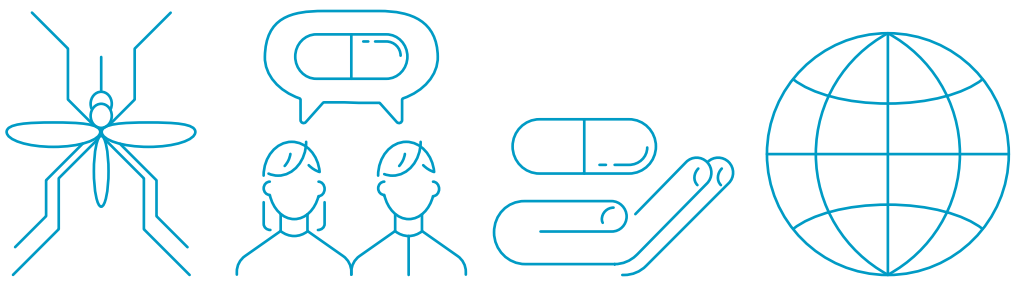
EMA

Medicines for use outside the EU *— EU-M4all

Promoting the development of medicines and vaccines for patients in low- and middle-income countries outside the European Union (EU)

How does it work?



- EMA assesses innovative or generic medicines and vaccines that address unmet medical needs or are of major public health interest, for use outside the EU;
- EMA evaluates the medicine in collaboration with the World Health Organization (WHO) and the relevant non-EU authorities, in the context of its use in the target population;
- Experts carry out a robust scientific evaluation and the medicines are required to meet the same high standards as medicines marketed in the EU;
- National regulators take the decision on whether or not to use the medicine or vaccine in their country.

What are the benefits?

EU-M4all combines EMA's scientific review capabilities with the epidemiology and disease expertise of WHO, experts and national regulators in the target countries, to promote the development of high-priority medicines.

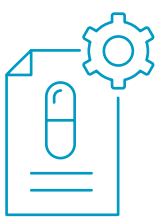
The goal is to facilitate the granting of a national marketing authorisation or the registration of a medicine at national or regional level.

Regulators, experts and observers from low- and middle-income countries are invited to participate in the scientific review. This helps to ensure that specific disease expertise and local knowledge are taken into account.

Regulators from target countries can decide on the use of the medicines based on EMA's scientific assessment.

EU-M4all medicines benefit from the full EMA regulatory toolkit including scientific advice, EMA's PRIME (PRIority MEdicines) scheme and accelerated review.

The process — step by step



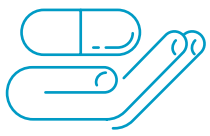
The sponsor (a pharmaceutical company, a non-governmental organisation (NGO) or academia) should engage with EMA early for scientific advice (with the involvement of WHO and national regulators)

The sponsor requests eligibility for EU-M4all

The sponsor submits an application for scientific review to EMA

The assessment is carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), in collaboration with WHO, experts and national regulators

EMA adopts a scientific opinion, which is published on its website



After the opinion, sponsors are required to implement risk management plans, just as for medicines approved for marketing in the EU

EMA can perform a benefit-risk review at any time if new safety data becomes available

*Article 58 of Regulation (EC) No 726/2004

EU-M4all — interesting facts

Throughout the evaluation, experts and regulators from target countries are invited to actively participate in or observe the process.

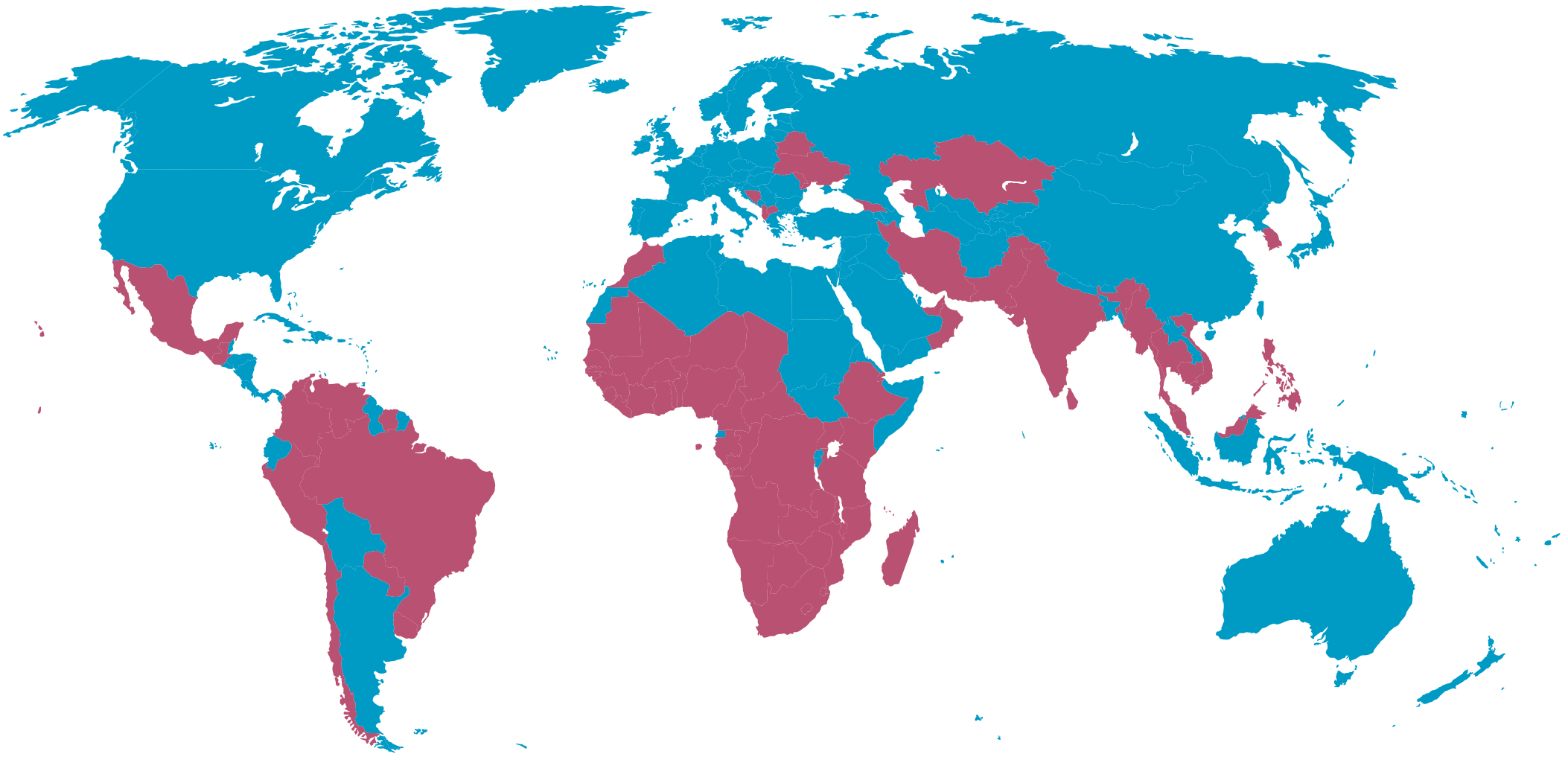
The EU-M4all procedure is open to innovative new therapies, new chemical and biological medicines, including biosimilars, vaccines and generic medicines.

NGOs and private/public partnerships play an important role in the development of medicines to prevent or treat public health priority diseases.

Many medicines are developed by pharmaceutical companies working together with NGOs and academia, or by NGOs working through product development partnerships.

138 approvals have been granted worldwide based on eleven scientific opinions through the EU-M4all procedure*

90 non-EU countries have authorised medicines evaluated through the EU-M4all procedure*



Non-EU countries in which EU-M4all medicines/vaccines have been authorised

Maternal and infant health

Umbipro
to treat umbilical cord infection in newborn babies
Hemoprostol
to treat post-partum haemorrhage

Childhood diseases

Hexaxim
Tritanrix HB
combination vaccines for childhood diseases including diphtheria, tetanus, pertussis (whooping cough), hepatitis B and polio

Malaria

Mosquirix
a malaria vaccine for children
Pyramax
to treat malaria

HIV infection

Aluvia
Lamivudine ViiV
Lamivudine / Zidovudine ViiV
to treat HIV infection
Dapivirine Vaginal Ring
for prophylaxis against HIV infection

Sleeping sickness

Fexinidazole Winthrop
to treat human African trypanosomiasis

Medicine has been centrally authorised in the EU

*as of July 2020