EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

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EUCOPE CONSULTATION FEEDBACK

ON THE ROADMAP FOR THE EVALUATION AND REVISION OF THE GENERAL PHARMACEUTICAL LEGISLATION

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) is the voice of small to midsize innovative companies active in the field of pharmaceuticals and medical technologies at the European level. The COVID-19 pandemic has again made the vital importance of the European pharmaceutical sector apparent, and while regulatory simplification is welcomed, broader business incentives should also be considered to address the EU's competitiveness. EUCOPE supports the 'targeted approach' pursued by the European Commission for the revision of the pharmaceutical legislation. For the sake of legal certainty and regulatory efficiency we suggest conducting the revision on the basis of the existing legal acts, and maintaining the coexistence of both a general Regulation and a general Directive.

Feedback on the proposed solutions:

Unmet medical needs (UMN) (item a)

EUCOPE supports the Commission's aim to reach a common understanding of UMN including in the area of AMR. A definition however runs the risk of overlooking the needs of diverse populations and disease areas. UMN is highly dependent on the scope and the value framework in which it is used based on different stakeholder needs and responsibilities. Thus, coming to a common understanding of UMN should be considered within the broader value framework of each stakeholder (e.g. patient, HCP, societal).

Simplify legislation and create regulatory attractiveness (item b)

Simplification is welcomed and particularly important for small to midsize companies. This should include reducing approval times and costs. It is not clear to us what is meant by "*provide regulatory authorities the possibility to adapt on their own initiative terms of marketing authorisations*". In any case, such processes must only take place after a profound consultation with MAHs. A strengthened cooperation between EMA and national HTA bodies is vital in order to further streamline the evidence requirements for authorisation and HTA procedures.

Revise the system of incentives (item c)

EUCOPE supports the introduction of incentives that complement the existing framework, in particular in areas of highest medical need. Incentives must not be linked to an obligation to launch: Market launch depends on the structure and requirements of each individual Member State. For smaller and midsize companies it is particularly difficult to navigate the different systems in a given time frame due to their operational and financial restrictions. Linking incentives to more transparency of R&D costs will prove unfeasible: Developing products is a complex process with a high failure rate, and methodologies are unlikely to capture the true R&D costs and investments. Further, R&D costs do not reflect the value of innovation and are not the correct link for incentives that aim to reward it. Consequently, linking the incentives system to the beforementioned obligations would substantially weaken the EU's ability to attract and promote innovation.

Increase support and accelerate product development and authorisation (item e)

Streamlined regulatory processes and expedited pathways (e.g. COVID-19 expedited approval and rolling review, PRIME), with earlier and more interactions with developers, early assurance of accelerated assessment and decreased regulatory burden could prove effective incentives.

Generic/biosimilar competition (item g)

It is important to maintain regulatory incentives and IP rights for innovation. Any weakening or disbalance will reduce predictability and undermine R&D investments. Market uptake of medicines, including generics, is determined by Member States' policies and therefore does not fall within the EU legislators' competence.

Enhance security of supply (item i)

Rather than introducing further obligations for supply and transparency, the efficient use of existing obligations will enhance the level of security. As learned from COVID-19 a constant and solution-oriented dialogue between the EU institutions and manufacturers enhances security while not imposing additional obligations on the MAH which might be impossible to achieve, in particular for small to midsize companies. Any reform of the existing system should therefore be linked to incentives that encourage advanced manufacturing capabilities for certain critical products.