



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



# Supporting regulatory science outside the EU

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## The Article 58 procedure



## What is the “Article 58” procedure?

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- EMA, through its scientific committees, can carry out scientific assessments and give opinions, in co-operation with the WHO, on medicines for human use that are intended exclusively for use outside the EU. When assessing these medicines, the same rigorous standards as for medicines intended for patients in the EU applies.
- This procedure allows access to essential medicines for countries with limited regulatory capacity for assessing new medicinal products for their markets.
- Medicines eligible for this procedure, which is derived from Article 58 of the Agency’s founding regulation, are used to prevent or treat diseases of major public health interest. This includes vaccines used in the WHO Expanded Programme on Immunization, or for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria, or tuberculosis.

## **Support for capacity building in low-and-middle-income countries (LMICs) through the "Article 58 procedure"<sup>1</sup>**

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- Responds to the need to protect public health and to give scientific assistance to non-EU member countries in the context of cooperation with WHO;
- Allows rapid access to important new medicinal products targeting diseases such as HIV/AIDS, malaria, tuberculosis;
- Involves non-EU regulators in specific scientific discussions;
- Provides supports for relevant WHO projects through the European regulatory network;
- Pool of scientific expertise available through EMA's scientific committees and expert network;
- Helps to understand the challenges of developing products for diseases primarily of low-and-middle-income countries.

### **Which products are eligible?**

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Includes but is not limited to:

- Vaccines that are or could be used in the WHO Expanded Program on Immunization (EPI);
- Vaccines for protection against a WHO public health priority diseases;
- Vaccines that are part of a WHO-managed stockpile for emergency response;
- Medicinal products for WHO target diseases such as HIV/AIDS, malaria and tuberculosis.

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<sup>1</sup> Article 58 of Regulation (EC) No. 726/2004

## CHMP Article 58 scientific opinion process



\*NRA: National Regulatory Authority

## What is the difference between an Article 58 and a centralised assessment?

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The same rigorous assessment process applies within the CHMP. However because the product is targeted for a non-EU population, the risks and benefits in that population will be assessed.

The possibility to involve experts and observers appointed by WHO or by a national regulatory authority with knowledge and experience of the endemic disease and/or local regulatory environment means that the assessment can be better targeted to the real needs of the patient populations.

The outcome of the Article 58 procedure is a scientific opinion that can be used by local regulators.

## Outcomes to date

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Medicines to treat HIV (**Alluvia, Lamivudine ViiV Lamivudine / Zidovudine ViiV**); combined Vaccines to combat diseases such as diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b (**Hexaxim, Tritranix HB**); Post-Partum Haemorrhage (**Hemoprostol**), Malaria (**Pyramax**) have all received positive opinions and most are now available in disease endemic countries.

A number of other exciting medicines for diseases that are often neglected are in the Article 58 pipeline.



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## Resources on the Agency's website

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Human Regulatory > Article 58 applications

## Further information

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