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EMA-WHO collaboration and partnership

The collaboration between the European Medicines Agency (EMA) and the World Health Organization (WHO) is multifaceted and aimed at enhancing global public health through cooperation on regulatory topics, scientific assessment and capacity building.

The partnership is underpinned by high-level strategic dialogues and a shared commitment to universal health coverage, global health equity, and adhering to Sustainable Development Goals. This alignment ensures coordinated action and resource mobilisation during health crises, as well as long-term resilience building.

The EMA-WHO collaboration is a key partnership that leverages EMA's scientific expertise and WHO's global public health mandate to improve access to safe and effective medicines worldwide. This long-standing engagement led to the signature of a confidentiality arrangement with WHO in September 2015.

In recent years, EMA has increased its regulatory and scientific engagement with WHO in areas that are strategically important for both, as well as for the European Commission and the European medicines regulatory network (EMRN).

This collaboration is vital for tackling global health priorities - such as public health threats, infectious diseases and vaccination programmes beyond the EU – while also ensuring that medicines are of high-quality and accessible where they are needed most.

Although EMA's mandate is Europe based, this partnership strengthens the development of medicines and decision making on a much larger scale. EMA remains committed to protecting public health with WHO in the European Union (EU) and beyond.

The following mapping describes different interactions and joint initiatives that enhance global health, particularly in areas of public health priorities and in support of low- and middle-income countries (LMICs).


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EMA-WHO partnerships

Strategic partnerships

- WHO Listed Authority
- Global regulatory fora
- Regional engagements

Accelerating access to essential medicines and vaccines

- Article 58 / EU-M4all
- OPEN framework
- Clinical development of vaccines

Good reliance practices

- Collaborative registration
- Certificates of products
- Prequalification

Safety of medicines

- Pharmacovigilance
- International drug monitoring
- World Patient Safety Day

Quality of medicines

- Inspections
- Shortages
- Expert groups

Public and animal health threats

- Global health products
- Vaccines
- Antimicrobial resistance

Research and development of medicines

- Clinical trials
- Scientific advice
- Paediatrics

Capacity building

- Regulatory systems strengthening
- Training programmes
- Convergence of standards

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Detailed key interactions

Strategic partnerships

WLA designation

EMA and the European medicines regulatory network (EMRN) were designated as WHO Listed Authorities (WLA) in May 2024. Because most WHO member states have limited capacity to carry out all core regulatory tasks, the WLA framework provides a transparent, evidence-based pathway for regulatory authorities operating at an advanced level to gain global recognition. It also builds trust in the regulatory capacity of the listed authorities and enables other parties to leverage their assessments and decisions. This framework promotes global access and supply of quality medicines, facilitates reliance and ensures optimal use of resources.

Multilateral interactions

EMA and WHO are active in global regulatory fora and initiatives, contributing to the development of international scientific guidelines and best practices for medicine regulation. This includes fora such as the International Council for Harmonisation (ICH), International Coalition of Medicines Regulatory Authorities (ICMRA), the Council for International Organizations of Medical Sciences (CIOMS), the International Pharmaceutical Regulators Programme (IPRP), and the International Conference of Drug Regulatory Authorities (ICDRA).

Regional engagements

EMA also supports initiatives with WHO at the regional level, for example with WHO EURO on the Access to Novel Medicines Platform and ad-hoc engagement to support non-EU European countries. There is also engagement with WHO AFRO and PAHO (Pan American Health Organization) with focus on facilitating product introduction, supporting crisis preparedness and responding to public health threats.

Additionally, EMA has participated in PAHO PANDRH (Pan American Network for Drug Regulatory Harmonization) and CARPHA (Caribbean Public Health Agency) conferences on topics such as digitalisation, artificial intelligence, working as a network and reliance.

Financial support

The EU is a leading donor to global health initiatives and works closely with WHO and other partners to help countries achieve universal health coverage. EMA supports these initiatives by collaborating with WHO in regulatory system strengthening.

Accelerating access to essential medicines and vaccines

Scientific opinions for medicines used outside the EU (EU-M4all/Article 58)

EMA, in cooperation with WHO, provides scientific opinions on high-priority human medicines, including vaccines, generics, and biosimilars intended for use outside the European Union. This process is known as EU-M4all (formerly Article 58).

The procedure involves rigorous scientific assessment by European experts, with input from WHO and national regulatory authorities in target countries. This ensures that benefit-risk assessments are tailored to the intended populations and local contexts. Eligible products typically address public health priority diseases such as HIV/AIDS, malaria, tuberculosis, maternal and newborn health, as well as vaccines used in WHO programmes or for emergency response stockpiles.

The involvement of WHO and local regulators in both product development and assessment facilitates faster prequalification, registration, and access to medicines, including vaccines at national or regional levels. This collaboration has resulted in numerous positive scientific opinions and subsequent approvals in countries outside the EU, accelerating access to essential medicines.

By involving regulators and experts from LMICs in the scientific review process, EMA and WHO foster regulatory capacity building and harmonisation of standards, contributing to stronger health systems globally.

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Support for WHO prequalification

EMA supports the WHO prequalification programme by providing scientific opinions that streamline the assessment and registration of medicines, including vaccines in countries with limited regulatory resources.

Support to clinical development of vaccines and reducing the gap between regulatory decisions and policy recommendations

EMA supports several initiatives aimed at rapidly advancing new vaccines that are mainly targeting LMICs. This activity covers the aspects of international regulatory harmonisation, advancement of regulatory science and support to National Regulatory Authorities in LMICs. Interacting directly with WHO expert groups, EMA hosts and contributes to workshops on specific vaccine topics and to dialogue on strain update for COVID and Influenza vaccines.

Contribution to disease areas

EMA representatives support activities by WHO to advance medicines for specific infectious diseases, including medical countermeasures for emergent pathogens. EMA also participates in expert groups for drafting target product profiles (TPPs) for new medicines.

OPEN framework

EMA collaborates with medicine regulators outside the EU, including WHO, in the scientific evaluation of certain medicines within a framework called OPEN. In the OPEN framework, several regulators can evaluate a medicine in parallel with EMA, remaining scientifically and procedurally independent from one another while sharing information, expertise and approaches during the evaluation. EMA piloted the OPEN framework during the COVID public health emergency. WHO took part in the pilot, which supported the WHO Emergency Use Listing Procedure for COVID vaccines and therapeutics facilitating accelerated registration in LMICs.

Good reliance practices

Reliance for regulatory efficiency

EMA international cooperation activities aim to promote informed regulatory reliance on effective use of global regulatory resources. Companies may share EMA assessment or inspection documents for their products with regulators outside the EU to facilitate national registrations. Reliance brings multiple benefits to regulatory authorities by facilitating shorter timelines for registration, reducing duplication of efforts, fostering collaboration between regulators, promoting capacity building and releasing resources for other critical areas.

Collaborative registration procedure

The collaborative registration procedure is one reliance mechanism coordinated by WHO that involves sharing EMA assessments with non-EU countries to streamline the approval process, avoid duplication and speed up access in target countries.

Certificates of pharmaceutical products

EMA issues more WHO certificates of pharmaceutical products (CPPs) than any other regulator. CPPs confirm the medicine's marketing authorisation status and that it complies with good manufacturing practice (GMP) standards, serving also as a tool to streamline the registration process outside the EU. It raises global manufacturing standards, supports procurement, and builds trust in quality, as well as supporting the European pharmaceutical industry.

Other harmonisation initiatives

EMA supports WHO in international forums and contributes to guideline development, for example through its working parties and participation in the WHO International Regulatory Cooperation on Herbal Medicines (IRCH).

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Safety of medicines

World Patient Safety Day

As part of the WHO initiative to promote safer healthcare, EMA makes yearly contributions to awareness campaigns around the World Patient Safety Day celebrated on 17 September.

Pharmacovigilance matters

According to legal obligations in place, EMA collaborates with WHO on pharmacovigilance primarily through enhanced international cooperation, data sharing, alignment of safety monitoring standards and addressing global safety concerns with medicines. EMA, the European Commission (EC) and WHO share information regularly on post-authorisation pharmacovigilance data. This mainly concerns adverse reactions and safety concerns from spontaneous reporting systems, periodic safety update reports, and post-authorisation obligations and commitments.

International drug monitoring

EMA is an observer of the WHO Programme for International Drug Monitoring (PIDM) and attends annual meetings. EMA regularly provides case reports of suspected adverse reactions occurring with medicinal products in the EU to the PIDM through VigiBase at the Uppsala Monitoring Centre (UMC). Informal meetings are also held with the UMC on topics of data management and analytics, and EMA is part of the Board of the UMC WHO Collaborating Centre for International Drug Monitoring. In the context of work done by the Council for International Organizations of Medical Sciences (CIOMS), EMA is involved in writing reports for and taking part in working groups with WHO.

Quality of medicines

Quality defect Rapid Alert system

The Rapid Alert system for defective medicines was established to ensure the swift exchange of information about the recall of medicinal products. This includes cases involving quality defects or falsification. Notifications are shared quickly between the National Competent Authorities, the EMA, the European Commission and other relevant partners, including regulatory authorities outside the EU and international organisations such as the Council of Europe / European Directorate for the Quality of Medicines & HealthCare and World Health Organization.

API International Inspection Programme Teleconference

WHO participates in this cluster with EMA and other international regulatory agencies. The cluster aims to rationalise international GMP inspections of active pharmaceutical ingredients/active substances manufacturers through increased transparency and visibility of inspection plans and outcomes.

Shortages

WHO interacts with EMA through the Global Regulatory Drug Shortages Working Group. The group aims to promote information sharing between regulators on respective efforts to prevent, monitor, and address medicine shortages.

Inspections

EMA and WHO collaboration is aimed at strengthening global regulatory oversight and promoting high standards for medicine quality and safety worldwide.

Good Manufacturing Practice

GMP inspections collaboration is focused on harmonisation of GMP inspection standards, sharing of inspection reports and expertise, and participation in each other’s inspection committees.

Good Clinical Practice

GCP and bioequivalence (BE) inspections collaboration includes WHO observing the GCP Inspectors Working Group meetings and attending EMA organised trainings in areas of GCP and BE, as well as exchange of BE compliance information and inspection reports.

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Public and animal health threats

Addressing cross-border and emerging health threats

EMA's expanded mandate and its collaboration with the European Commission and the European Centre for Disease Prevention and Control (ECDC), in close partnership with WHO, enable a comprehensive approach to cross-border health threats, including AMR and the health impacts of climate change

Public health emergencies

EMA has engaged proactively during public health emergencies such as Zika, Ebola, COVID and mpox, which has underlined the important role that EMA and the EMRN can play. EMA contributes to the prioritisation of investigational products for emergencies and to the drafting of core protocols for clinical evaluation of antivirals and vaccines in emergencies. EMA is part of the Strategic Advisory Group for the WHO R&D Blueprint and its working group on clinical trials, as well as the Pathogens Advisory Committee.

Antimicrobial resistance

EMA and WHO collaborate on antimicrobial resistance (AMR) by aligning policies, co-hosting strategic meetings, sharing data and best practices, and jointly promoting research and public awareness to ensure a unified and effective response to this global threat. EMA contributes to WHO-led initiatives and taskforces that develop and implement guidelines for responsible antimicrobial use, pipeline review of products in development, prioritisation of pathogens, clinical trials in vulnerable groups and for specific medicines such as bacteriophages.

Infectious Disease Working Party

This forum interacts with WHO experts and groups through working party meetings or teleconferences.

Vaccines

EMA supports the WHO Evidence Considerations for Vaccine Policy (ECVP) to provide early guidance on the data needed to support WHO policy recommendations for vaccine development. These considerations aim to inform vaccine developers, policy makers, and other stakeholders about the types of data required to make informed decisions about vaccine introduction, implementation, and policy. EMA and WHO share information and collaborate on the assessment of vaccines for major public health interest. This includes activities targeting pandemics and seasonal influenza. EMA fosters dialogue with policy bodies such as WHO Strategic Advisory Group of Experts on Immunization (SAGE) and Regional Technical Advisory Group on Immunization/National Immunization Technical Advisory Group (RITAGs/NITAGs) to ensure that regulatory decisions are rapidly followed up by recommendation and funding, e.g. through Gavi, ultimately providing access. EMA is also part of specific WHO technical advisory groups (TAGs), e.g. TB vaccine TAG and SAGE Working Group, mpox vaccines Working Group.

Global health products

EMA intensified collaboration with WHO on COVID, for example on product-related issues, inspections, pharmacovigilance and hybrid inspections. EMA has also engaged proactively during public health emergencies such as Zika, Ebola, and mpox.

Emergency Task Force

The Emergency Task Force (ETF) is an advisory and support body at EMA that handles activities in preparation for and during a public health emergency. The ETF considers the monitoring done by EMA together with information from WHO on emerging pathogens and their epidemiological situation. ETF advices on vaccines development for emerging pathogens, global surveillance and for vaccines with impact on AMR.

WHO Collaborative Open Research Consortium

EMA participates in and coordinates the Thematic Group "Compliance and Regulation" within the WHO Collaborative Open Research Consortium (CORC) on Flaviviridae. EMA therefore aligns with WHO's mission to strengthen global pandemic prevention, preparedness, and response, especially considering the priority pathogens Dengue, Zika, Yellow Fever and West Nile Fever. EMA contributes very actively also to the CORC on Filoviruses, including interactions with the African Vaccine Regulatory Forum (AVAREF) and lectures/tutorials on platform studies to address outbreaks of e.g. Ebola and Marburg.

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Research and development of medicines

Global alignment

EMA's participation in global discussions and alignment with international best practices supports WHO's broader clinical research goals.

Clinical trials

EMA supports the development of streamlined and harmonised processes across UN countries to promote large multinational clinical trials and establish regional hubs for coordinated trial approval. It also leads the working group on regulatory and ethical matters. The EMA programme manages the ACT EU Initiative (accelerating clinical trials in the EU) fostering collaboration with stakeholders, including WHO, to harmonise trial standards, modernise guidelines, promote innovative trial designs, and improve the efficiency and transparency of clinical trials. Moreover, EMA/ACT EU has been invited to join the Global Clinical Trials Forum network which aims to create synergies and leverage efforts from organisations with similar goals.

Clinical Trials Information System (CTIS)

CTIS is the European Union's centralised, web-based portal for the submission, assessment, supervision, and public registration of clinical trials on medicinal products in the EU. CTIS aims to streamline all interactions between sponsors, regulatory authorities, and the public. CTIS was officially designated as a WHO primary registry in April 2025, meaning it meets the WHO's standards for data quality, accessibility, unique identification, and technical capacity. This ensures that clinical trial data registered in CTIS is recognised internationally and integrated into the global International Clinical Trials Registry Platform (ICTRP) search portal.

Scientific advice

Collaboration of WHO in the EMA scientific advice procedure aims to align regulatory expectations, streamline evidence generation, and support medicine developers in particular for medicines that will potentially use the EU-M4all procedure.

Paediatrics

EMA collaborates with WHO-led networks such as the Paediatric Regulatory Network (PRN), which aims to build capacity for the development and assessment of paediatric medicines globally.

INN for pharmaceutical products

EMA also contributes to the development of international non-proprietary names (INN) and participates in the WHO INN expert group to facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients (APIs).

Rare diseases

EMA participates in international policy dialogues with WHO to ensure that rare disease research, drug development, and patient care reflect global best practices. Information on orphan medicine designation, marketing authorisation and post-authorisation activities of significant public health interest are shared with WHO.

Capacity building and regulatory harmonisation

Training programmes to promote harmonisation

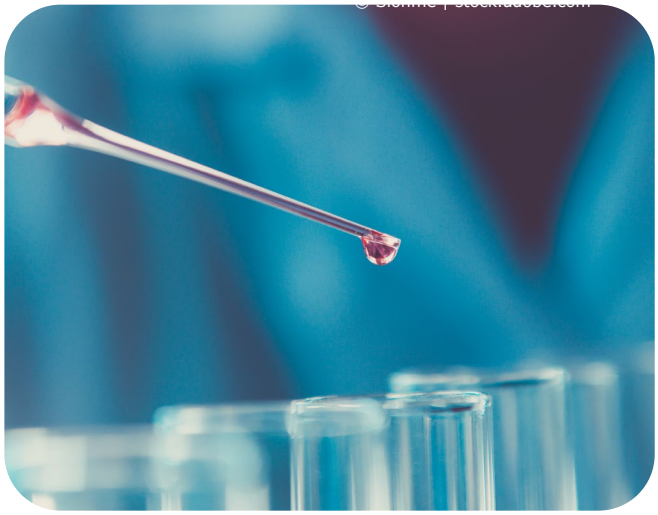
EMA supports WHO in capacity building by providing scientific training and regulatory education, involving non-EU regulators in its processes, sharing assessment expertise, and collaborating on global regulatory initiatives, thereby strengthening regulatory systems and expertise in WHO member countries. By involving regulators and experts from LMICs in the scientific review process, EMA and WHO foster regulatory capacity building and convergence of standards, contributing to stronger health systems globally.

African Medicines Agency (AMA)

With funding from the European Commission, EMA collaborates with WHO in supporting the operationalisation of AMA is part of a multi-stakeholder, international partnership focused on regulatory harmonisation, capacity building, and technical assistance to ensure AMA's effective and sustainable functioning.

Regulatory systems strengthening

As a Coalition of Interested Parties (CIP) member, EMA collaborates with WHO and other international and regional organisations to provide more effective support for regulatory strengthening activities, and aligning strategies to enhance access to safe, effective, and quality medicines products.



Impact on global health

The impact of EMA–WHO collaboration on global health is evident through a range of mechanisms that facilitate strategic alignment, knowledge exchange, and coordinated regulatory action.

- Supporting research and development and joint scientific assessments to **accelerate access** to essential, **quality-assured safe and effective** medicines, including vaccines globally, as well as to support safety monitoring.
- Facilitating access to medicines to **reduce inequalities**, boost local capacities and ensure sustainable access to health technologies.
- Enhancing crisis preparedness and emergency response to enable coordinated, rapid response to health emergencies and pandemics, **protecting vulnerable populations.**
- Promoting regulatory harmonisation and capacity building to build local expertise, harmonise standards and **strengthen national health systems.**
- Encouraging good reliance practices to increase efficiency, reduce duplication, **and accelerate regulatory decisions** for medicines, including vaccines.

- Contributing to prequalification opinions to raise global manufacturing standards, support procurement, and **build trust in medicines' quality.**
- Engaging in multilateral engagement initiatives to **ensure coherent action** on global health priorities and policy frameworks.
- Strengthening health systems to enhance **resilience in LMICs.**

More information

For more information on EMA-WHO collaboration and partnership visit the EMA website.

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