



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public Declaration of Interests and Confidentiality Undertaking of
European Medicines Agency (EMA),
Scientific Committee members and experts

Public declaration of interests

I, **Gert Laekeman**

Organisation/Company: Catholic University of Leuven

Country: Belgium

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

No Interest Declared

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2.7 Grant / Funding to organisation /institution

No interest declared

2.8 Close family member interest

No interest declared

2.9 Repurposing of a medicinal product

No interest declared

2.10 Any other interests or facts

The Organisation I was employed by occasionally receives unrestricted grants from pharmaceutical companies. These grants are used by my collaborators for scientific grounds. I do not receive any personal gain. I am retired since October 2016, and do not have responsibilities in the organisation any more.

I participated in a continuous education programme for community pharmacists (available to all pharmacists in Belgium) on new oral anticoagulants, dealing with this new therapeutic class of medicines and focusing on the role of community pharmacists in risk management activities (RMA) with dabigatran as an example. The company involved was Boehringer Ingelheim (period: July 2012).

Past interests

From January 2003 to October 2009: co-investigator of a clinical trial on a combination product used as an OTC-medicine in Belgian community pharmacies. Involved pharmaceutical companies: Pfizer Consumer Healthcare & Johnson-Johnson Consumer Health Care. Product name: Sinutab[®] (paracetamol 500 mg + pseudoephedrine 30 mg). The therapeutic indication was headache and nasal congestion in case of cough and cold.

From January 2016 on, I was involved as co-investigator in a clinical safety study with pregnant patients, taking a food supplement containing an extract of ginger for intestinal comfort. This study is conducted in our university hospital. I did not receive any personal benefit related to this study. Reporting on this study was finalised in March 2017.

2.11 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality as long as the information or document has not been made public/is not in the public domain.

Classified as public by the European Medicines Agency

- Not to disclose (or authorise any other person to disclose) in any way to any third party any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.
- When expressing views to clearly indicate that the views are my own if acting in my own capacity or those of the EMA, Committee, Working Party, Expert Group or other group if acting on behalf that group.
- Not to disclose any commercially confidential information.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

Full Name:	LAEKEMAN Gert
Date:	2021-12-09

For Definitions of activities etc, refer to Policy on Handling of competing interests / Electronic DOI template