Response to the Revision of the EU General Pharmaceuticals Legislation

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Health Action International (HAI) welcomes the opportunity to provide feedback to the evaluation and revision of the general pharmaceuticals legislation and appreciates the importance of the initiative taken by the European Commission to update and adapt a keystone of the European Health Union. Whereas the European Pharmaceutical Strategy is of substantive significance, other initiatives are also valuable for comprehending and responding to ongoing and upcoming health problems, such as anti-microbial resistance, medicine shortages or lack of accountability in public funding of research and development (R&D).

While we commend the efforts in place to ensure policy coherence, we encourage decision makers to clearly distinguish pharmaceutical policy goals from industrial policy objectives. Boosting private for-profit pharmaceutical manufacturing must not be a priority for health authorities. It is our understanding that listing topics of a very different nature together—such as unmet medical needs or unequal access to affordable medicines alongside legislative and regulatory reforms in fields like artificial intelligence and market authorisations—may be misleading. HAI believes that guaranteeing equitable access to health technologies in a sustainable way should be an overarching priority.

We note positively the connection to the European Green Deal and the pledge to reduce the environmental footprint, already part of the Strategic Approach to Pharmaceuticals in the Environment (PiE). We differ on the diagnosis regarding the best response for unmet medical needs: as a public interest civil society organisation with four decades of evidence-based advocacy and expertise on access to medicines, we believe that actionable innovation to meet health needs shall not be harnessed only by legal reforms or regulatory amendments, but that it is necessary to address the core issue at the heart of the current R&D model and the incentives system upon which it is built. IP-based monopolies and other forms of market exclusivity have shown their limited capacity to reward true innovation with no apparent commercial return, and their potential for abuse and market tampering. We seek a thorough revision of all pharmaceutical incentives, including orphan designation, pediatric formulations and supplementary protection certificates. It is not acceptable that some of these mechanisms are, by instilling notions of data exclusivity, de facto nullifying EU Member States' ability to make use of such TRIPS flexibilities like compulsory licencing in a moment when these mechanisms are needed the most.

Finally, we are heartened to read for the first time European Health authorities acknowledge that affordability of medicines is an obstacle that must be overcome to guarantee access and fulfil the right to health for all citizens. We also note positively that transparency safeguards, march-in rights and pooling of IP rights will be part of the new

Health Emergency Preparedness and Response Authority (HERA).

As we have shown in the past, we remain willing to collaborate with the European Commission and engage will all stakeholders to implement a public health agenda guided by general interest and common good.