



AIM'S REPLY TO THE EUROPEAN COMMISSION CONSULTATION ON THE REVISION OF THE BASIC PHARMACEUTICAL LEGISLATION

AIM welcomes the release of the European Commission's inception impact assessment on the revision of the basic pharmaceutical legislation. AIM, the International Association of Mutual Benefit Societies, is providing its preliminary feedback on the roadmap.

To improve medicines affordability, AIM calls for:

- ➔ The creation of an Expert Group on medicines cost transparency
 - Such a Committee would be hosted by the European Commission and gather representatives of Member States exclusively
 - Such a Committee would be in charge of initiating reflection and calculation estimated [fair price](#) ranges of a number of key drugs specifically taking into account:
 - Estimates on the amount spent by companies for research and development;
 - Estimates on data on the amount received for public funding for medicines;
 - Data on the number of expected patients;
 - Production and overhead costs;
 - Costs of medical information to physicians (R&D department size, etc...);
 - Basic profit;
 - As well as taking into account the medicines added therapeutic value
 - The Committee would work under voluntary cooperation and would focus on the exchange of information at first stage
 - The Committee would be in charge of delivering a legal feasibility study on linking fair drug price with Single Market access mechanisms for Europe
 - The Committee would be tasked with developing rules for accounting for R&D costs
 - The Committee would be tasked with circulating the information on medicines costs to member states OR to the HTA Coordination Group *as an information*
- ➔ The disclosure at the time of marketing authorisation of whether a medicine that is approved at EU level was developed using public funds, as well as of the amount of such public funds.
- ➔ The revision of the orphan medicinal products legislation, making sure that both the prevalence and return on investment criteria are used to grant orphan designation.
- ➔ The strengthening and substantiation of the conditions to revoke market exclusivity in Article 8(2) of Regulation (EC) No 141/2000 and in the Guideline on aspects of its application.
- ➔ Companies to report yearly on orphan medicines' EU patient population to make sure that an orphan medicinal product actually covers an orphan population and not more.
- ➔ In general, better conditions for the review of market exclusivity should also be adopted, allowing for more frequent opportunities to do so.
- ➔ The European Commission to better define what is "sufficient" and "excessive" return on investment.
- ➔ Put in place mechanisms that would facilitate competition between products in disease areas where generics entry could be difficult.
- ➔ The revision of the Transparency Directive 89/105, and agree on which elements of the pricing and reimbursement of medicinal products in Member States could be shared publicly between Member States in order to foster stronger negotiations power and better access.

To secure medicines supply, AIM calls for:

- An EU-wide definition of medicines shortages and of critical shortages.
- The creation of an EU platform for the collection and sharing of data on shortages to improve oversight of pharmaceuticals supply chain.
- Public tenders for essential medicines, whose notion needs to be duly defined, must require shortage management plans, transparency, and diversification of supply.
- Emergency contingency plans co-financed by the industry must be in place to mitigate future crises.
- The opportunities offered by digital tools to be used to their full capacity.
- The relocation back to Europe of some of the production of APIs can only be part of a comprehensive exercise looking at health systems' needs, market failures, relevant solutions, and their cost.
- Condition medicinal products' access to specific protections or to public funds (especially for paediatric, or orphan medicinal products) to their placing on national markets where unmet needs exist.

In order to keep high standards for evidence generation to support decision-making, AIM calls for:

- The basic pharmaceutical legislation to uphold double-blind randomised clinical trials as the preferred form of evidence generation for medicinal products, while looking into possibilities to make them more efficient and less costly.
- Accelerated assessment to not take precedence over standard assessments and to not become the preferred route to marketing authorisation.
- Ensure, that quality and certainty over medicinal products' evidence (safety, quality, efficacy) is collected in the best possible way. We're concerned that the Commission's commitment to respond quickly to innovation translates into the reduced safety of approval procedures.
- Manufacturers as well as the European Medicines Agency to record in disease registries the real-life performance of those medicines that reach the market via accelerated assessment procedures.
 - Information on such disease registries should be collected and made public by EMA. In addition, the name of the disease registry or registries to which the relevant product is linked should be given as part of the marketing authorisation as well as available in EMA's EPAR.
 - Access as well as the processing of the sensitive data within those registries should be protected using the highest level of protection standards under the GDPR
 - In general, AIM supports the creation of an adequate legal and regulatory framework built on ethical guidelines to regulate the use of sensitive health data and to turn digital health data promise into positive outcomes for health systems and patients.
- Bringing EU collaboration in the field of HTA further. However, mandatory scientific assessments of clinical aspects can only be possible if Member States have the possibility to do national, context-specific additional clinical assessments.

To bring to market innovation that matters, AIM calls for:

- Creating a new business models for the development of [antimicrobials](#).
- Such models would delink R&D costs and innovation from price and sales volumes in order to prevent overselling. Such a model should provide long-term supply continuity. A market entry reward (MER) system is suggested by major reports and many journal articles as a solution. A pharmaceutical company can receive initially (minimum) incentives to cover some of the expenses for efficient R&D and to set up a supply system. Later, the annual payments may increase depending on the outcome of post-marketing data on effectiveness, resistance profiles and stewardship arrangements (based on the concepts of the Health Impact Fund).

- We welcome the European Commission's concerns with steering investment in currently underserved disease areas but AIM believes that we do not need to have more, but better, qualitative incentives in disease areas that are of relevance to our societies.
- Agree on a common understanding of what are the areas of unmet need in the EU and translate these into strong public pharmaceutical research and innovation programmes specifically supporting the development of medicinal products in underserved areas, as well as non-price incentives at EU level.

