Article 58 procedure

What is Article 58?

- EMA assessment of quality, safety and efficacy of a medicine or vaccine intended for use only outside the EU;
- Evaluation carried out in collaboration with WHO and relevant non-EU regulatory authorities;
- Licensing decision taken by non-EU regulators in countries where the medicine or vaccine will be used;
- Same standards and procedures as for medicines marketed in the EU.

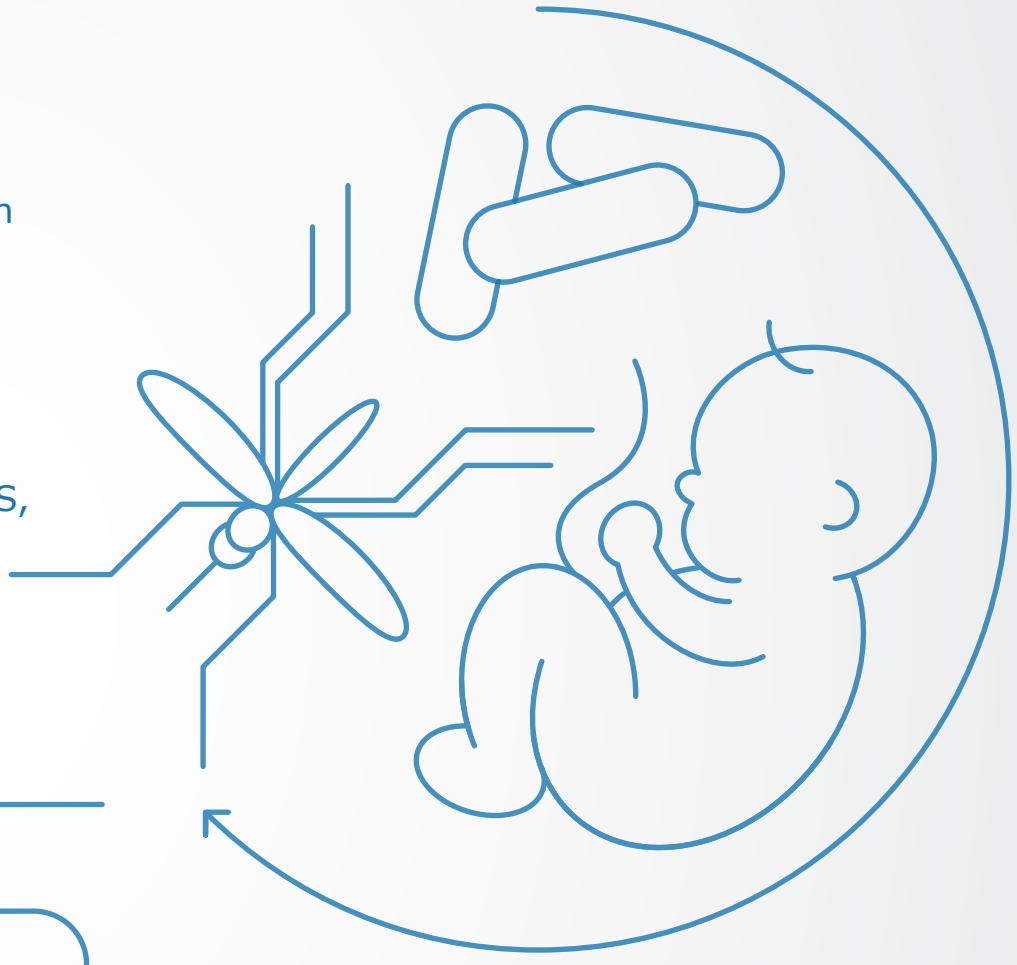
Outcomes 2005–2016

Umbipro: umbilical cord infection treatment;
Mosquirix: malaria vaccine;
Pyramax: malaria treatment;
Hemoprostol: post-partum haemorrhage treatment;
Alluvia, **Lamivudine ViiV**, **Lamivudine/ Zidovudine ViiV**: HIV treatments;
Hexaxim, **Tritanrix HB**: combination vaccines against childhood diseases.

Which medicines are eligible?

Vaccines or medicines used to prevent or treat public health priority diseases:

- Vaccines used in the WHO Expanded Programme on Immunization;
- Medicines for protection against diseases, such as HIV/AIDS, malaria and tuberculosis;
- Medicines for maternal and newborn healthcare.



What is the process?

Company requests eligibility for Article 58

Company submits application for scientific review to EMA

Scientific assessment carried out in collaboration with WHO and non-EU regulators

EMA adopts scientific opinion

After the opinion

- WHO may include the medicine or vaccine in public health recommendations;
- Companies can use EMA's opinion to support marketing authorisation applications to regulators in non-EU countries;
- Companies are required to implement risk management plans and follow-up measures;
- EMA can perform a benefit-risk review at any time if new safety information becomes available.