PRESS RELEASE

AIM Healthcare and social benefits for all

"A STEP IN THE RIGHT DIRECTION BUT A MORE AMBITIOUS FINAL LEGISLATION IS NEEDED"

MUTUALS REACT TO THE PUBLICATION OF THE GENERAL PHARMACEUTICAL LEGISLATION PROPOSAL

The much-awaited proposal of the European Commission, aimed at reforming the European Union's pharmaceutical legislation, is a step in the right direction. However, this should not be a missed opportunity for our societies. While we agree on the overall objectives of improving access to, and affordability of medicinal products, we regret that the proposal does not contain more ambitious provisions leading to fair medicines prices, nor does introduce provisions leading to more transparency of underlying R&D costs. We are also concerned that this reform will strain our regulatory system and put the quality of medicinal products regulatory assessment at risk.

That is the first reaction of AIM to the Commission's legislative proposals. AIM is the International Association of Mutual Benefit Societies counting 50 members in 26 countries globally providing access to healthcare coverage to around 240 million people in the world.

"After much delay, we are relieved to read the proposal for reform of the European Union pharmaceutical legislation. However, a more ambitious final legislation is needed in order to correct the current imbalances in pharmaceutical markets and keep our solidarity-based healthcare systems sustainable."

Loek Caubo, AIM President

We need a pharmaceutical legislation that truly benefits citizens

AIM deplores the numerous delays that have plagued the publication of the legislative proposal. These delays prevented the start of a democratic exchange on a much-awaited legislation designed to improve the health of all European citizens. AIM also calls for a fair and balanced representation of interest around the discussion and adoption of the new framework, which should not be captured by specific interests. It is important that the new framework is firmly oriented towards the attainment of better public health for citizens and society at large, which is and should remain the main objective of this legislative reform.

A missed opportunity to enshrine conditions leading to fair medicines prices in the EU legislation

The current proposals are a modest step in the right direction in terms of transparency of underlying costs of medicinal products. They will not suffice to reverse the trend of upward medicinal products prices, which threatens the sustainability of our healthcare systems. AIM has developed and launched as early as end December 2019 a model and calculator[1, 2] for fair medicines prices in Europe. Based on a simple algorithm, these tools would help calculate a fair price for medicines covering the costs of research and production, offer reasonable profit, and grant a significant bonus for medicines with an added therapeutic value. With fair prices being reduced significantly in comparison with prices that are currently paid, our proposal is a key element to bring affordability, an aspect that the European Commission targeted as part of the Pharmaceutical Strategy for Europe. We regret that the European

[1] European Fair Price Calculator for Medicines, AIM, 2021: https://fairpricingcalculator.eu/

[2] AIM Offers a Tool to Calculate Fair and Transparent European Prices for Accessible Pharmaceutical Innovations, AIM, 2019: https://www.aim-mutual.org/wp-content/uploads/2021/06/AIMs-fair-pricing-model-Accompanying-paper-to-the-fair-pricing-calculator_June2021.pdf

Commission failed to take into account our proposal in its legislation, or to even introduce provisions leading to more transparency of underlying R&D costs.

The final legislation must make evidence on medicines' benefit for public health available for payers

AIM members sit in decision-making committees on pharmaceutical products prices. They have witnessed first-hand the deterioration of the quality of evidence provided by manufacturers at the stage of pricing and reimbursement. For AIM, the introduction of so-called "accelerated assessment procedures" whereby the European Medicines Agency speeds up the approval of medicines while lowering the level of data that's necessary for marketing authorisation, is a clear contributor to this trend. AIM notes with concern that the European Commission chose to introduce more regulatory flexibility in the new legislative framework while speeding-up the assessments. Concretely, this means that even more medicines with insufficient information on their concrete contribution to public health will undergo swifter assessments. This will make decision on their prices more difficult and will have concrete and deep implications on the management of healthcare budgets. The decision to make this move also contradicts the European Commission's efforts to improve the generation of data on medicines' added therapeutic value as part of the implementation of the Health Technology Assessment legislation. The legislation must ensure that the necessary evidence is fully submitted in a timely manner after medicinal products' entry on the market if it could not be submitted during the accelerated approval procedure.

Transferable exclusivity vouchers: a disproportionate solution to solve the problem of the lack of development of new antimicrobials

AIM also notes with concern the introduction of transferable exclusivity vouchers (TEVs) to stimulate the development of antibiotics. Rewarding the development of antibiotics by creating sellable exclusivity rights will allow for the most expensive medicines to enjoy monopoly prices for longer. The cost-effectiveness of such a measure in comparison with other measures, such as delinkage and better designed push and pull mechanisms, which AIM prefers[3], is not clear. In addition, many experts have claimed that TEVs do not make sure that the medicines will be supplied on the market once the voucher has been transferred, or once the company that used the voucher no longer benefits from the relevant market exclusivity. TEVs are therefore not adapted and would be a disproportionate one-off payment borne by healthcare systems that risks not delivering on its promise.

AIM and its members are ready to work with the European institutions now in charge of deciding on the proposal to work towards a more balanced legislation that finds the right balance between affordability, access and innovation.

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The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 50 members from 26 countries in Europe, Latin America and Africa and the Middle East. AIM members provide compulsory/and/or supplementary health coverage to around 230 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion. Members are either mutual or health insurance fund. They are private or public legal entities; solidarity based; not-for-profit orientations: surpluses are used to benefit the members; democratically elected members play a role in the governance of the organisation.

[3] AIM Position Paper on Antibiotic Use and Antimicrobial Resistance (AMR), AIM, 2020: https://www.aim-mutual.org/wp-content/uploads/2016/03/Factsheet-n5-Antibiotic-Use_FINALdoc.pdf