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International Affairs

# Questions and Answers on the Pilot Project 'OPEN'

## Opening our Procedures at EMA to Non-EU authorities

Questions and Answers on a pilot project regarding the participation of non-EU regulatory authorities in the Emergency Task Force (ETF) and the Committee for Human Medicinal Products (CHMP) assessment processes during the COVID-19 pandemic.

**Introduction and Objectives**

The COVID-19 pandemic is a global challenge for public health and requires the urgent development of new treatments and vaccines across the globe. International collaboration brings multiple benefits to regulatory authorities, and eventually to patients. Collaboration facilitates patient access through harmonisation or convergence, brings additional scientific expertise to a regulatory authority and simplification for pharmaceutical industry. It also increases overall transparency and can contribute to public trust because regulatory decisions are open to peer-review, either formal or informal.
The objective of the OPEN pilot project is to allow active international participation in our scientific evaluation, in the context of COVID-19 by regulatory authorities with confidentiality arrangements. This is in line with the principle of reliance and global regulatory good practices.

Participation of non-EU regulatory authorities, or selected international organisations, may support the accelerate development and assessment of medicines in the context of COVID-19, where the needs and potentials treatments and vaccines are the same globally. Participation of non-EU regulators can bring additional expertise at a time our network is stretched due to the pandemic. It shows leadership and the strength and robustness of the EU regulatory network. This active participation can also benefit the non-EU countries, including the possibility to receive applications earlier, to speed up their own assessments and make COVID-19 medicines available to the public faster. International collaboration may increase public trust in the EU procedures and approvals, at a time when vaccine hesitancy has increased.

Participation in rolling reviews of COVID-19 vaccines and treatments at the ETF and in CHMP will not be systematic and is subject to agreement by EMA based on set priorities. This is limited in time to

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COVID-19 medicines and will be subject to an analysis by the end of this pilot project. The participation is seen as scientific collaboration essentially. An additional benefit may be increased chances of having similar outcomes between health authorities globally.

There is no intention, guarantee or obligation to align opinions, approvals or policies. Participation of non-EU regulatory authorities should not limit or threaten the independence of the CHMP, the ETF, nor of the EU. Therefore, the non-EU regulatory authorities will not be participating in the finalisation or adoption of the ETF recommendations to CHMP, nor the CHMP's scientific opinion, nor in the EU decision-making phase. The participating authorities will retain their independence as well.

**Procedures for COVID-19 medicines including vaccines:**
The pilot project is limited to the following authorities: Health Canada (HC), Japan Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency (MHLW/PMDA), Swissmedic, Therapeutic Goods Administration (TGA) and World Health Organization (WHO). This pilot project is only for CHMP and ETF and is not extended to other Scientific Committees such as PRAC or CAT. Participation of other authorities and status in other Committees (as observers) remains unchanged during the pilot project.

The following Q&A explains the principles of this collaboration.

### 1. Who can participate?

The participants are the regulatory authorities listed above, with which EMA has a permanent confidentiality arrangement in place.

### 2. What are the conditions?

There should be an agreement between the non-EU regulatory authority and the EMA Executive Director. The request must be agreed by the CHMP and the CHMP Secretariat, as workload must be taken into consideration. EMA can always, after internal discussion, refuse participation without having to justify its refusal.
The concerned marketing authorisation applicants will be informed of the participation. The marketing authorisation submissions to the participating authorities should be made at about the same time as to EMA and the scientific content of the submissions should be similar; the applicant is invited to point out any difference justified, for example, by the different territory or legislation.

### 3. What is the status of participants?

<u>Conditions for expert nomination</u>
The participating OPEN experts will be proposed by the participating authorities and appointed by EMA once they have met all criteria of the policy applicable to experts. This requires 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 will apply to the experts (in particular with respect to medicine procurement or purchase decisions).

The number of OPEN experts attending the ETF or CHMP is limited to 2 per authority, with possible justified exceptions based on area of expertise and need. In the case of WHO, participation is limited to WHO staff.
WHO can also bring observers from non-EU regulatory authorities in the context of an OPEN procedure and the maximum number of observers will be four.

Assessment
It is assumed that each non-EU authority will conduct its assessment in parallel. Individuals considered as 'OPEN experts' should be able to present the compiled scientific evaluation and overall assessment of their authority. The experts can also discuss and report back within their authority (e.g. to their product team) on the discussions taking place at EMA.
OPEN experts should interact with the Committee or ETF, rather than contact the Rapporteurs directly, or can interact through the EMA product team.
OPEN experts should be allowed to contribute actively to:

- the CHMP discussions on the evaluation of the product.
- the ETF (COVID-19) discussions.

They will not be allowed to contribute to the CHMP or ETF conclusions (nor voting) for all key procedural milestones, in particular opinion-making. They can still listen to these opinion-making steps, etc. but are not allowed to take part.

Note: the participation as OPEN experts is distinct and independent from participation as 'observers' at any Committee meetings, described here [https://www.ema.europa.eu/en/documents/other/chmp-rules-procedure_en.pdf].

## 4. What can be exchanged?

Under the terms of the Confidentiality arrangements, authorities can receive the necessary outputs of the Committee. This includes (but is not limited to) Rapporteurs' assessment reports, List of Questions, Reader's guidance, joint assessment report, interim and final opinion.
The participating authorities may share their own documents with the ETF or CHMP, without prejudice to the CHMP assessment.

## 5. What should be redacted?

According to the EU data protection regulation, EMA documents should be redacted for personal data according, 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). The EDPS has accepted that COVID-19 creates a justified exception and COVID-19 related documents can be exchanged without prior redaction of personal data.

### 6. What if the non-EU authority brings a new or different scientific issue in their assessment, not identified by the Committee or the Rapporteurs?

One of the objectives and potential benefits of OPEN is to increase expertise, broaden and strengthen EMA and EU network scientific reasoning. Participating OPEN experts will be able to provide the compiled scientific evaluation of their authority, including divergent analyses. Such scientific differences can be addressed explicitly in the CHMP assessment report or in the minutes of the CHMP/ETF meetings, to enhance visibility of the overall scientific discussion in an objective way, without attributing each single view to the expert who expressed it. For the sake of clarity, there is no obligation for the Committee to agree with the views of an OPEN expert, but in terms of Good Scientific Practice, transparency of debate about scientific views leads to better quality of assessment. Any convergence is welcomed.

### 7. What should be included in the Assessment reports and other documents?

The CHMP assessment reports represent the view of the CHMP only. Additionally, assessment reports should not present the views, policies or decisions of non-EU authorities as potentially influencing the outcome. Opinion-making remains the sole competence of the Committee and its members.

### 8. Which information will be included in scientific documents?

Communication in Committee scientific documents: As for any expert participation in the process, the OPEN experts from the non-EU regulatory authority and their domain of expertise should be listed. The names will appear in the list of participants in the minutes of the CHMP meeting that they attended, while names are not listed for observers.
The non-EU authorities will not be mentioned in the benefit/risk opinion, nor in divergent opinions by Committee members in case of a majority vote.

The following sentence will be included in the Assessment report and EPAR, presenting the role of the OPEN experts from non-EU regulatory authorities, while highlighting the independence of the Committee.
'*During the assessment of the application for marketing authorisation of <product name>, the following non-EU authorities (Health Canada, Japan MHLW/PMDA, Swissmedic, Therapeutic Goods Administration, World Health Organization) were allowed to participate in and contribute to the scientific discussions of the ETF and/or CHMP. These authorities had no influence on the final benefit/risk determination, which was decided by the Committee members only*.'