

Standard declaration of interests (DOI) form for individuals applying to be appointed as members or experts of Scientific Committees and their Working Groups in a personal capacity

Legal basis:

Commission Decision C(2015)5383 on establishing Scientific Committees in the field of public health, consumer safety and the environment, Article 16, and Commission Decision C(2016)3301 establishing horizontal rules on the creation and operation of Commission expert groups, Articles 2(4) and 11.

Definitions:

"Conflict of interest" means any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest when providing advice to the Commission in relation to the subject of the work performed by the Scientific Committees and their working groups in question.

"Immediate family member" means the individual's spouse, children and parents. "Spouse" includes a partner with whom the individual has a registered non marital regime. "Children" means the child(ren) the individual and the spouse have in common, the own child(ren) of the individual and the own child(ren) of the spouse.

"Legal entity" means any commercial business, industry association, consultancy, research institution or other enterprise whose funding is significantly derived from commercial sources. It also includes independent own commercial businesses, law offices, consultancies or similar.

"Body" means a governmental, international or non-profit organisation.

"Meeting" includes a series or cycle of meetings.

Please answer each of the questions below. If the answer to any of the questions is "yes", please briefly describe relevant interests and circumstances, as appropriate.

If you do not describe relevant interests, your DOI form will be considered incomplete and, therefore, your application to be appointed as a member of an expert group or subgroup in a personal capacity shall be rejected.

First name:	Tanja
Family name:	Schmidt
Expert group/sub-group:	SCHEER WG on Guidance document for benefit -risk assessment of Phthalates in Medical Devices

1 EMPLOYMENT CONSULTANCY AND LEGAL REPRESENTATION

<i>Within the past 5 years, were you employed or have you had any other professional relationship with a natural or legal entity, or held any non-remunerated post in a legal entity or other body with an interest in the field of activity of the Scientific Committees and their working groups in question?</i>	yes	no
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1a	Employment	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1b	Consultancy, including services as an advisor	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1c	Non-remunerated post	<input type="checkbox"/>	<input type="checkbox"/>
1d	Legal representation	<input type="checkbox"/>	<input type="checkbox"/>

Activity	Time period (from... until month/year)	Name of entity or body	Description
1a) Professor Biomedical Engineering	10/2010 – 02/2019 (ongoing)	University of Applied Sciences – Hochschule Ansbach, Ansbach, Germany	Teaching areas: Diagnostic Systems, Therapeutic Systems, Biostatistics, Anatomy, Physiology
1b) Consultant Regulatory affairs in medical devices	01/2004 – 02/2019 (ongoing)	Self-Employed	Regulatory affairs Clinical Evaluations Planning and analysis of clinical trials Benefit-Risk-Analysis HTA assessments Biocompatibility analysis Systematic literature reviews sponsored by multiple legal manufacturers

2 MEMBERSHIP OF MANAGING BODY, SCIENTIFIC ADVISORY BODY OR EQUIVALENT STRUCTURE

	<i>Within the past 5 years, have you participated in the internal decision-making of a legal entity or other body with an interest in the field of activity of the Scientific Committees and their working groups in question or have you participated in the works of a Scientific Advisory Body with voting rights on the outputs of that entity?</i>	yes	no
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2a	Participation in a decision-making process	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2b	Participation in the work of a Scientific Advisory Body	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Activity	Time period (from... until month/year)	Name of legal entity or body	Description

3 RESEARCH SUPPORT

	<i>Within the past 5 years, have you, or the research entity to which you belong, received any support from a legal entity or other body with an interest in the field of activity of the Scientific Committees and their working groups in question?</i>	yes	no
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3a	Research support, including grants, rents, sponsorships, fellowships, non-monetary support	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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Activity	Time period (from... until month/year)	Name of legal entity or body	Description

4 FINANCIAL INTERESTS

	<i>Do you have current investments in a legal entity with an interest in the field of activity of the Scientific Committees and their working groups in question, including holding of stocks and shares, and which amounts to more than 10,000 EUR per legal entity or entitling you to a voting right of 5% or more in such legal entity?</i>	yes	no
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4a	Shares	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4b	Other stock	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Investment	Name of legal entity	Description

5 INTELLECTUAL PROPERTY

	<i>Do you have any intellectual property rights that might be affected by the outcome of the work carried out by the Scientific Committees and their working groups in question?</i>	yes	no
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5a	Patent, trademarks, or copyrights	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5b	Others	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Intellectual property	Description

7b	<i>If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in the DOI and to provide them with the privacy statement attached to the guidance for filling in this DOI, and this at the latest when you file the DOI form with the Commission.</i>
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8 OTHER RELEVANT INFORMATION yes no

8a	<i>Are there any other elements that could be seen as undermining your independence when providing advice to the Commission in the field of activity of the Scientific Committees and their working groups in question?</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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Description:

I hereby declare on my honour that I have read the guidance for completing this form. I also declare on my honour that the information disclosed in this form is true and complete to the best of my knowledge.

Should there be any change to the above information, including as regards upcoming activities, I will promptly notify the competent Commission department and complete a new DOI form describing the changes in question.

I am informed that my personal data are stored, processed and published by the Commission in accordance with Regulation (EC) N° 45/2001.

Date: 14/02/2019

Signature:

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Your DOI form shall be made publicly available on the Register of Commission Expert Groups and Other Similar Entities, as long as you are appointed as member of the expert group or sub-group in a personal capacity. Technical measures will be taken to indicate to search engines that your DOI form should not appear in search results.