AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

European Health Response: Getting together to better prepare

AESGP Reply to EC's Inception Impact Assessment
on a European Health Emergency Preparedness and Response Authority

AESGP welcomes the European Commission's efforts to strengthen the EU's preparedness and response for serious cross-border threats to health, as an integral part of the EU Health Union.
AESGP supports the proposed Better Regulation approach which integrates an impact assessment to accompany the legislative proposal for the establishment of the European Health Emergency Preparedness and Response Authority (HERA). In this early phase of this initiative, AESGP would like to share some views regarding the objectives and policy scenarios described in the Inception Impact Assessment.

As preconized in the impact assessment, such an Authority is set to take a whole value chain approach, from threat assessment to conceptualisation to deployment in case of need. The purpose will be to support Member States' response capacities and access and ensuing availability and releasing of countermeasures to prepare for and address human cross-border health threats.

People-centric approach allows to weigh the possible impacts of a crisis

AESGP believes that the **impacts should be evaluated from both a health system and a people-centric approach, factoring in other options such as the availability of other** disease prevention and therapeutic solutions **aiming at the same healthcare outcomes. There needs to be a strict dialogue with the supply chain stakeholders**, responsible for the different stages of manufacturing and distribution, taking into consideration the benefits of affordability drawn from a competitive global market of pharmaceuticals and medical devices.

Good structure and communication avoid duplicating regulatory and executive efforts

Equipping the Union with such an instrument, that could address future serious cross-border threats to health, will have to take into account the EU institutional setting, namely already existing structures such as RescEU, EMA and ECDC (taking into account their reinforced mandates), and **provide for a coordinated approach to health preparedness encompassing Member States competences in this area**. Leveraging the network of Human Medicine's Authorities could also expedite mutual recognition procedures, which AESGP deems of critical importance in emergency situations.

Evidence-based policies and decisions help getting it right first time

Any of the policy options to be followed should be proportional to the aims of *equitable access, availability and distribution*. AESGP would highlight the counter-productiveness of increasing manufacturing capacity or stockpiling finished product in a Member-state to the detriment of API availability to other Member-states. To that point, AESGP would welcome the **prior collection of evidence to support** that *pooling resources into a centralised focal point to be the most effective way to ensure the scale necessary for speedy and successful outcome*, e**specially given the unpredictable nature of the health crises** – and the necessary products thereof.

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Foster several short-, mid- and long-term solutions to a multifactorial problem

AESGP understands the long-term reach for a European strategic autonomy and production capacities, but also believes that **reinforcing diplomacy channels is paramount to secure transit** of not only APIs, but other raw materials as well, which would be indispensable for the manufacturing of the to-be-determined essential products for each crisis.

Production capacity and adaptability needs to be paired with regulatory flexibility

So far, as part of their contingency and emergency planning, pharmaceutical industry has been able to **work with stockpiles at the API manufacturing level**, which have helped to, within a reasonable time frame, **adapt production to manufacture a final product according to the crisis-led needed characteristics** (such as dose or pharmaceutical form) and to market particularities (such as packaging and labelling). Also, AESGP believes that having local capacity and to *create redundancies and overlaps in the European single market* needs to be strengthened with flexibility on approvals and registrations for companies to resort to local players in time of need.

Healthcare product manufacturers and distribution companies are private sector enterprises promoting better healthcare outcomes with the strictest legal obligations in respect to contracts and agreements. The extent of powers of any centralised authority would need to recognise this nature and to be able to, in times of crises, work out solutions with these stakeholders.

Health literacy makes for more responsible citizens and avoids market distortions

Finally, AESGP would like to draw attention to the importance of creating conditions to **avoid unnecessary surge demand and panic provisioning** by European citizens, which distort market supply, by **leveraging trustworthy information sources** and **reinforcing health literacy** to deal with each crisis.

It is paramount that the EU efforts to strengthen its preparedness and response in terms of medical countermeasures for serious cross-border threats are assessed in the broader context of the other EU Strategic initiatives (e.g. Pharmaceutical Strategy for Europe) as well as ongoing efforts to establish the necessary infrastructure to make the existing regulatory frameworks successful (e.g. Regulation on Medical Devices) 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.

AESGP is determined to further contribute to the discussions on COVID-19 recovery and resilience to prepare and manage future health threats and is looking forward to the dialogue with the Commission, European Parliament, Member States and European Medicines Regulators on the proposed actions.

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