group**?

(If you work in a large institution, it is sufficient to relate the required information to your working unit, e.g. hospital department, research group.)

- ☐ Yes (if yes, please provide details in the following table)  
☐ No

If yes, please add the following details (separately for each company and project topic)

Company etc.	Project type	Project topic	Period	Total sum of third-party funds	Recipient: personal/institution

**Supplementary question:**

Apart from any employment or advisory function, have you personally **ever** received financial support for research work, other scientific services or patent applications **from the company affected** by the benefit assessment in connection with the **preclinical or clinical development of the product to be assessed**?

- ☐ Yes  
☐ No

If yes, please also add details on activities that you were involved in more than three years ago in the table above.

**Question 5: Other support**

Have you or the institutions you have listed in question 1 received, within this year and the last three calendar years, any other financial remuneration or payment in kind (e.g. equipment, staff, support for the organization of meetings, reimbursement of travel expenses or registration fees for trainings/conferences) from

a **company, an institution or an interest group** in the health care system, in particular from a **pharmaceutical company, a manufacturer of medical devices or an industrial interest group**?

(If you work in a large institution, it is sufficient to relate the required information to your working unit, e.g. hospital department, research group.)

- ☐ Yes (if yes, please provide details in the following table)  
☐ No

If yes, please add the following details (separately for each company etc.)

Company etc.	Type of support	Period	Sum	Recipient: personal/ institution

**Question 6: Stocks, shares, patents, utility models**

Do you possess stocks, options or other shares from a **company or other type of institution** in the health care system, **in particular from a pharmaceutical company or a manufacturer of medical devices**?

Do you possess shares in a “sector-specific fund” that is targeted towards pharmaceutical companies or manufacturers of medical devices?

Do you possess patents for a pharmaceutical product or a medical device, or a medical method or a utility model for a pharmaceutical product or a medical device?

- ☐ Yes (if yes, please provide details in the following table)  
☐ No

If yes, please add the following details (separately for each type of share/fund/patent/utility model etc.)

Share/fund/patent/utility model	Current value



**Question 7: Other**

Are you or have you ever been involved in the production of a

- guideline or
- study

with a topic similar to this project?

Are there any other circumstances that, from the point of view of an impartial observer, may be assessed as conflict of interest (e.g. activities in health-related interest groups or self-help groups, political, academic, scientific or personal interests)?

- ☐ Yes (if yes, please provide details in the following table)
- ☐ No

If yes, please list them


I hereby confirm with my signature that I have truthfully and completely provided these details.

I consent to the above-mentioned details being published in the corresponding product, which is accessible on the IQWiG website and forwarded to the Bonn University and State Library and to the German National Library, in a summarized form together with my name. “Summarized form” means that the answers to the questions of this form will be published as “yes” or “no”, but without stating the specific details (including the amount of remuneration/fees).

The names of patients or other people affected who are involved in discussions about patient-relevant outcomes are only published after their explicit consent (separate form).

Beyond this, the details provided will not be published.

\_\_\_\_\_  
(Place, date)

\_\_\_\_\_  
(Signature)