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Comments from the Netherlands on a 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 (COM(2020)725)

With this proposal the Commission aims to provide a clear framework for the activities to be deployed by the EMA in preparation for and during public health emergencies and other major events. The Covid-19 pandemic showed that the Union's ability to respond in a coordinated, quick and efficient manner to cross-border health threats in order to ensure the functioning of national health care systems is insufficient. Individually and independently, Member States are unable to guarantee the availability of (certain) medicinal products and medical devices. Reinforcing coordination at the EU-level is therefore justified.

Several proposals in the Regulation contribute to a stronger crisis preparedness and response of the Union. The central monitoring of shortages that could potentially lead to a 'major event' or a public health crisis contributes to an EU-wide overview of availability issues and to Member States addressing shortages in a coherent manner. Similarly, the central evaluation of information on the quality, safety and efficacy of medicines avoids Member States having to individually carry out such assessments. Also, the establishment of an Emergency Task Force for the assessment of all scientific data and the provision of advice on clinical trials could ensure that these trials are carried out in a coordinated manner. Further, action at the EU-level could prevent Member States from taking unilateral measures and, as such, safeguard the functioning of the internal market.

The Netherlands therefore generally supports a reinforced role of the EMA in crisis preparedness. However, there are several concerns and uncertainties that need to be addressed and clarified. The main concerns are listed below.

Definition of 'major events'

The proposal provides for a reinforced role of the EMA in case of 'major events'. However, the definition of 'major events' is considered too broad, which makes the scope of the extended EMA mandate unclear. For instance, under the current definition the Executive Steering Group on Shortages and Safety of Medicinal Products should act on almost every shortage occurring in more than one member State. The definition should therefore be clarified and tightened to ensure that EMA's additional responsibilities and activities do not go beyond what is required to prevent or mitigate (imminent) cross-border public health crises.

Executive Steering Groups for medicinal products and medical devices

The proposal officially establishes the Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Steering Group'). This Medicines Steering Group has been active since March 2020 to prevent and mitigate supply disruptions during the pandemic, through the development of methods for the collection and sharing of data on medicine demand and through improved forecasting thereof. The Netherlands recognises the added value of the work done by the Steering Group during the Covid-19 pandemic. However, the proposal foresees additional tasks for the Medicines Steering Group which need clarification. According to the proposal the Steering Group should provide advice to the Commission and Member States on appropriate action it believes should be taken at Union level regarding the quality, safety and efficacy of medicines related to health crises and 'major events'. Further, Member States should take into account any recommendations and guidelines and comply with any measures taken at Union level. More clarity is needed here as the scope of this additional task is very broad; what type of advice or recommendations are in fact foreseen? Also, it is unclear how an advice or recommendation should lead to EU-level action.

The proposal also foresees in the setting up of an Executive Steering Group on Medical Devices ('the Medical Devices Steering Group'), which focuses on crisis preparedness. It is unclear how the Medical Devices Steering Group relates to the already existing Medical Devices Coordination Group (MDCG) and whether and to what extent this new steering group provides added value to existing bodies in achieving an efficient approach to cross-border health crises. Moreover, in regards feasibility of this proposal, attention is needed to the fact that, so far, the EMA has developed only limited knowledge and expertise in the field of medical devices.

Monitoring of shortages of medicines and medical devices and distortion of the internal market

In principle, the Netherlands supports the proposal for a single comprehensive overview of shortages in the EU, because this provides clarity on the extent of the issue. However, the feasibility of monitoring data on supply and demand is questioned. Member States and EMA are conducting a pilot to monitor such data for Covid-19 related medicines. During this pilot, several practical issues have emerged. For example, the collection of supply data from all pharmaceutical companies and wholesalers in the EU is not permitted under competition law. Also, it is difficult for Member States that do not purchase medicines centrally, such as the Netherlands, to provide data on medicine demand. Further, according to the proposal the Medicines Steering Group may provide recommendations on measures to be taken by the Commission, Member States, marketing authorisation holders or other entities to prevent or mitigate potential or actual shortages. This raises two concerns. First, with national governments having to monitor demand and supply and providing targeted advice on required quantities, the responsibility to maintain a sufficiently large stock of medicines shifts away from the marketing authorisation holder. Second, it is unclear what type of recommendations is foreseen and whether procedures are in place to avoid that the measures following from these recommendations jeopardise the functioning of the internal market.

At the same time, the proposal does not protect the internal market from Member States unilaterally imposing EU internal export restrictions, which could significantly distort product value chains and supply. Such unilateral impositions occurred during the initial phase of the Covid-19 pandemic. The proposal should address this issue, since a well-functioning internal market is essential to ensure security of supply across the EU.

Emergency Task Force

Although the Netherlands generally supports the setting up of an Emergency Task Force (ETF), clarity is required about its precise role and responsibilities. The Netherlands is of the view that the ETF should be an advisory and supporting body, since the legal responsibility and competence for scientific decision-making and recommendations lie with EMA's scientific committees.

Support for expert panels on medical devices

The proposal provides that an appropriate framework should be established to support the work of the expert panels on medical devices referred to in Regulation (EU) 2017/745. The objective is to enable them to provide in a decisive and effective manner scientific advice relevant for crisis preparedness and management. However, above all, these expert panels have a regular legal task under the legislation for medical devices and in vitro diagnostics which does not specifically focus on crisis preparedness or management. The Netherlands therefore has doubts about the current form of this proposal. It is important that the expert panels take shape in such a way that they can properly fulfil their legal tasks. In view of this, and in view of EMA's so far limited knowledge on and experience with medical devices, it should be discussed whether the management of these expert panels is best placed with the EMA or whether an alternative option is to be preferred.