No further excuse to delay digital regulatory infrastructure for medicines after Covid-19 pandemic

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MEDICINES FOR EUROPE STATEMENT TO EUCO REPRESENTATIVES IN VIEW OF THE EXTRAORDINARY MEETING ON COVID-19 PANDEMIC AND HEALTH UNION PACKAGE

Medicines for Europe calls on Heads of State and Governments to apply the lessons learned from the COVID-19 pandemic to build a more robust European crisis preparedness system and to enhance European solidarity. This unpreceded public health crisis has highlighted long-standing issues: a low level of crisis preparedness, a lack of cooperation and coordination with stakeholders and insufficient market demand predictability that can impact product supply.

Early in the Covid-19 outbreak, the EU policy response to the massive surge in demand for ICU and other medicines was undermined by unilateral decisions to close internal EU borders, to hoard critical medicines and other supplies, and to disrupt transport and logistics. Europe's solidarity was affected and European patients suffered the consequences. The industry adhoc ICU project helped address these gaps with the support of the Commission, EMA and national agencies and delivered lessons learned which cannot be ignored. To prevent this happening in future, we need systemic changes to enable clear and comprehensive crisis preparedness plans that can be rapidly deployed where there are serious threats to public health. The **EU needs swift and direct two way communications and cooperation between** EU Institutions and agencies, the Member States and relevant **stakeholders,** including medicine manufacturers, to coordinate an effective crisis response and to address potential supply bottlenecks. This cooperation needs to be based on data and evidence, and reported to national authorities via an interoperable and digitalised reporting system connected with EMA,so as to enable fast informed discussions between all parties, on matters such as major health crisis.

The crisis has indeed exacerbated longstanding issues related to **lack of digitalisation in healthcare**, including regulatory processes for the approval and maintenance of medicines. We now know that **robust and harmonised digital regulatory systems for addressing challenges such as shortages** of medicines can make a tangible difference in handling health emergencies. This should be reflected in the European Medicines Agency legislation. Digital solutions in the regulatory field can bring us much-needed flexibility, a rapid response to a fast-changing environment and enable regulatory authorities to monitor and promptly react to major health events. We also underline the importance of EU-industry

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coordination in a crisis, which is absent from the draft legislation. Medicines cannot manufacture themselves to meet a surge in demand.

Although we are still in the midst of the Covid crisis it is crucial to act now. Together, Europe can build a fairer and more resilient system for its citizens. The European Health Union and the proposals for Regulation are the first steps to fulfilling this aim.