

**PERSONAL INFORMATION** Karen Van Malderen**WORK EXPERIENCE**

- May 2017–Present **Belgian delegate at Paediatric Committee (PDCO); Chair of the PDCO Non-Clinical Working Group**  
European Medicines Agency (United Kingdom)
- July 2011–Present **Non-Clinical Assessor**  
Federal Agency for Medicines and Health Products (Belgium)
  - Evaluation of the non-clinical efficacy and safety data of human medicinal products for the purpose of marketing authorizations, clinical trials, scientific advice and paediatric investigation plans.
  - Member of the Non-Clinical Working Group of the Paediatric Committee (PDCO)
- January 2008–June 2012 **Member of the Committee for Risk Assessment (RAC)**  
European Chemicals Agency (Finland)
  - Preparing opinions related to the risks of chemicals to human health and the environment within the framework of the REACH and CLP Regulations
- August 2008–June 2011 **Team leader REACH**  
Federal Public Service for Health, Food Chain Safety and Environment (Belgium)
  - Regulatory toxicology in the framework of Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
  - Coordination and people management of the team responsible for the implementation of the REACH legislation at the Belgian Federal level.
- August 2005–July 2008 **Expert Risk Assessment of Chemicals**  
Federal Public Service for Health, Food Chain Safety and Environment (Belgium)
  - Risk assessment of chemicals within the framework of Dir. 67/548/EEC and ESR 793/93
  - Belgian delegate at the European Technical Committee on New and Existing Substances (TCNES) (JRC, Arona)

**EDUCATION AND TRAINING**

- 2000–2005 **MSc Pharmaceutical Sciences**  
VUB Brussels (Belgium)  
Chemistry, Toxicology, Pharmacology
- 2010–2015 **MSc Applied Toxicology**  
University of Surrey (United Kingdom)  
Toxicology

**ADDITIONAL INFORMATION**

- Expertise** More than 10 years of experience in regulatory toxicology and safety assessment in the field of chemicals and pharmaceuticals. European Registered Toxicologist since 2012. Focus on Paediatric Toxicology.
- Publications** Co-author of:

- o De Fays L, Van Malderen K, De Smet K, Sawchik J, Verlinden V, Hamdani J, Dogné J, and Dan B (2015) Use of paracetamol during pregnancy and child neurological development. *Developmental Medicine & Child Neurology*, volume 57(8):718-724.
- o J. Stewart, W. J. Breslin, B. K. Beyer, K. Chadwick, L. De Schaepdrijver, M. Desai, B. Enright, W. Foster, J. Y. Hui, G. J. Moffat, B. Tornesi, K. Van Malderen, L. Wiesner, and C. L. Chen (2015) Birth Control in Clinical Trials: Industry Survey of Current Use Practices, Governance, and Monitoring. *Therapeutic Innovation & Regulatory Science*
- o Stage II evaluation of the environmental risk assessment for Cadmium and Cadmium Oxide, May 2008.  
[http://esis.jrc.ec.europa.eu/doc/risk\\_assessment/ADDENDUM/cdmetal\\_cdoxide\\_add\\_303.pdf](http://esis.jrc.ec.europa.eu/doc/risk_assessment/ADDENDUM/cdmetal_cdoxide_add_303.pdf)
- o REACH restriction proposal for Dimethylfumarate (DMFu), March 2011.  
[http://echa.europa.eu/documents/10162/13641/seac\\_opinion\\_dmfu\\_en.pdf](http://echa.europa.eu/documents/10162/13641/seac_opinion_dmfu_en.pdf)
- o CLP harmonized classification proposal for Polyhexamethylene biguanide (PHMB), September 2011.  
<http://echa.europa.eu/documents/10162/13579/OPINION+OF+THE+COMMITTEE+FOR+RISK+ASSESSMENT+PHMB>
- o CLP harmonized classification proposal for Aluminium Phosphide, December 2011.  
[http://echa.europa.eu/documents/10162/13626/opinion\\_for\\_aluminium\\_phosphide\\_adopted\\_final\\_en.pdf](http://echa.europa.eu/documents/10162/13626/opinion_for_aluminium_phosphide_adopted_final_en.pdf)
- o CLP harmonized classification proposal for 4-vinylcyclohexene (VCH), September 2012.  
[http://echa.europa.eu/documents/10162/13579/rac\\_clh\\_opinion\\_vch\\_en.pdf](http://echa.europa.eu/documents/10162/13579/rac_clh_opinion_vch_en.pdf)

#### Projects

#### Memberships

- Member of the Non-Clinical Working Group of the PDCO since 2012.
- Alternate member of the Paediatric Committee (PDCO) since 2017.
- European Registered Toxicologist.
- Member of the Belgian Society of Toxicology.

#### Other Relevant Information