Council of the European Union
General Secretariat

Interinstitutional files:
2020/0321 (COD)

Brussels, 27 May 2021

WK 7011/2021 INIT

LIMITE

SAN
PHARM
MI
COMPET
COVID-19
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (General)
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

With a view to the informal videoconference of the members of the Working Party on Pharmaceuticals and Medical devices that will take place on 28 May, delegations will find attached a note on funding prepared by the Commission services.

The Legislative Financial Statement of the proposal

The Legislative Financial Statement serves to indicate the financial and budgetary impact of the proposal.

The Multiannual Financial Framework (MFF) sets the ceiling for EU expenditure. The budget envelope for the EU4Health will be used to finance the extended mandate of EMA during the period 2022-2027, within the MFF 2021-27. Funding of the Agency for 2021 has already been assigned from the margins of the MFF for 2021.

Remuneration by EMA of Member States' NCAs

ETF

National competent authorities (NCAs) directly involved, as Rapporteurs and Co-Rapporteurs, in the assessment of COVID-19 procedures that are discussed at ETF, including scientific advice, compassionate use, rolling reviews and conditional marketing authorisation, will be remunerated for those assessments by EMA, according to currently applicable rules. Fee reductions and waivers applied to the abovementioned procedures will not affect the corresponding remuneration to NCAs which will be paid in full. The corresponding shortfall in EMA's budget will be covered by the amounts of the increased EU budget contribution to EMA for ETF presented in the Legislative Financial Statement of the proposal.

Following the same operational arrangements, coordinating NCAs of scientific advice procedures will also be fully remunerated for their role in temporary free COVID-19 scientific advice procedures. It is important to note that in these instances, industry fees will be fully waived.

It is acknowledged that member states have been under increased pressure, for carrying out COVID-19 product-specific assessments in significantly reduced timeframes. Further to the request from the European Commission to look into possible financial support to be provided to Member States via EMA, the EMA will consider whether an additional remuneration could be provided to the MSs assessment teams that are actively involved in product-specific assessment work, in addition to the normal share of the EMA fee that the CHMP Rapporteurs, Co-Rapporteurs and SAWP Coordinators receive, under existing provisions in the EMA fee regulation (e.g. for "scientific services"). Similarly, partial or full fee waivers will not affect the corresponding NCA remuneration which will be paid in full, while the corresponding shortfall in EMA's budget will be covered by the amounts of the increased EU budget contribution to EMA for ETF presented in the Legislative Financial Statement of the proposal.

In line with the applicable rules, EMA cannot provide further remuneration than those foreseen for Rapporteurs, Co-rapporteurs and coordinators.

Other Member State funding opportunities

The EU budget cannot legally be used as a mechanism to directly subsidise Member States for tasks specified in the proposal.

Member States may request financial support from the Union through the EU4Health Programme. One such option is through a currently proposed joint action on shortages of 3 years duration,

however it should be noted that the 2021 work program is not yet adopted. Further information will be made available in due course.

It is important to note that MSs obtain important benefits in exchange for their contribution to work at EU level, i.e. for ETF this includes accelerated vaccine approvals and prompt EU-wide action in case of emerging safety issues and for medicines shortages this includes coordinated EU actions to support availability of medicines.

EMA Fee Regulation

The Agency is funded by general EU and EEA contributions as well as fees paid by industry for obtaining and maintaining marketing authorisations and providing other authorisation-related services. The EMA works in close collaboration with NCAs in EEA Member States, which undertake activities related to assessments aimed at granting, maintaining and monitoring EU marketing authorisations, and other services related to medicinal products for human and veterinary use including pharmacovigilance activities for medicines for human use at EU level. NCAs are remunerated by the EMA for undertaking these activities, which are subject to fees. The future EMA Fee Proposal will be preceded by a separate assessment of impacts, including an analysis of the basis for NCA remuneration within the EMA fee system.