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NOTE

From:	General Secretariat of the Council
To:	Delegations
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 discussion on the above-mentioned proposal at the informal videoconferences of the members of the Working Party on Pharmaceuticals and Medical devices that will take place on 22 and 23 April, delegations will find attached a working document from the Presidency.

ANNEX

In the meetings of the Working Party on Pharmaceuticals and Medical Devices on the 5th and 23rd of March the proposal for a reinforced role of the EMA was discussed in full.

Following the fruitful initial discussion at working party level and based also on the written comments received from the delegations, several issues have been identified for further discussion.

These relate mainly to the administrative and financial impact of the proposal, the scope and definitions, the functioning, the composition and interactions of the ETF and the approach to medical devices.

The aim of this working document is to deepen the discussions on these issues. For this purpose, we have selected specific topics to enable a more detailed discussion on each one of these. This document aims also at providing additional information and clarification on some of these issues.

This document has been drafted considering the interventions of Member States during the meetings, the written comments received from the delegations and also clarifications gathered from the European Commission.

Following this discussion, the Presidency intends to further refine the text of the proposal.

1) **Administrative Impact**

   a. **National Competent Authorities**

Many delegations expressed concerns on an alleged increase of the administrative burden for National Competent Authorities when monitoring declared major events and public health emergencies. These concerns are mainly related to:

- Possible interference with national responsibilities and competences on the management of shortages (non-centrally authorised products) – art. 3;
- Clarification on the links envisaged between existing structures (HMA TF on Availability, SPOC network) and the new structures proposed (MSG, ETF) – art. 3;
- Possible duplication of tasks with already existing structures, namely SPOC – art. 4 (2);
- New reporting systems that must be interoperable with national IT systems – art. 9 (1) c;
- Member States' obligations under art. 11(1) and (2): this article places obligations on the national competent authorities to submit available and estimated data on demand. While information requested should be harmonised any duplication of information previously collected should be avoided;

The Presidency considers that it is extremely important to make clear that the new responsibilities and procedures are necessary and proportionate to their purpose, ensuring that resources needed from all sides will be available. Information requested must be harmonised, avoid duplication and follow agreed European guidelines.

According to the European Commission, the proposal does not intend to duplicate the national competent authorities' administrative support nor to impact existing practices at national level and the required information reflects the already gathered information.

However, given the comments received, the discussion of this issue would be beneficial to clarify questions and provide the Commission with an opportunity for further clarifications with a view to identify the need for possible adaptation to the text on this point.

b. Stakeholders

Concerns were also expressed on the reporting of information by stakeholders namely to ensure proportionality and to avoid duplication. These concerns are mainly related to:

- Harmonisation of data sets to be requested by EMA and Member States to avoid inconsistencies – art. 10.
- Art. 9(3) h) – MAH may have difficulties to assemble information from wholesalers and pharmacies as medicines are distributed by many entities in the supply chain. Need to specify information to be requested under art. 9 (3) h)

The Presidency considers necessary to clarify the extent to which all requested information is adequate and proportionate. Additionally, the information requested shall be harmonised, any duplication shall be avoided and agreed European guidelines shall be followed.

2) Funding

The proposal refers to the need to facilitate the work and the exchange of information through the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices.

However, questions regarding the funding of the activities planned under the proposal were identified.

The concerns expressed by Member States can be divided in two main areas: on the one hand the financial support foreseen for the implementation of the IT tool (Art. 18), on the other hand the impact this proposal may have at national level namely due to the need to ensure interoperability of IT systems.

National authorities are compensated for the work of their experts and for the involvement of their staff members in the Agency's scientific committees, working groups and other activities from the Agency's budget. This budget derives from charges from the EU contribution for public-health issues and other sources for the coordination of the scientific evaluation of applications and related work with the national medicine's regulatory authorities in the EU Member States.

In this domain, the Commission clarifies that the funding of activities is linked to EMA costs under EU4Health Programme. Additional financial support may be available to the national competent authority through the joint action on shortages.

Moreover, a legislative proposal on the European Health Data Space will likely be made in 2021 and a reference is made to it here to allow the Agency to play a role as a 'node' facilitating the agency's access to and analysis of 'real-world' health data.

From the comments received, the Presidency considers that these points may be further clarified in the recitals to make clear where funding for these tools shall be made available.

3) Scope and Definition

Several delegations pointed out the importance of including veterinary medicines within the scope of the extension of the EMA mandate and support for the inclusion of the "One Health Approach". In this perspective, this regulation should also address animal health crises as future health crises may have dependencies on veterinary medicines since most epidemics are of zoonotic origin.

In this regard, the Commission considers that veterinary medicines should not be covered by this proposal as there is already a system in place under the Veterinary Medicinal Products legislation allowing for crisis management in the case of shortages. This system allows for the possibility of using veterinary medicines intended for other species or human medicines and sharing veterinary medicines between Member States.

Additionally, a similar situation of shortages for veterinary medicines during COVID-19 was not yet observed. Where a disease or event in animals causes a major event or public health emergency, this would trigger the relevant provisions in the proposal and where necessary veterinary medicines could still be subject of medical countermeasures under the Proposed CBHT Regulation.

The Presidency sees merits in an in-depth discussion on the added value of including veterinary medicines in the scope of the regulation in order to fully accomplish the objective of improving crisis preparedness and management.

a. Major events

The operational phase of the work of the Steering Groups and Emergency Task Force provided for in this Regulation should be triggered by the recognition of a public health emergency in accordance with Regulation (EU) 2020/ […] on Cross-Border Health Threats and, as regards the Medicines Steering Group, the existence of a major event. Continuous monitoring of the risk to public health from major events products should also be ensured.

Therefore, the definition of major event is, alongside the recognition of a public health emergency, the trigger for the activation of the mechanisms foreseen in this proposal as well as the basis for its termination (articles 5 to 12 shall apply).

Many delegations consider this definition too broad/vague and believe it may lead to disproportionate measures. Particular emphasis was given to the timing of its recognition and its occurrence, in one or more Member States.

The Commission defines major event as an event likely to pose a serious risk to public health, of a cross-border nature and related to medical products. It can be a health threat or an incident affecting supply or quality (Q)/ safety (S)/efficacy (E) of medical products. Its nature i.e. whether it affects supply or Q/S/E will determine whether shortages' monitoring or ‘regulatory’ advice (Art. 5) is needed. In some cases, both may be needed. Something that starts as a major event could become a public health emergency.

In light of this clarification, the Presidency considers that this definition should be further discussed and clarified namely regarding the criteria for its applicability. One possibility could be a categorisation of the events that constitute a major event in order to deploy an adequate and proportionate response.

4) Emergency Task Force (ETF)

The scope of ETF's activities during 'public health emergencies' should be further clarified, to avoid that its mandate goes beyond what is necessary to support the EMA's foreseen responsibilities in crisis preparedness and response. Additionally, clear mechanisms of coordination and communication should be in place as well as the definition of the cessation of ETF's activities.

ETF tasks outlined in Article 14 refer to: "provide fast-track scientific advice, carry out 'rolling reviews' and give advice on the use of new or repurposed medicines". All these tasks aim at facilitating the development of new or repurposed 'candidate medicines' to treat, prevent, or diagnose the disease causing the public health emergency. These tasks do not replace requirements for Clinical Trials (CTs) and marketing authorisation but can complement and feed into these processes too, including the regulatory work of the Agency (CHMP).

A possible solution could be the inclusion of ETF termination in the proposed new regulation, amending Art 14.1 (ETF establishment) to indicate that ETF tasks will cease after ending the activating public health emergency.

Member States also lack clarity on (division of) competences and interactions between the ETF and CxMP (in particular CHMP, PRAC, CAT, SAWP) in the Commission proposal. ETF is intended to be set up as a structure working in parallel but separately from existing committees and working parties, (WP) which should exclude possible duplication of responsibilities.

According to the Commission, the ETF can provide input (e.g. recommendations on use) to the CHMP that can be considered when CHMP gives an opinion on such use. The scientific advice given by the ETF will be endorsed by the CHMP. However, the work of the ETF will remain separate from the work of other bodies and committees in the Agency. The aim of the ETF does not replace the remit of any other committee or WP. Competencies of current EMA committees and working parties remain unchanged as per the role and tasks set-up in Regulation 726/2004.

In accordance with the scientific advice under Art 57.1(n) of Regulation 726/2004, the preparation of the advice on public health emergency undertaken under the extended mandate is being prepared by a multidisciplinary expert group, namely the ETF. The final review and adoption of the advice, i.e. for general scientific advice prepared by SAWP and for public health emergency -related prepared by ETF, lies with the CHMP, where all Member States are represented. The CHMP remains the final decision maker.

Currently the COVID-ETF is accountable and under the direction of the CHMP for all its activities. COVID-ETF can assist the CHMP, take part on behalf of the CHMP in early scientific discussions and products reviews and contribute to formal rapid or standard scientific advice procedures as advisor to SAWP, among other tasks.

Taking this into account, a possible solution could envisage a clarification by amending Art 14.7.

The Composition of the ETF also poses a concern to some delegations since not all MS are represented, which may limit the uptake and implementation of recommendations at national level.

The aim of the Commission proposal is to assemble the required expertise in an efficient manner but also allow the ETF to be of a manageable size. Furthermore, the Commission prefers the text of the regulation to be lean rather than include too many details. The composition based on current experience is primarily based on assessors and experts sitting in different committees or working parties and the overwhelming majority part of the competent authorities of Member States. The rules of procedure can provide more details on composition and management of the ETF. The composition can be adapted to the scope of the crisis, as not for each crisis the same representatives/experts may be needed. To be noted that the ETF aims at assembling the best expertise available in the Network whereas the CHMP is consisting of representatives from all Member States.

To address this issue, ETF composition could be clarified indicating that it includes representatives nominated from the scientific committees and working parties, and should be publicly available. The ETF could be chaired by a representative of the scientific committees and co-chaired by the Agency. The presidency could propose to amend Art 14.3 (ETF composition) to include these suggestions.

ETF advice on CTs is another concern raised by Member States. It is unclear how the activities of the ETF in requesting and submitting data align with the authorisation of CTs because the protocols for CTs are in the remit of competences of the national competent authorities. CTs are approved by national decision and this should be respected. It is also suggested that a representative of the Clinical Trials Facilitation Group (CTFG) is involved in the ETF because the Clinical Trial Coordination and Advisory Group (CTAG) representation foreseen has extremely limited tasks and its mandate is not adequate to the activities assigned by this proposal.

The Commission clarifies that the ETF tasks do not replace national requirements for CTs but will complement and feed into the process of CT authorisation. The usual (national) decision on CTs remains. ETF advice only relates to the CTs' protocol; approval of CTs remains national responsibility.

The ETF will provide an advice on the protocol (15(1)(a) which is a scientific advice (SA) on the study design, population, endpoints etc. as normally set out in the protocol. The data to be submitted apart from the protocol, for a rapid scientific advice per article 15(2) would depend on questions the developer may want to ask, and subsequent questions that would come from ETF (at pre-submission or as part of rapid SA process).

Representatives from the Member States will be involved in the ETF discussion on specific clinical trials. In addition, ETF has a representation from the CTAG that is set up by article 85 of the Clinical Trial Regulation 536/2014. The role of the CTAG representatives in ETF would be to be involved horizontally in all discussions at the level of ETF to present views on CT matters. Additionally, their role would be to work (together with the representatives of Member States involved), on the advice on specific protocols. The CTAG is the group in the Clinical Trial Regulation that is composed of the national contact points, designated by each Member States to facilitate the functioning of the procedures for initial submission and changes to the initial submission in the Member States (so overarching the responsibility of the national competent authority and ethics committees); the list of those contact points is public. Hence the role of the CTAG is different and distinct from that of the ETFs.

A possible solution could be the amendment of Art 15.1 (ETF advice on CTs) to make clear that the activities and advice of the ETF on CTs should be without prejudice to the responsibility of the Member States in accordance to Regulation (EU) 536/2014.

Data exchanged with ETF (by developers and MSs) is yet another problem identified. More clarity is needed on the type of information/data that can be requested by the ETF to the developers (Art. 14.2.a) and/or to marketing authorisation holders (Art. 16.2) or MS (Art. 16.6) in preparation of a review of medicinal products and recommendations on their use. Further, a clear definition is needed on the ‘data generated outside the scope of clinical trials’ (Art. 16.2 and Art. 18.a).

According to the Commission, and based on current experience, data exchanged with the ETF relate primarily to development data from manufacturers, scientific data from published literature and exchanged information from other regulatory bodies such as the FDA, WHO, etc. The Agency has long experience with the handling of sensitive data. This data relates mainly to data submitted by developers to Member States for requesting compassionate use authorisation, national assessment of such data or other type of information that Member States may consider relevant for ETF (e.g. information from use of the product in their territory under "named patient use").

The Commission clarifies that, "data generated outside the scope of clinical trials" refers to routinely collected data relating to a patient health status or the delivery of health care from a variety of sources other than traditional clinical trials as well as information derived from analysis of such data.

5) Medical Devices

The involvement of the EMA in this area has raised various questions which have been addressed by the Commission but still require further analysis.

In what regards the Commission, it is of the view that in the absence of a dedicated agency for devices at Union level, a pragmatic solution is needed to deal with a clear need for a body to handle crisis preparedness and response functions in the future. During the current crisis medical devices and medicines have faced common challenges in terms of shortages and, given the Agency's experience in dealing with medicines shortages, the number of synergies between devices and medicines and lack of alternative structures, the Agency is, in the opinion of the Commission, the obvious choice to fill this gap. To this effect, there is a need to establish a steering group under the EMA. The Medical Devices Coordination Group (MDCG) has a precise mandate for the implementation of the medical devices regulation which does not include the monitoring of shortages, which is outside its scope. The Commission considers that it is not a transfer of competences as the proposal does not aim at giving EMA new competences. EMA will carry out the administrative tasks of hosting the panels, which remain independent. It will not provide a 'scientific secretariat' as it does for some other committees or working parties.

In light of main issues identified, the Presidency considers that further discussion is needed on the following aspects:

- The composition, chairmanship and the expertise of the Medical Devices Steering Group (MDSG) as well as the liaison with MDCG as per article 19.
- Establishment of a communication link between the MDSG and the MDCG.
- Differences in Member States national competent authorities for medical devices regarding their intervention in the management of shortages, and how to implement the provision of data.
- Coordination with EUDAMED as source of information.