Workshop on benefit-risk of medicines used during pregnancy and breastfeeding

Date: 22 September 2020
Time: 12.30 – 17.45 (CEST)
Virtual meeting

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Background

Medicine use in pregnancy is common for treating acute as well as chronic disorders. This includes use while the woman does not yet know she is pregnant, and treatments for conditions that can be pregnancy-specific, worsened by pregnancy, or require continued medication during pregnancy. In Europe, very few medicines are licensed explicitly for use in pregnancy and breastfeeding. This is due to the limited understanding of benefits and risks to mother and child and how they should be balanced.

It is EMA's ambition that in the medium- to long term, women should have sufficient information, provided appropriately, to enable decision making on their medical treatment, given their (plans for) pregnancy or given they wish to breastfeed their baby.
The PCWP and HCPWP would like to provide an opportunity for their members and the wider stakeholder community to contribute towards developing and implementing EMA's strategy for developing better information regarding benefits and risks of medicines in pregnancy and breastfeeding, and to encourage a discussion on how to progress towards obtaining evidence on medicine utilisation and safety for this population.

The workshop will be broadcast live on EMA's website. You can follow the broadcast by clicking on the 'multimedia' tab on the event page on the day of the event. We will ask for audience participation using an interactive polling platform, through which participants will be asked their views on a range of issues around this topic.

Objectives

- Share experiences and expectations from real life and clinical practice;
- Provide input into the draft EMA strategy on drug safety in pregnancy and breastfeeding;
- Discuss how to progress with implementing the EMA strategy towards obtaining evidence on medicine utilisation and safety for pregnant and breastfeeding women.

Agenda – Workshop on benefit-risk of medicines used during pregnancy and breastfeeding

Multi-stakeholder meeting with the EMA Patient and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

22 September 2020, 12.30 – 17.45, Virtual meeting

12:30	***Connection to virtual room and technical checks***
12:45	Welcome and introduction, *Guido Rasi, Executive Director, EMA* Workshop objectives, *Juan Garcia Burgos, EMA* Opening remarks, *Kaisa Immonen, PCWP/Ulrich Jaeger, HCPWP*
13:00	Introduction to Sli.do, *Juan Garcia Burgos, EMA/Corinne de Vries, EMA*

SESSION 1: An EMA strategy towards inclusion of pregnant and breastfeeding women in medicines research and development

Chair: Kaisa Immonen, PCWP

13:10	Problem statement and strategy outline, *Corinne de Vries, EMA*
13:20	The information gap: addressing the information need of medicines use in pregnancy and breastfeeding, *Hildrun Sundseth, EIWH*
13:30	Treating pregnant and breastfeeding women: the reality of clinical practice, *Paul Ryan, ICGP/UEMO*
13:40	***Structured plenary discussion on strategy***
14:35	Session summary, *Kaisa Immonen, PCWP*
14:40	***Break***

SESSION 2: Safe use of medicines in pregnant and breastfeeding women

Chair: Sabine Straus, PRAC

14:50	How pharmacovigilance guidelines are addressing this special population, *Ulla Wändel Liminga, PRAC*
15:05	***Structured plenary discussion on risk minimisation***
16:00	Assessing benefit-risk for medicines in pregnancy: research & infrastructure development, *Miriam Sturkenboom, UMC Utrecht*
16:15	Session summary, *Sabine Straus, PRAC*

SESSION 3: How to achieve a paradigm shift in clinical research and practice

Chair: Ulrich Jaeger, HCPWP

16:25	Challenges and opportunities, *Helen Dolk, EUROmediCAT*
16:40	***Structured plenary discussion on implementing change***
17:25	Session summary, *Ulrich Jaeger, HCPWP*
17:30	Concluding remarks and next steps, *Juan Garcia Burgos, EMA*
17:45	***End of meeting***

Practical information

- Please note the entire workshop will be broadcast live and recorded; no prior registration to follow the broadcast is required.
- Participation in the virtual meeting room has been subject to prior application and places have been distributed among different stakeholders on the basis of their EU-wide representation and/or expressed motivation to contribute to the discussion.
- The workshop recording will be published afterwards on the EMA website, together with the workshop report.
- At certain points throughout the discussions, the audience will be able to give their input on Sli.do. Please go to www.slido.com and enter the event code "PregnancyEMAWorkshop". During the Sli.do interaction you may opt to remain anonymous; for more information on data protection considerations that apply to the use of Sli.do please refer to their privacy policy on www.sli.do/terms#privacy-policy
- For more information on data protection considerations that apply to EMA meetings and events please refer to our privacy statement on www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-organisation-meetings-events_en.pdf
- Should you have any questions, please contact us via: Public-Engagement@ema.europa.eu