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SCIENCE MEDICINES HEALTH

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## **OPEN Pilot: One-year review and recommendations**

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# 1. Executive summary

## 1.1. About the OPEN initiative

With the COVID-19 pandemic, regulatory authorities round the globe faced many challenges including an increased workload coupled with regulatory resources limitations. It rapidly became clear that new innovative approaches and adaptation of regulatory tools and resources were needed to ensure a swift response to COVID-19. With this in mind, the Management Board endorsed the launch of the [OPEN Pilot](#) at its 16-17 December 2020 meeting, with the aim of increasing international collaboration in the EU review of COVID-19 vaccines and therapeutics.

The pilot phase of the OPEN Initiative (**O**pening our **P**rocedures at **E**MA to **N**on-EU authorities) is intended to run for the duration of the declared COVID-19 pandemic. Regulators from Australia, Canada, Japan, Switzerland and the World Health Organization participate in the pilot under the terms of existing [confidentiality arrangements](#). These non-EU experts are invited to attend and contribute to ETF and CHMP evaluations and discussions for COVID-19 vaccines and therapeutics. All regulators keep full scientific and regulatory independence in their final decision making.

## 1.2. Purpose

The OPEN Initiative allows medicines regulators from outside the EU and WHO to take part in EMA's scientific evaluations. The initiative aims to:

- Facilitate sharing of scientific expertise,
- Tackle common challenges,
- Enhance transparency on regulatory decisions,
- Support the assessment of vaccines and therapeutics for COVID-19.

The participation is seen primarily as scientific collaboration. An additional benefit was to increase the chances of having similar outcomes between health authorities.

## 1.3. Implementation of the pilot

All the COVID-19 vaccines and therapeutics evaluated since the launch of the pilot were assessed under OPEN.

The initiative went beyond the simple exchange of information to actively engage with nominated experts from international partners.

The OPEN experts were invited to all ETF and CHMP meetings where the rolling review or assessment of any of the COVID-19 vaccines or therapeutics was discussed. Under the terms of the confidentiality arrangements, non-EU authorities also received the assessments of the CHMP, which included rapporteurs' assessment reports, lists of questions, joint assessment reports, interim and final opinions. The participating authorities were encouraged to contribute to the discussions and share their own documents with the ETF or CHMP.

Each regulatory authority remained independent in their final decision, and OPEN regulators did not contribute to the ETF or CHMP conclusions during the final benefit-risk decision.

This analysis considers one year's experience of the pilot operation and its impact on both the EU and the global regulatory systems. Questionnaires were shared with CHMP and ETF members, participating

regulators, applicant companies, and relevant EMA staff. The results are presented in this one-year review report and have been used to inform the proposed recommendations.

#### **1.4. First-year experience and impact**

The review showed very positive feedback from all stakeholders.

Collaboration among international regulators was key in the context of COVID-19 and the OPEN pilot facilitated the assessment of the same data by multiple authorities. The pilot enhanced communication channels and facilitated discussions and exchanges. In addition, OPEN allowed regulators to accelerate and align on decisions, leading to fewer labelling differences, while maintaining independence in the decision making. The evaluation of applications is only one of the roadblocks to access, and sharing scientific expertise brings efficiencies to all regulators, allowing faster access to vaccines and therapeutics across the globe.

The partnership with WHO also meant that the OPEN pilot contributed to global health by breaking down regulatory barriers and facilitating access and equity for COVID-19 vaccines and therapeutics. The WHO Prequalification team, leveraging its participation in OPEN, uses the EMA assessments for the WHO Emergency Use Listing (EUL) of the vaccines and therapeutics authorised in the EU. WHO then encourages the recognition of the WHO EUL and Prequalification list for national authorisation of or other regulatory action for the COVID-19 vaccines or therapeutics. These reliance mechanisms are crucial tools to make best use of regulatory capacities in resource-limited settings, avoid duplication where possible and reduce the time to access to medicines for patients.

Some opportunities to achieve a greater impact were also identified during the review of the pilot. The first is that the collaboration could be further enhanced with more detailed rules of engagement and the next steps should focus on improving the operational aspects that facilitate interactions where added value has been identified during the pilot.

A second was the submission gap between applications. Concurrent or near-concurrent application allows for maximum collaboration. This was not a requirement for the pilot, and we saw lower engagement from participating authorities when the submissions were not aligned.

Thirdly, the need for more communication and visibility of the initiative was also identified during the review.

Although not related solely to OPEN, facilitating collaboration and expertise sharing also requires adapted tools. As documents are the heart of the collaboration, a reliable document management and exchange platform accessible externally and internally is essential to ensure a future-proof solution adapted to the constantly growing flow of documents exchanged.

## 1.5. Recommendations

International collaboration brings multiple benefits to regulatory authorities, developers, and eventually to patients. The OPEN pilot 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 is also in line with the [Pharmaceutical Strategy for Europe](#) (November 2020) as it contributes to strengthening the EU voice globally and promoting the EU model.

To better consolidate the impact of the pilot several activities are recommended to:

- Improve **operational processes** and strengthen further the collaboration based on the learnings of the pilot.
- Identify **future scopes** for OPEN in a stepwise approach.
- Increase **visibility of the initiative**.

Clearer terms of reference should be defined considering the following:

A driving factor for OPEN is to facilitate scientific collaborations that can expedite and inform independent decision making in each jurisdiction.

EU experts would also like to see more reciprocity of information exchange and more active participation of non-EU regulators in our scientific evaluation. However, we could also envisage different types of engagement at the start of the evaluation by giving the choice to regulators to actively contribute or to only receive the EU assessment and therefore setting clear expectations.

Alignment of submissions and increased interactions should always aim to facilitate assessment, without slowing down actions in the EU.

EMA is already working to increase visibility of OPEN on the EMA website and efforts will be made to align communications with regulators to increase engagement and transparency. EMA will also request the participating OPEN regulators to be explicit when they have made use of OPEN in their decision-making for a given medicinal product.

Following this one-year experience review the main objective during 2022 is to engage with all stakeholders to better define the terms of reference and agree on a stepwise approach to expand the use of OPEN in line with all the stakeholders' goals and objectives.

## 2. Implementation of the Open initiative

Prior to OPEN, the EMA already exchanged information at product level with the participating regulatory authorities through bilateral exchanges or as part of cluster discussions. However, OPEN provided a framework for near-concurrent review by multiple non-EU authorities each conducting its own assessment in parallel to that of EMA.

Under the terms of the confidentiality arrangements, authorities received the assessments of the CHMP and ETF. This included rapporteurs' assessment reports, lists of questions, joint assessment reports, interim and final opinions.

According to the EU data protection regulation, EMA documents should be redacted for personal data, unless an administrative arrangement endorsed by the European Data Protection Supervisor is in place, or an adequacy decision (as is the case for e.g. Switzerland). However, the EDPS accepted that COVID-19 creates a justified exception and COVID-19 related documents could be exchanged without prior redaction of personal data.

The OPEN pilot was designed to facilitate interactions to permit OPEN experts to actively engage and share the scientific evaluation and overall assessment of their authority. The experts could also discuss and report back within their authority on the discussions taking place at EMA.

OPEN experts could interact actively with the CHMP or ETF during the meetings or through the EMA product team. However, they did not contribute to the CHMP or ETF conclusions (or voting) during the final benefit-risk or opinion decision.

OPEN experts were proposed by the participating authorities and appointed by EMA once they have met all criteria of the policy applicable to experts. This required filling in a Declaration of Interests and confidentiality undertaking, as well as providing a CV and being included in the Experts database before any participation. The EMA policy on handling of competing interests of scientific committees' members and experts ([link](#)) is applicable to involvement of these experts in the concerned EMA activities. The same safeguards of independence as for CHMP members applied to the experts.

OPEN experts did not participate in PRAC discussions, however many of the safety updates were also discussed at ETF where OPEN experts were invited.

All COVID-19 vaccines and therapeutics were included in the pilot, from the moment the rolling review started throughout the evaluation of the marketing authorisation application. Extensions of indications, major variations, or inspections were also part of the discussions.

There was no requirement from industry to submit an application to all participating countries, and all OPEN experts were invited to all COVID-19 discussions, even when submissions were not aligned.

## 3. First-year experience of the Scientific collaboration

### 3.1. COVID-19 vaccines and therapeutics assessed during the pilot's first year

#### 3.1.1. COVID-19 vaccines

In adults from 18 years of age

- December 2020: Comirnaty (BioNTech and Pfizer)
- January 2021: Spikevax (Moderna), and Vaxzevria, (AstraZeneca)
- March 2021: Jcovden (Janssen)
- December 2021: Nuvaxovid (Novavax)

In children and adolescents

- May 2021: Comirnaty in 12 to 15-year-olds
- July 2021: Spikevax in 12 to 17-year-olds
- November 2021: Comirnaty in 5 to 11-year-olds
- The use of Spikevax in children aged 6 to 11 is currently under evaluation.

Booster and extra doses in people from 18 years of age

- October 2021: Spikevax and Comirnaty, booster at least 6 months after the second dose and extra dose for severely immunocompromised people at least 28 days after the second dose
- December 2021: Jcovden, booster at least two months after the first dose

The conditional marketing authorisations for Spikevax, Comirnaty, Vaxzevria and Jcovden were renewed.

#### Manufacturing

One of the major challenges with the new vaccines was to ensure adequate supply and reliable manufacturing process. Throughout 2021, EMA reviewed new manufacturing sites and lines, additional suppliers of raw materials and other manufacturing changes to enable a rapid scale-up in the production of Comirnaty, Spikevax, Vaxzevria and Jcovden. In total the number of approved EU and non-EU manufacturing sites rose from 19 to 52, leading to a significant increase in vaccine supply.

#### Vaccines under review

As of the end of December 2021, four vaccines were under rolling review (Sputnik V Gam-COVID-Vac, COVID-19 Vaccine Vero Cell Inactivated, Vidprevtyn and VLA2001).

### 3.1.2. COVID-19 therapeutics

#### Therapeutics approved

- In December 2020, the Committee recommended a change to the product information for Veklury (remdesivir) to provide more details in the instructions for use COVID-19 patients requiring supplementary oxygen, which had been previously approved earlier in 2020.
- November 2021, two monoclonal antibodies to treat COVID-19: Ronapreve, to treat COVID-19 in patients from 12 years of age and weighing at least 40 kilograms who do not require supplemental oxygen and who are at increased risk of their disease becoming severe. It can also be used for preventing COVID-19. Regkirona to treat adults with COVID-19 who do not require supplemental oxygen and who are also at increased risk of their disease becoming severe.

December 2021,

- Xevudy, third monoclonal antibody to treat COVID-19 in patients from 12 years of age and weighing at least 40 kilograms who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.
- Three extensions of indication
  - RoActemra, to include treatment of adults with COVID-19 who are receiving systemic treatment with corticosteroids and require supplemental oxygen or mechanical ventilation
  - Kineret, to include treatment of COVID-19 in adults with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure (determined by plasma concentration of soluble urokinase plasminogen activator receptor (suPAR)  $\geq$  6ng/ml).
  - Veklury, to include the treatment of adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

The conditional marketing authorisation for Veklury was renewed.

#### Therapeutics under review

As of the end of December 2021, an oral antiviral, Lagevrio (molnupiravir), and an existing immunosuppressant medicine, Olumiant (baricitinib), were under evaluation. Another oral antiviral, Paxlovid (PF-07321332/ritonavir), and a combination of monoclonal antibodies, Evusheld (tixagevimab/cilgavimab), were under rolling review.

#### Recommendations for use of medicines not yet authorised to treat COVID-19

EMA adopted harmonised scientific opinions (Article 5(3) opinions) for six treatments that were not yet authorised specifically for patients with COVID-19: two combinations of monoclonal antibodies (bamlanivimab + etesevimab and casirivimab + imdevimab), two single antibodies (regdanvimab and sotrovimab), and two antivirals, Lagevrio (molnupiravir) and Paxlovid (PF-07321332 + ritonavir). This advice supports national authorities who may decide on possible early use of the medicine prior to marketing authorisation.



## 3.2. Key findings from the pilot

### 3.2.1. What worked well

- **Collaboration** among international regulators was considered **key** in the context of COVID-19
- **Enhancement of communication** channels and **facilitation of discussions and exchanges** between the EMA and the participating non-EU regulatory authorities
- Better understanding by EU and OPEN regulators of labelling discussions leading to **fewer labelling differences**
- Assessment of **similar data** by multiple authorities
- **Acceleration** of COVID-19 assessments and **access to patients** outside of the EU
- **Independence** of decision-making
- International collaboration during assessment perceived as beneficial by **applicants**
- Global **public health impact**

For more than 90% of the EU and OPEN regulators, OPEN **improved communication channels** and facilitated **discussion and exchanges** between the EMA and the participating non-EU authorities.

*"I find the idea of collaboration globally very favourable" – CHMP/ETF member*

*"[Our Agency] has collaborated on two submissions to date and the opportunity to engage the rapporteur and co-rapporteur has been invaluable in terms of exchanging information and expediting assessments." – OPEN regulator*

The participation of OPEN experts in the scientific discussions provided **additional value** to the discussions and exchanges by bringing a better understanding of potential labelling differences. Moreover, participating regulators stated that they had **broadly similar decisions** to the EMA. **Labels were not 100% identical** since each regulatory Agency followed their own national requirements; some applicants also confirmed that OPEN facilitated **fewer labelling differences**.

*"[What worked well was to] share knowledge and experiences that could allow a more harmonized approach in the international settings." – EMA product lead*

*"The OPEN pilot allowed our regulatory agency an opportunity to see the opinions of other regulators. While agencies may differ in their opinion, it was interesting to see the rationale behind those opinions." – OPEN regulator*

*"Experts from Non-EU Regulatory Authorities attended our discussions at CHMP quite regularly, confirming the continued interest in the pilot project." – CHMP/ETF member*

With the pandemic, there was an urgent need for vaccines and treatments across the globe and although it was not a requirement, OPEN regulators confirmed receiving similar submissions as the EMA. Participating regulators and applicants perceived that OPEN **promoted parallel submissions** while also contributing to accelerating decisions outside the EU hence **accelerating COVID-19 vaccines and treatments patient access** in regions sometimes used to approve medicines last due to smaller market size.

*"The project works quite well. It gives us an insight of what is going with procedures, discussions and views from a different perspective, and from different nationalities. Very valuable scientific forum. It gives us a wider scientific and regulatory view on product and procedures." – OPEN regulator*

*"Access to real-time decisions on therapeutic product regulation that was concurrently occurring within our Authority meant that our decisions were more well-informed and robust" – OPEN regulator*

*"For the COVID-19 vaccine, in most cases, the EMA approval review preceded that of [our Agency] by about two months. As a result, [we were] able to fully discuss the issues raised in the EMA's evaluation of the vaccine's efficacy and safety. It makes the evaluation in [our Agency] more fruitful." – OPEN regulator*

The **applicants** surveyed were well informed of and comfortable with the participation of OPEN experts in the EMA assessment, and they **perceived OPEN as beneficial** for them (Fig. 1).

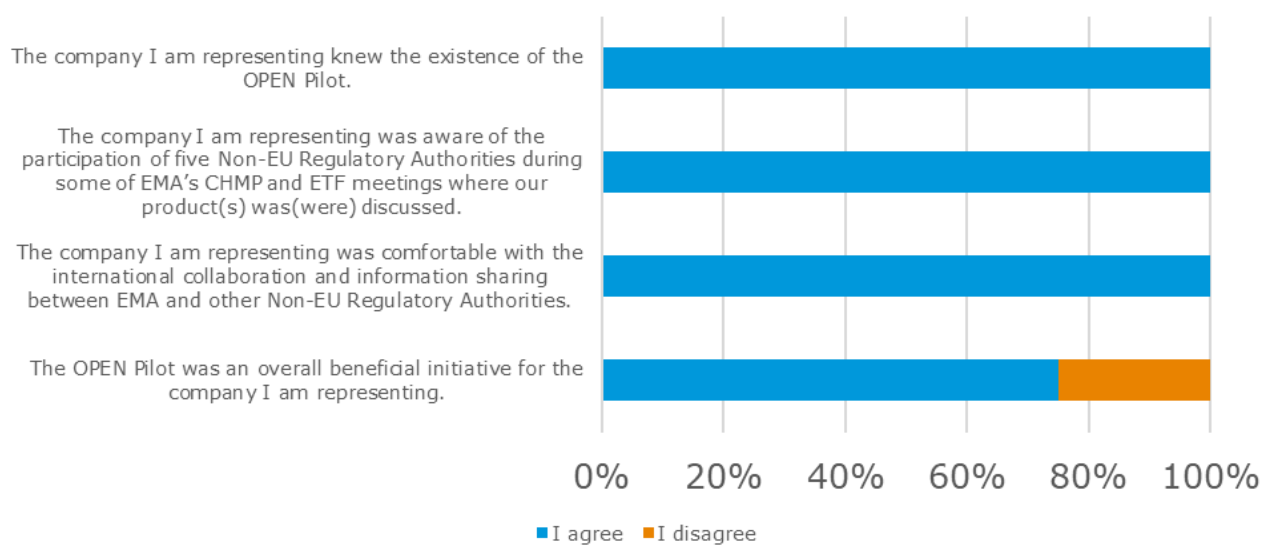


Figure 1

### 3.2.2. Areas of improvement highlighted in the surveys

The difficulty for some OPEN experts to actively engage was highlighted in the surveys' results.

While OPEN experts were able to provide compiled scientific evaluation from their authority or any other document (including divergent analysis) that could benefit the EMA assessment, **in practice**, the **level of contributions** perceived by the EU experts **was heterogeneous** but overall, EU experts indicated a strong interest for more active participation from OPEN experts.

Going forward, more explicit **rules of engagement** for OPEN experts will facilitate understanding on how and when to engage during the EU assessment.

**The submission time gap** for marketing authorisation and variation applications between some regulators and EMA was highlighted by some regulators as a reason for lower engagement during the assessment. In addition, time zone differences could have also influenced meeting participation.

The possibility of different levels of engagement that are **adapted to eventual un-aligned assessment timelines** between regulators should also be considered.

### 3.2.3. COVID-19 regulatory timeline – December 2020 to December 2021

Participating regulators perceived that OPEN promoted parallel submissions, although COVID-19 vaccines and therapeutics **submission dates to OPEN regulators were not fully aligned**.

Most regulators received **similar applications for COVID-19 vaccines'** initial marketing authorisation and extension of indication applications, and those applications, when submitted to multiple regulators, contained similar data. However, **COVID-19 therapeutics** were not always submitted in all the regions and the submission gap was more heterogeneous.

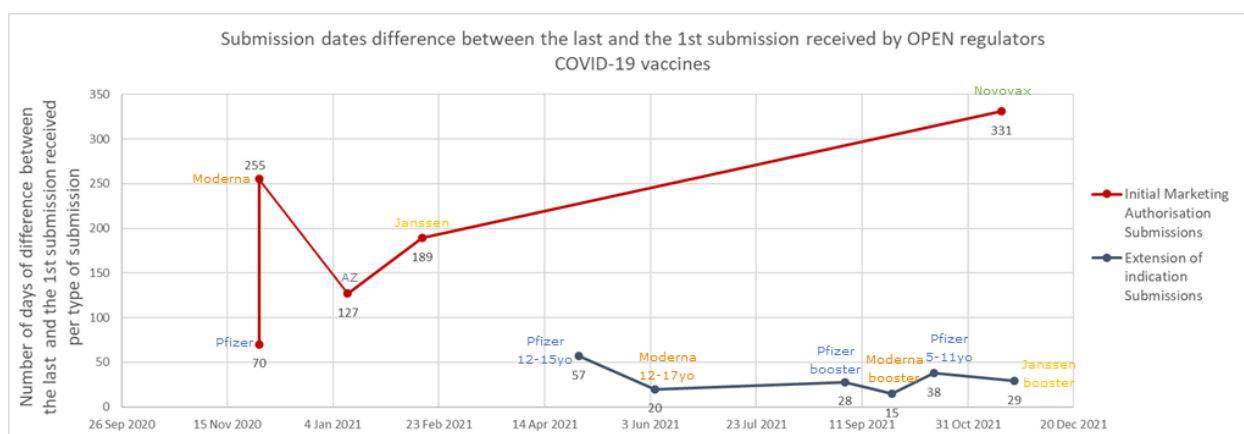


Figure 2

When looking at the **submission time gap between OPEN regulators for similar COVID-19 vaccines applications**, we can see that the gap is lower for extension of indication applications compared to initial marketing authorisation applications. This submission gap difference between the first OPEN regulator to receive a submission and the last varies between 70 days gap range (*i.e. Comirnaty application*) to almost a year (*i.e. Nuvaxovid application*) for initial marketing authorisation applications, and between 2 weeks gap range (*i.e. Spikevax booster application*) to 2 months (*i.e. Comirnaty 12-15 years old application*) for extensions of indication (Fig. 2).

This submission time gap was identified by OPEN regulators as a **hurdle** for them to actively contribute to EMA assessment. For example, one regulator commented that:

*"It has become clear that the timing of the review of vaccines and therapeutic agents varies depending on the application strategy of companies and the procurement strategy of governments, even for the limited item of drugs and vaccines for COVID-19. It makes it difficult to make good contributions to EMA." – OPEN regulator*

For COVID-19 therapeutics it is difficult to draw conclusions, but it can be noted that there is a significant difference between the submission time gap for Veklury (*remdesivir*, Gilead) assessed in the second and third 2020 quarters, before the launch of the OPEN Pilot, and the following submission time gap for therapeutics assessed in the third and fourth 2021 quarters (*Fig. 3*).

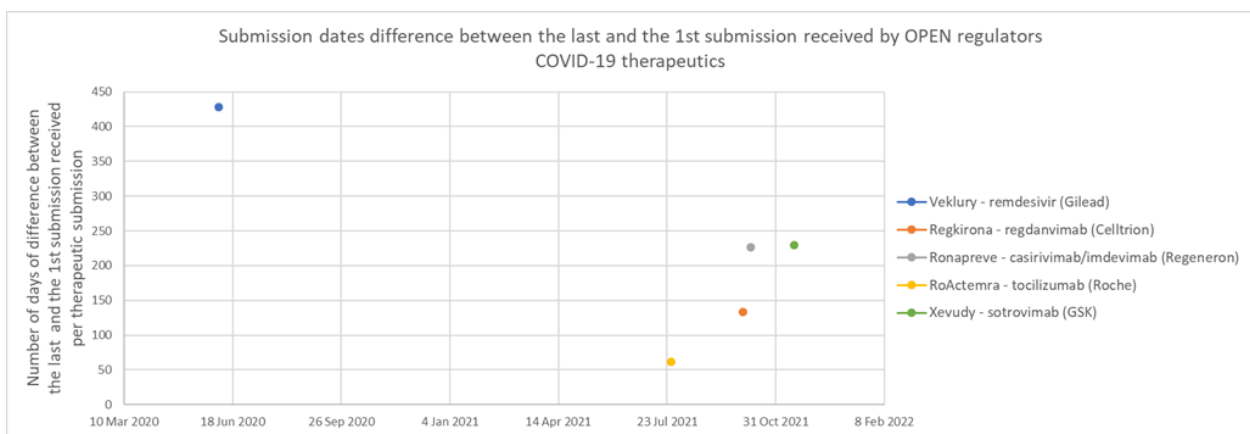


Figure 3

### 3.2.4. OPEN Pilot communication and visibility

An analysis of the websites and publications (including assessment reports and public announcements) showed relatively little communication of the OPEN initiative by the participating authorities or applicants; this is despite the positive feedback about pilot in survey responses.

Some participating regulators do not appear to have actively communicated on their participation in the OPEN Pilot. While others mention OPEN in their public assessment reports or in some of their public communication on COVID-19 medicines and/or on their webpages dedicated to international activities.

EMA published a [Question and Answer](#) document to inform the public and there were regular mentions to the pilot were made in EMA presentations at stakeholder conferences throughout the year. References to the initiative were included in the COVID-19 vaccines and therapeutics pages. The EMA 2021 Annual Report highlights the initiative as part of the Agency’s COVID-19 public health response.

However, clear ground rules for communication were not specified in the initial framing of the OPEN pilot. To better align the programme’s process and goals, some general communication principles should be considered as part of any future terms of reference. Additionally, EMA should develop a more detailed

section on OPEN on the EMA website with links to the products included in the initiative and similar information should be provided by OPEN regulators. Greater communication about the initiative is indeed a way to facilitate convergence and further promote scientific collaboration and engagement of the OPEN regulators. Making public the participation of OPEN regulators should be a pre-requisite for participation in the initiative.

### 3.2.5. Global health impact through WHO participation

Reliance has been used by WHO as an indispensable tool to optimise resources, speed up approvals and ensure faster and more equitable access to therapeutics and vaccines globally. The WHO Prequalification team, collaborating within OPEN, has used, among others, the EMA assessments for the [WHO Emergency Use Listing \(EUL\)](#) of the vaccines authorised in the EU and the prequalification of COVID-19 therapeutics.

To list a new vaccine on the EUL, WHO relies on the assessment of a regulatory authority of record (NRA of record). For example, on 31 December 2020, the first COVID-19 vaccine approved on the WHO EUL was the BNT162b2 mRNA vaccine (Comirnaty). Its listing on the WHO EUL was based on the EMA assessment for which the EU decision was adopted only ten days prior to WHO EUL initial listing of Comirnaty. New therapeutics can similarly be prequalified based on the approval by a regulatory authority of reference such as the EMA. WHO then encourages the recognition of the WHO EUL and prequalification list for national authorisation or other regulatory action of the COVID-19 vaccines or therapeutics (e.g. marketing authorisation, EUA, import permit, etc.) In addition, the procurement of COVID-19 vaccines and therapeutics by UN agencies, such as UNICEF, GAVI, COVAX, etc., is only possible for vaccines and therapeutics listed on the WHO EUL or that have been prequalified.

For all the vaccines approved in the EU, EMA is the sole or one of the regulatory authorities of record on the WHO EUL. Moreover, for four vaccines (Comirnaty, Spikevax, Jcovden, Nuvaxovid) the initial listing on the EUL was based on the EU assessment (*Table 1*).

| MAH               | Name of Vaccine | NRA of Record  | WHO Emergency Use Listing dates |
|-------------------|-----------------|--|---------------------------------|
| Pfizer – BioNTech | Comirnaty       | EMA – core data  | 31 Dec 2020                     |
|                   |                 | US FDA – for additional sites                              | 16 Jul 2021                     |
| AstraZeneca       | Vaxzevria       | Korea MFSD   | 15 Feb 2021                     |
|                   |                 | EMA – core data  | 16 Apr 2021                     |
|                   |                 | Japan MHLW/PMDA – for additional sites                     | 9 Jul 2021                      |
|                   |                 | Australia TGA – for additional sites                       | 9 Jul 2021                      |
|                   |                 | Mexico COFEPRIS and Argentina ANMAT – for additional sites | 23 Dec 2021                     |
| Janssen           | Jcovden         | EMA  | 12 Mar 2021                     |
| Moderna           | Spikevax        | EMA – core data  | 30 Apr 2021                     |
|                   |                 | US FDA – for additional sites                              | 06 Aug 2021                     |
|                   |                 | Korea MFSD – for additional sites                          | 23 Dec 2021                     |
| Novovax           | Nuvaxovid       | EMA  | 20 Dec 2021                     |

Table 1 WHO Emergency Use Listed COVID-19 vaccines as of 23/12/2021

The rapid WHO EUL or prequalification listing was greatly facilitated by OPEN. Hence, the EMA, supported WHO in expediting access to quality-assured, effective and safe medical products in LMICs.

## **4. Recommendations**

After a year of operation, EMA reviewed the pilot together with the results from the stakeholder survey.

The pandemic has been the catalyst for change in global and regional regulatory practices, and collaboration among international regulators was considered key in the context of COVID-19.

The survey confirmed that the OPEN Pilot facilitated the assessment of the same data by multiple authorities and all respondents agreed that the initiative should continue after the pilot. In addition, EU experts would find beneficial to increase collaboration and contributions from participating OPEN experts within each procedure, while maintaining full scientific and regulatory independence.

Therefore, the following recommendations are put forward:

### ***4.1. Develop more detailed rules of engagement***

Clearer terms of reference should be defined considering the following:

A driving factor for OPEN is to facilitate scientific collaborations that can expedite and inform independent decision making in each jurisdiction.

EU experts would also like to see more reciprocity of information exchange and more active participation of OPEN regulators in our scientific evaluation. In the survey, ETF and CHMP members found most useful to receive from OPEN regulators: assessment reports, comments on the EU scientific evaluation, divergent analysis, advanced planned regulatory actions or advanced public communications.

However, we could also envisage different types of engagement at the start of the evaluation by giving the choice to OPEN regulators to actively contribute or to only receive the EU assessment and therefore setting clear expectations.

Alignment of submissions and increased interactions should always aim to facilitate assessment, without slowing down actions in the EU. In addition, when non-EU authorities decide to participate in OPEN, in principle it should not be possible to have access to the CHMP assessments and adopt a decision earlier than the EU. It is also expected that personal data will have to be redacted prior to any information sharing, as currently done for any information exchange outside covid.

## **4.2. Expand OPEN to other high-impact areas**

One of the findings from the stakeholders' surveys was support for transitioning to a more permanent way of working in specific diseases/product areas. COVID-19 vaccines and therapeutics was a well-defined scope for the OPEN pilot with clear interests both for the EU and other regions. Yet, other areas could also highly benefit from international collaboration. The following areas will be explored:

### *Phase 1*

- **Antimicrobial resistance (AMR)** is a global health threat where progress requires a collective effort for human and veterinary products. Assessing AMR products as part of OPEN could be the first step after the pilot to facilitate a global collective assessment.
- **Cross-regional collaborative assessment of CMC aspects** for innovative methods or applications with potential to increase availability of key medicines to patients. OPEN could be a continuation of the recently launched ICMRA pilot for cross-regional collaborative assessment of CMC aspects (Post-Approval Change Management Protocols).

### *Phase 2*

- Priority medicines designated under the **PRIME** scheme.
- Vaccines and medicines that respond to health threats or **public health emergencies**, or where additional expertise brings added value to the EU assessment or impact for global health.

The consolidation of OPEN should evolve in a stepwise approach, improving first the operation of the current initiative and broadening later the scope to areas that would benefit the most from international collaboration and also provide value-added and visibility for the EU.

## **4.3. Increase communication**

No clear ground rules for communication on OPEN by international regulators were specified in the initial setting-up of the pilot.

The terms of reference should provide guidance for more systematic communication on the products assessed under the pilot and more information on the initiative on all participants' websites. All stakeholders, EMA and non-EU regulators, should specify their participation in OPEN in their decision making. The promotion of the initiative can also be done with our industry, patients, and healthcare professionals stakeholders meetings.

## **4.4. Integrate OPEN in the IT development of the Agency**

Facilitating collaboration and expertise sharing also requires adapted tools. As documents are the heart of the collaboration, a reliable document management system accessible externally and internally is essential to ensure a future proof solution adapted to the constantly growing flow of documents exchanged.

## 5. Action Plan as endorsed by the Management Board in March 2022

### Online survey and pilot review

1. The analysis gathered as part of the stakeholder's **online survey** have been used to inform the stakeholder's analysis strategy. The recurring themes identified as strengths and weaknesses of the pilot will be used as input for the recommendations proposed so far.

### Stakeholders' analysis and workshops

2. As per the **CHMP 2022 workplan**, the EMA will first engage with CHMP and its other Committees to define the **terms of reference and strengthen the value-added exchanges** where a greater focus should be put to facilitate submission, review and approval of the specific medicines.
3. In 2022, EMA will also organize a series of review meetings with **OPEN regulators** to better define the framework, increase the efficiency of the interactions and align future goals & objectives
4. Consultation of priorities with the pharmaceutical industry will be done as part of the **industry stakeholders** meeting scheduled for mid-2022.
5. Expanding the OPEN initiative to non-COVID areas will be done in a stepwise approach, starting with AMR and then considering the priorities put forward by Committees (**CHMP, ETF, CAT, and CVMP**) in collaboration with the **Human and Veterinary Divisions**.
6. Consultation with the **Regulatory Science and Innovation Task Force and the Product Portfolio Office**, to **monitor the pipeline and identify priority medicines** of major public health interest.

### Communication and operation

7. Throughout 2022 and in coordination with international regulators, the EMA will also increase communication and transparency on the initiative with a more detailed OPEN section on our EMA website, highlighting the OPEN initiative in our communication and regulatory conferences and reaching out to other stakeholders like **patients and health care professionals**. EMA will also request participating regulators to provide visibility about their participation in OPEN, as a requirement for the participation.
8. Templates used to exchange information are being revised to promote more collaboration and engagement from OPEN regulators. The EMA will continue to monitor and review the impact of implemented changes throughout the year.
9. EMA will support the integration of OPEN in its **IT tool** development strategy.