Health Action International Statement on the European Commission Pharmaceutical Strategy

Statement | 25 November 2020

AMSTERDAM— The long-awaited European Commission <u>Pharmaceutical Strategy</u> and the Intellectual Property Action Plan, to which Health Action International (HAI) contributed through the public consultation phase, were released today. The former constitutes an ambitious plan that attempts to address the main problems affecting pharmaceutical policy within the European Union (EU): from lack of availability due to shortages to obstacles to access to medicines linked to high prices, or the ever rising threat of anti-microbial resistance (AMR). The latter seeks to achieve greater clarity in the management and enforcement of intellectual property (IP) rights, including the use of compulsory licenses or setting up patent pools for publicly funded research. Also, today the Commission made public the evaluation of supplementary protection certificates (SPC) for medicinal and plant protection products. Three different documents with substantial implications for access to medicines.

While the strategy mentions worthy initiatives already in place, like the Europe's Beating Cancer Plan or the Clinical Trial Regulation, it also relies on other stalled processes, such as the proposed Health Technology Assessment Regulation. Meanwhile the Intellectual Property Action Plan acknowledges the urgency surrounding access to COVID-19 related technologies and suggests ways in which national authorities could make use of flexibilities, including voluntary and compulsory licenses, while noting efforts at World Health Organization (WHO) to coordinate a global response.

The evaluation of SPC impact on access to medicines and innovation was a long-standing demand of civil society, however we do not believe that the document presented by the Commission effectively responds the main question, largely looking at how to harmonise national SPC regimes in order to set up a unitary instrument. We do not believe that SPCs contribute to promote innovation but have a demonstrated negative impact on access to medicines by extending market exclusivity and stifling competition.

Here lies the main weakness of three well-intentioned documents: industrial policy does not necessarily reflect patient need, and what is good for EU-based pharmaceutical industry does not imply better access to medicines for its citizens. The Commission had an opportunity to come through on its promises of no business as usual and a bold new approach after COVID-19 laid bare its own shortcomings but has fallen short of the mark. Civil society must keep on insisting that access to safe, effective and affordable medicines remains a priority in the EU. A commitment to be fulfilled and a duty to be honoured by national governments and supranational bodies.

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<u>Health Action International</u> is a non-profit organisation that conducts research and advocacy to advance policies that enable access to medicines and rational medicine use for all people around the world. We pursue advocacy from the patient level up to the highest levels of government through our 'official relations' status with the World Health Organization and respected relationship with the European Medicines Agency. To safeguard our objectivity and integrity, we are resolutely independent of the pharmaceutical industry and protect ourselves from all other conflicts of interest.