EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

OPEN and other collaborative procedures

Workshop - Challenges in drug development, regulation and clinical practice in haemoglobinopathies
1st July 2024

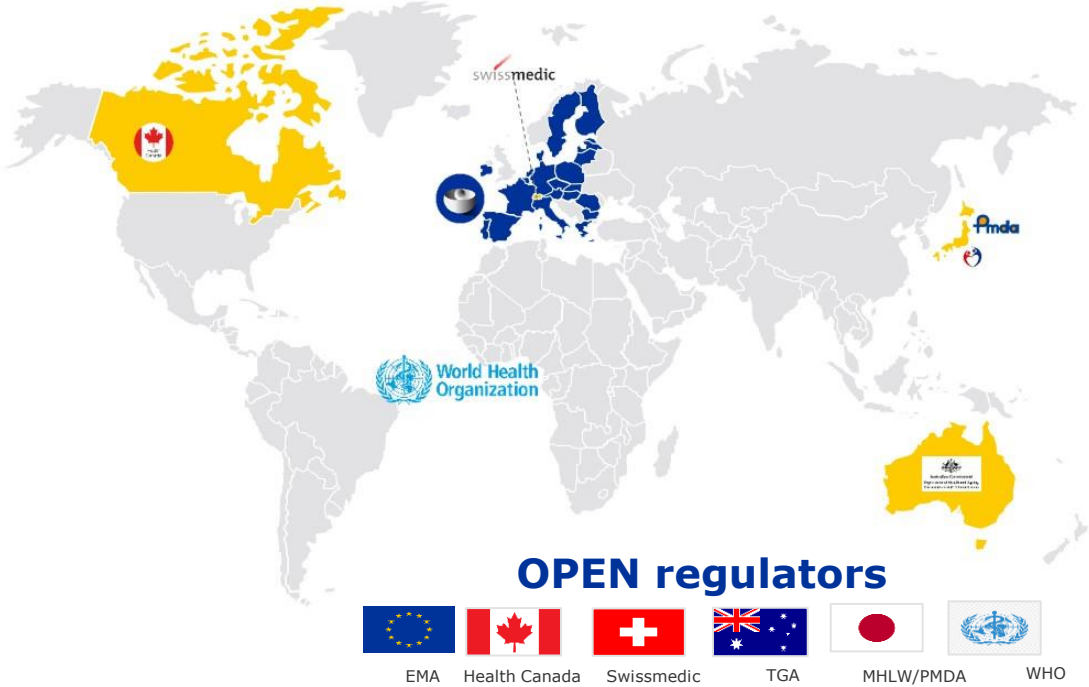
Radhouane Cherif – International Affairs

Opening our **P**rocedures at **E**MA to **N**on-EU authorities
COVID-19 vaccines and therapeutics - PILOT

Goal: Sharing scientific expertise
to tackle common challenges on COVID-19 vaccines and therapeutics

Interaction: Participating non-EU experts invited to **attend and contribute** to **ETF and CHMP evaluation**

OPEN experts follow **similar requirements** as the EU experts *(e.g., confidentiality, absence of conflict of interests).*



All participating under the terms of their Confidentiality Arrangement with the EU.

Reliance in action: 'OPEN' global health impact

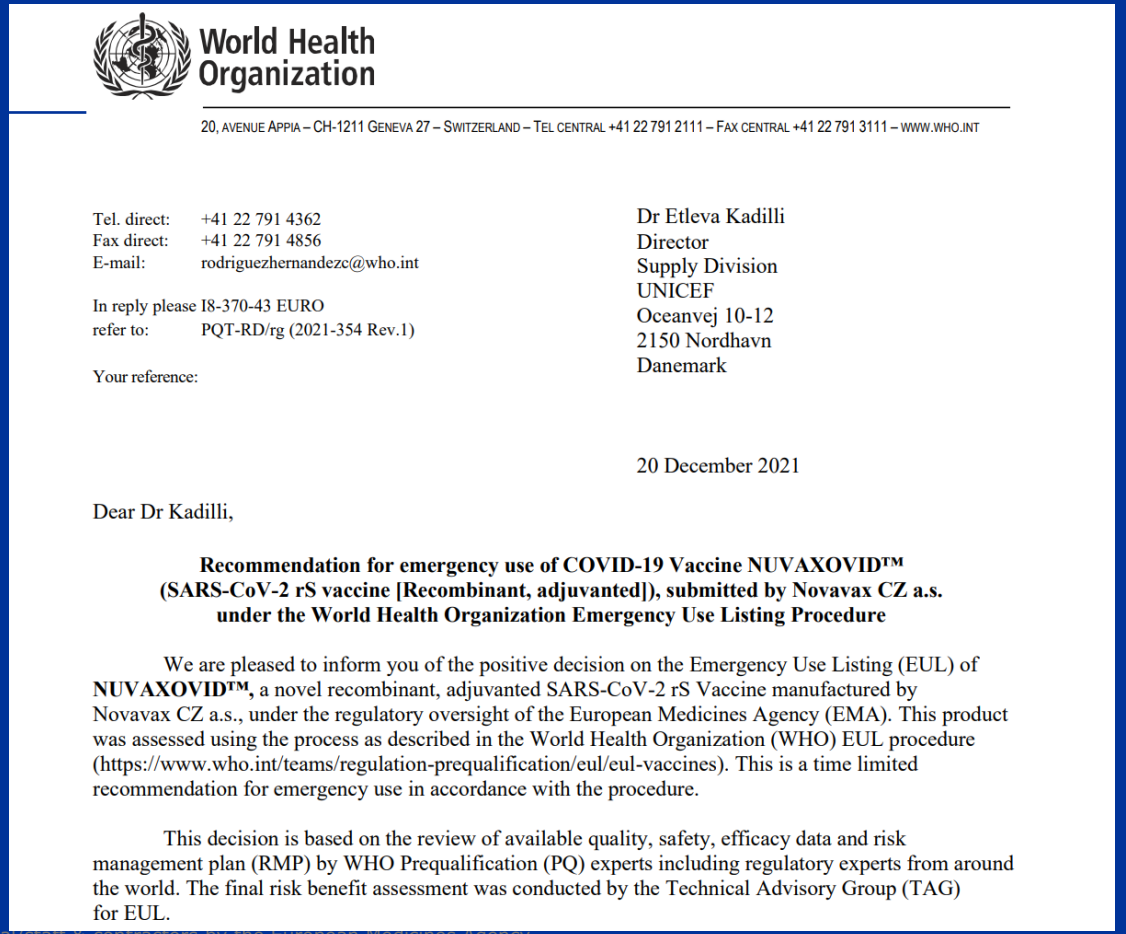
Reliance significantly **accelerated decisions** from national regulatory authorities in **LMICs**.

EMA is regulatory authority of record for the **WHO Emergency Use Listing** (EUL) for the 5 of the vaccines approved in the EU.

The WHO EUL enables LMIC national regulatory authorities to **speed the registration** of COVID-19 vaccines. It is also needed to allow **procurement** by UN agencies and World Bank Group partners.

OPEN's global health impact

WHO recommendation to GAVI, UNICEF and stakeholders for the emergency use of the vaccine within **two hours** of the EMA opinion.



World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 4362
Fax direct: +41 22 791 4856
E-mail: rodriguezhernandezc@who.int

In reply please refer to: I8-370-43 EURO
PQT-RD/rg (2021-354 Rev.1)

Your reference:

Dr Etleva Kadilli
Director
Supply Division
UNICEF
Oceanvej 10-12
2150 Nordhavn
Danemark

20 December 2021

Dear Dr Kadilli,

Recommendation for emergency use of COVID-19 Vaccine NUVAXOVID™ (SARS-CoV-2 rS vaccine [Recombinant, adjuvanted]), submitted by Novavax CZ a.s. under the World Health Organization Emergency Use Listing Procedure

We are pleased to inform you of the positive decision on the Emergency Use Listing (EUL) of **NUVAXOVID™,** a novel recombinant, adjuvanted SARS-CoV-2 rS Vaccine manufactured by Novavax CZ a.s., under the regulatory oversight of the European Medicines Agency (EMA). This product was assessed using the process as described in the World Health Organization (WHO) EUL procedure (https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines). This is a time limited recommendation for emergency use in accordance with the procedure.

This decision is based on the review of available quality, safety, efficacy data and risk management plan (RMP) by WHO Prequalification (PQ) experts including regulatory experts from around the world. The final risk benefit assessment was conducted by the Technical Advisory Group (TAG) for EUL.

OPEN pilot - Benefits

International collaboration benefits regulatory authorities, developers, and patients.

OPEN **facilitated the assessment** of the same data by multiple authorities, deepening the collaboration and moving the exchange of information to active engagement.

OPEN allowed regulators to **accelerate and align on decisions**, leading to **fewer questions for industry and labelling differences**, while maintaining independence in the decision making.

OPEN demonstrated the value of international collaboration to **avoid duplication of efforts**, improve **efficiency**, and bring vaccines and medicines to patients earlier in the **interest of public health**.

OPEN - Extended scope

- Antimicrobial resistance (AMR)
- PRIME products (not including ATMPs)
- Other products that address high unmet needs (e.g. RSV, Alzheimer's, ALS...)
- Vaccines or therapies for health threats or public health emergencies

- Three medicinal products reviewed under OPEN:

  - Arcturus COVID-19 vaccine
  - Moderna RSV vaccine
  - Valneva Chikungunya vaccine

Operationalisation of the OPEN framework – High level process

Principles

- OPEN experts invited to comment during the CHMP evaluation as any other EU MS.
- OPEN experts are not contributing to CHMP conclusions during the final benefit-risk decision.
- OPEN experts participate in ETF (when applicable) CHMP meetings and other scientific meetings where relevant and agreed by EMA and the Rapporteurs
- Applicant request that their product is reviewed under the OPEN framework

OPEN regulators

EMA | Health Canada | Swissmedic | TGA | MHLW/PMDA | WHO | ANVISA | MFDS

Expected benefits for global health and industry

- Alignment of dossiers to improve regulatory convergence within OPEN partner countries
- Potential faster overall global approval through leveraging existing or ongoing assessments and expertise beyond the EU regulatory network (e.g. fewer questions for industry and labelling differences)
- Potential to align also the post-approval lifecycle management for major changes and/or also using reliance mechanism
- Promoting capacity optimisation and convergence of assessment standards

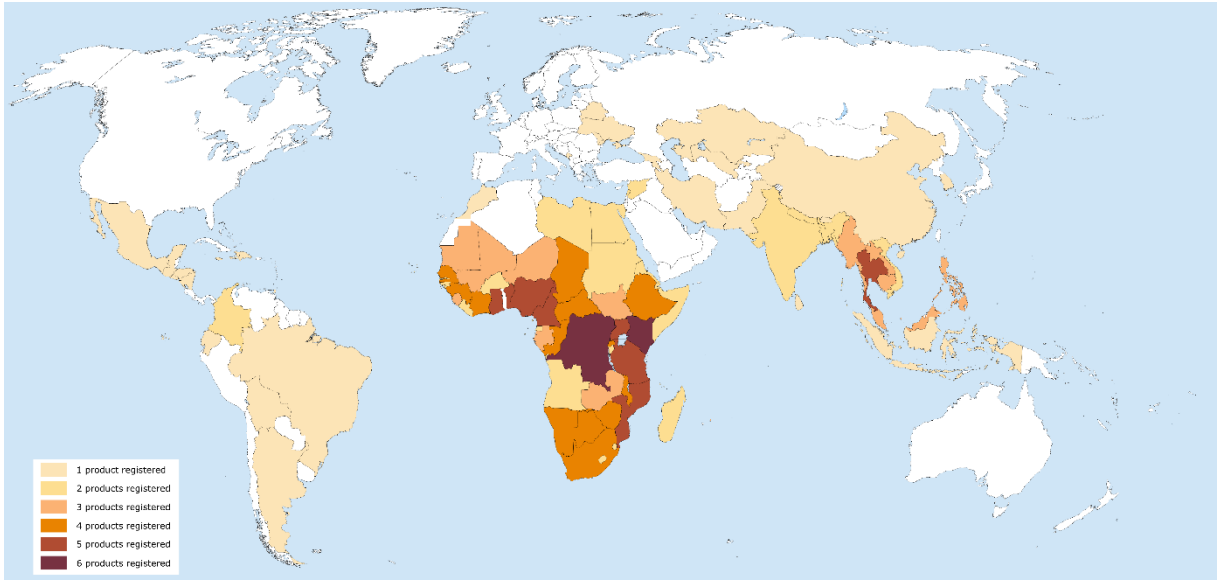
EU-Medicines for all (EU-M4all)

EMA supports the global regulatory system through its collaboration with **WHO** using two main regulatory mechanisms:

1. EU-M4all (Art. 58):

EMA evaluates and gives an opinion, in cooperation with **WHO**, on medicinal products for human use intended for markets outside of the EU.

Since 2021, this procedure can also be performed in parallel to a centralised procedure to accelerate medicines access at a global scale.



17 medicines with an EU-M4all scientific opinion*

94 countries worldwide

229 Marketing Authorisations

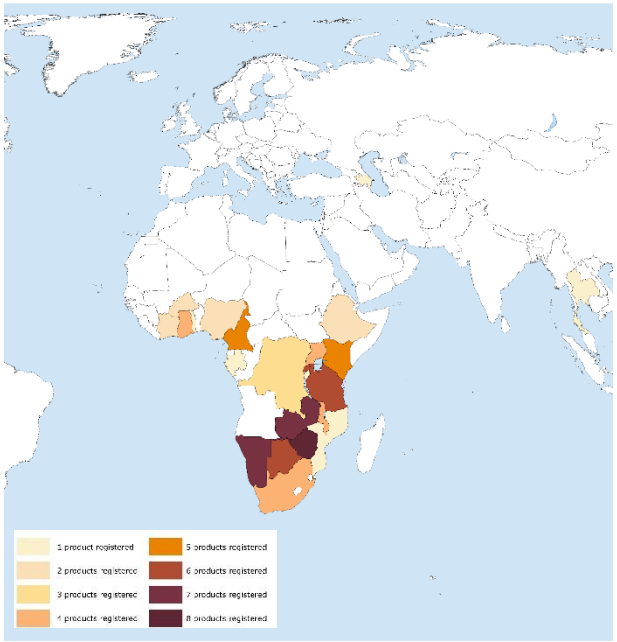
*7 of which have been withdrawn or surrendered and 1 pending as of June 2024

WHO Collaborative Registration Procedure (CRP)

2. WHO SRA CRP:

Accelerates national approval in countries where resources may be limited, based on the regulatory work already carried out by Stringent Regulatory Authorities (SRAs), such as EMA.

This facilitates earlier access to essential medicines for patients worldwide, improving global public health.



13 medicines with EU marketing authorisation

23 countries

83 marketing authorisations via CRP

As of June 2024

Further reading:

OPEN - One-year review of the OPEN pilot and recommendations

EMA/6881/2022

https://docs.eudra.org/webtop/drl/objectId/090142b2852c9d85

Any questions?