AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

AESGP feedback on the draft proposal for a *Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices*

The Association of the European Self-Care Industry (AESGP), representing the European manufactures of consumer healthcare products (including non-prescription medicines and selfcare medical devices), would like to use the opportunity provided by the Commission to comment on the draft *Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices* (2020/0321 (COD)).

As part of the healthcare continuum, self-care products can prevent illness, address minor health problems, reduce pressure on health systems, and its use was an essential part of facing the COVID-19 pandemic. Self-care entails responsible self-assessment, self-treatment and self-monitoring, only possible by consumer and patient empowerment, by increased health literacy and by professional guidance on healthy lifestyle choices.

AESGP acknowledges that the EU must have all the tools and governance in place, including at high level, to build a stronger European Health Union, and ensure resilience and coordinated actions to face future health emergencies. The role of existing EU agencies, such as the European Medicines Agency (EMA), should be further reinforced not only with greater competences but also with sufficient allocation of resources in terms of staff and funding. In line with this Commission's commitment for a sound and flexible regulatory system, AESGP agrees that it is crucial to pursue a better regulation agenda for a modern pharmaceutical sector, to reduce red tape and improve access and timelines, after an impact assessment that addresses the specificities of the assorted range of medicinal products and medical devices.

AESGP fully supports the general objectives of the proposal to

(1) *ensure a high level of human health protection by strengthening the Union's ability to manage and respond to public health emergencies, which have an impact on medicinal products and medical devices, and*

(2) *contribute to ensuring the smooth functioning of the internal market for such products during public health emergencies.*

Nonetheless, AESGP would like to share the following significant concerns on the draft proposal for consideration by the Commission and ask for:

- an impact assessment to accompany this legislative proposal;
- where appropriate, a revision of the draft proposal to address the following concerns.

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Concerns on the lack of an Impact Assessment procedure

As explained in its Explanatory Memorandum, the proposal for a Regulation is not accompanied by an impact assessment due to its urgent nature.

Impact assessments form a key part of the Commission's better regulation agenda and are carried out on initiatives expected to have significant economic, social or environmental impacts[1]. Per the 2002 Commission's internal guidelines on the new impact assessment procedure[2], AESGP understands that *particularly urgent proposals, in response to cases of emergency or force majeure, may be exempted from the normal impact assessment procedures. Exemption will be the exception to the rule and will be assessed on a case-by-case basis (…).*

Given the measures introduced by the legislative proposal, notably regarding its **specific objectives 1 and 3**, AESGP questions the urgent nature of certain measures introduced by the proposal and, hence **the exemption from the normal impact assessment procedures which is not clearly justified by the Explanatory Memorandum.**

This proposal is clearly a response to the unprecedented experience of the COVID-19 pandemic and AESGP fully supports the general objectives of the proposal**.** However, looking at the specific objectives of the proposal, notably 1 and 3, it does not appear to require an immediate action without carefully assessing its economic and social impact:

1. *monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health;*

   This is proposed to be reached by anchoring in the legislation the ad-hoc solutions found during the COVID-19 crisis and currently operated since the beginning of the crisis by contingent arrangements between the actors involved. In other words, the ad-hoc solutions already exist and are being operated. The justification for having them anchored in the legislation is to make these solutions efficient and predictable by clarifying the respective roles and obligations of the different entities.

   The proposal should therefore be accompanied by an impact assessment to justify how this objective is appropriately reached by the proposed measures.

3. *ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.*

   Ensuring that the Expert Panels on medical devices can efficiently and effectively provide scientific advice, relevant for crisis preparedness and management, may require some immediate action. However, the management of their core function – to provide opinions on the verification by notified bodies of the clinical and performance assessments for certain high-risk medical devices, including certain in vitro diagnostic devices – is outside the scope of an urgent proposal.

   The proposal should therefore be accompanied by an impact assessment to justify the appropriateness of the permanent Agency role to support the expert panels on medical devices beyond crisis preparedness and management.

AESGP would like to share the following elements for the Commission's consideration when reviewing the urgency justification of the proposed measures:

[1] https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/impact-assessments_en
[2] https://ec.europa.eu/governance/docs/comm_impact_en.pdf

- **Establishment of permanent mechanisms to be applied beyond the times of public health emergencies**

  The Executive Steering Groups for both medicinal products and medical devices are to be used in preparation for and during public health emergencies and other major events.

  Accordingly, with regards to medicinal products, **EMA shall continuously monitor all events** (e.g. Art. 4(1)) and Member States or national authorities shall report all events, including supply shortages that may lead to a major event or a public health emergency (e.g. Art. 4(2)). In other terms, this means that a permanent monitoring system is planned and the competences of the EMA are to be further expanded.

  With regard to medical devices, it is foreseen that EMA will provide the secretariat of the MDR and IVDR expert panels on a continuous basis. Therefore, EMA will integrate those panels under its auspices permanently.

  AESGP fully supports the general objectives of the proposal and welcomes an approach based on strong preparedness.

  The development of common tools and agreed methods for monitoring, reporting and data collection to achieve this preparedness require a careful impact assessment as they are established as permanent instruments intended to replace the *ad-hoc* mechanisms currently in place.

- **The scope of the 'shortage' definition is not restricted to the times of public health emergencies**

  AESGP acknowledges the current lack of a common approach within the European Union on definition and management of shortages for medical devices. With regard to medicinal products, guidance on detection and notification of shortages of medicinal products throughout the European Union already exist.

  In order to achieve the specific objective of the proposal (1) regarding the monitoring and mitigation *of potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health,* **the definition of shortages should be carefully defined and its impact carefully assessed as it establishes the first harmonised EU definition of shortages which is common to both medicines and medical devices.**

Concerns on the application of the principles of Subsidiarity and Proportionality

Principles of Subsidiarity and Proportionality forward the amplitude of public policies and healthcare intervention strategies, allowing for the establishment of more equitable and close-managed measures.

An impact assessment *ex ante* is notably essential to assess the correct application of these principles in order to justify that the proposal constitutes an adequate response to the demonstrated limitations of the Union's ability to coordinate work to ensure the availability of medicinal products and medical devices and facilitate their development during public health emergencies.

> As stated in the Commission Communication on the principles of subsidiarity and proportionality: Strengthening their role in the EU's policymaking[3], *subsidiarity and proportionality are core elements of the Commission's approach to better regulation which is built on the three fundamental processes of evaluation, impact assessment and stakeholder consultation*.

While AESGP does not question the necessity of an EU action, the Explanatory Memorandum does not provide a detailed assessment of the proposal against the principles of subsidiarity and proportionality.

In particular, the proposal is only based on an assessment of the data collected during the first months of the pandemic and exchanges held with public and private stakeholders in the framework of the COVID-19 pandemic on issues encountered and possible means to address them. Since the proposal intends to make the *ad-hoc* solutions found during the COVID-19 crisis more efficient and predictable by clarifying the respective roles and obligations of the different entities, the following questions remain unanswered:

- Are the *ad-hoc* solutions found during the COVID-19 crisis fit for purpose?
- Are these *ad-hoc* solutions the most appropriate compared to other options available to reach the same objectives?
- Is the form of the EU action proposed as simple as possible?

AESGP would like to share the following elements for the Commission's consideration in assessing the impact of the EU proposed actions in the proposal:

- **Consistency with the actions considered for medicinal products under the Pharmaceutical Strategy for Europe and the medical devices legislative framework being implemented**

  As elaborated in the Explanatory Memorandum, *the proposal is a tailored approach for medicine and medical device management focusing on public health emergency preparedness.* For consistency purposes with other Union policies, the measures introduced by the proposal *will be complemented by additional actions under the Pharmaceutical Strategy for Europe to address structural challenges.*

  Among its objectives, the Communication from the Commission for a Pharmaceutical Strategy for Europe[4] includes *Enhancing resilience: Diversified and secure supply chains; environmentally sustainable pharmaceuticals; crisis preparedness and response mechanisms*.

  Since this legislative proposal acknowledges the complementarity between the measures it introduces and the actions considered under the Pharmaceutical Strategy for Europe to

[3] COM(2018) 703 final https://ec.europa.eu/info/publications/communication-principles-subsidiarity-and-proportionality-strengthening-their-role-eu-policymaking_en

[4] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pharmaceutical Strategy for Europe COM/2020/761 final

address structural challenges, an integrated approach should apply between the two initiatives to ensure consistency of the measures with regard to medicines.

With regard to medical devices, the necessary infrastructure to make the new regulatory frameworks for medical devices and *in vitro* diagnostics are still being implemented and need to deliver. Having a functioning legislative framework is a prerequisite to ensure the continued patient access to existing and new medical devices, especially during a health crisis.

Further assessing the measures proposed in the tailored approach for public health emergency preparedness should ensure their compatibility with the running of healthcare systems for 'normal' health purposes in an efficient and sustainable manner. Such assessment must take into account the legislative framework being implemented for medical devices and the various actions considered for medicinal products under the Pharmaceutical Strategy for Europe.

- **Complexity of the Structures and Procedures proposed compared to the Existing Regulatory Frameworks applicable to Medicines and Medical Devices**

  The Regulation Proposal provides for the creation of complex structures and procedures, which do not necessarily support and enhance the Union's capacity to react quickly, efficiently and in a coordinated manner in a crisis situation, and which is a main objective of this proposal. Five new bodies are to be created by this Regulation Proposal: Executive Steering Groups to monitor possible shortages of Medicinal Products (Chapter II) and Medical Devices (Chapter III) respectively, corresponding working groups and the envisaged emergency task force, which is to be convened in the event of public health emergency.

  The respective procedures are complicated, whereby the procedures of the two Executive Steering Groups are regulated differently, i.e. with regard to their initialisation.

  - "Major event" concept

    The introduction of the concept of "major event" and its usefulness is unclear. It does not appear necessary to envisage two scenarios for the terms of reference of the Medicines Steering Group – either an emergency or a major event.

    The definition of a major event is included in Art. 2 f) and describes an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. This leads to an unnecessary complexity of the regulations with, for example, two separate lists of critical medicines in each case.

    Rather, it should be based on one criterion: an appropriately defined emergency or crisis situation.

  - Risk of Duplication of Existing Infrastructure (EUDAMED) with regard to Medical Devices

    In the context of the Executive Steering Group on Medical Devices, it is further indicated that EMA will develop a "streamlined electronic monitoring and reporting systems" (Art. 23(1)). In addition, the Medical Devices Steering Group may also make use of data from device registries and databanks which are already available (Art. 21(2)). Such data will already be included in the EUDAMED database.

    Duplicate reporting obligations and duplicate database structures must be absolutely avoided. It should be mandatory for the Executive Steering Group to use data that are already available.

- Unclear coordination mechanisms with existing bodies under MDR and IVDR

  At the same time, a smooth functioning and coordination between the Medical Devices Steering Group, that is to be established under this proposal, and the existing Medical Devices Coordination Group (MDCG) established under the MDR and IVDR is of the essence.

These elements add complexity to the existing mechanisms and appear in direct contradiction with the explicit objective of the proposal to clarify the respective roles and obligations of the different entities for more efficiency compared to the current ad-hoc solutions currently in place.

- **Lack of transparency and predictability of the proposed mechanisms**

  The proposal foresees that *upon the entry into force of the Regulation, the Agency should put in place the framework which will be used to manage future public health emergencies (crisis preparedness and response) including the development of procedures for data submission, reporting and monitoring tools, and rules of procedure and working methods for the Steering Groups and Emergency Task Force.*

  Among other provisions, there is no further official regulation regarding the envisaged lists of critical medicinal products and medical devices, to the working methods of the Executive Steering Groups and the working groups reporting to them. According to Art. 9 and 23 of the Regulation Proposal, the EMA itself specifies the procedures for establishing the lists of critical medicines and medical devices, as well as the working methods.

  Importantly, AESGP believes that the working methods of the Executive Steering Groups and the working groups reporting to them need to ensure regular consultation of the stakeholders concerned including the industry.

  Many aspects related to the functioning of the various mechanisms proposed are not specified in the proposal itself and left to the EMA to put in place. This appears in direct contradiction with the explicit objective of the proposal to clarify the respective roles and obligations of the different entities for more predictability compared to the current ad-hoc solutions currently in place.

- **Necessity to develop further expertise in the Field of Medical Devices on part of EMA**

  EMA does have a long-standing and proven record of expertise in the field of medicinal products, whereas for medical devices the same level of expertise may not exist.

  On this basis, the proposal should elaborate on how the Agency will build the relevant expertise – beyond the related financial means – AESGP emphasises the need to develop further expertise in the field of medical devices so that it is to carry adequately its new responsibilities concerning the Medical Devices Steering Group and the hosting of the MDR and IVDR expert panels.

- **Unfit definition of "shortage" for non-prescription medicines and self-care devices**

  The proposed definition of shortage according to Art. 2d) of the Regulation Proposal would establish the first harmonised EU definition of shortages which would be common to both medicines and medical devices.

  In order for a harmonised approach to be effective in managing patients' risks even in times of public health emergencies, AESGP advises that the definition of shortages should be carefully defined and the management of a shortage should be proportionate to the impact on the patient. Therefore, the definition should provide flexibility for the Marketing Authorisation Holder (MAH) and Medical Devices manufacturers to determine whether the shortage will involve a risk to the patient (risk-based approach), taking into account

several factors and in particular the duration of the shortage, the criticality of the medicine/medical device and whether alternatives exist.

For more details on AESGP position on shortage, please refer to our Position paper on *Shortages of medicinal products for citizens in Europe: the particular case of non-prescription medicines*[5].

Conclusion

It is paramount that a tailored approach for medicine and medical device management focusing on public health emergency preparedness is **further assessed in the broader context of the Pharmaceutical Strategy for Europe so as to avoid unnecessary duplication of initiatives, to guarantee a proportional and adequate effort allocation, and to create the necessary synergies with other policies and stakeholders**.

Also, AESGP also calls EU decision makers to continue their efforts in establishing the necessary infrastructure to make the new regulatory frameworks for medical devices and *in vitro* diagnostics a success. **Having a functioning legislative framework is a prerequisite to ensure the continued patient access to existing and new medical technologies, especially during a health crisis.**

AESGP is determined to further contribute to the discussions on COVID-19 recovery and resilience to prepare and manage future health threats.

[5] https://aesgp.eu/content/uploads/2020/07/AESGP_PP_Shortages_2020.pdf