Irish Pharmaceutical Healthcare Association

Submission to the European Commission's Inception Impact Analysis for the revision of EU legislation on medicines for rare diseases and for children

The Irish Pharmaceutical Healthcare Association represents 47 global companies that research, develop and bring to market innovative medicines. We partner for better healthcare and economic development in Ireland and, by extension, in the European Union.

We support key goals in the proposed EU Pharmaceutical Strategy. We welcome the opportunity to input to the Inception Impact Analysis (IIA) for the revision of EU legislation on medicines for rare diseases and for children.

We believe there is a fundamental problem, in principle and in practice, with seeking to improve equitable access to medicines for all European citizens by reducing intellectual property (IP) rights, envisaged in Options One and Four for orphan products and Options Two and Three for paediatric products.

Here, we are briefly sharing the experience of Ireland on a recent track record of delayed access to new medicines. It is a case in point about the root causes of inequitable access and delays. The reduction of IP rights would not have addressed these causes. It will not address them in the future, either.

According to data produced by IQVIA for the European Federation of Pharmaceutical Industries and Associations, Ireland ranked 19th of 34 European counties in the rate of availability and the timeliness of access in 2019. Ireland has been near last in the former EU15, despite being much higher in that ranking in terms of income per capita and, therefore, affordability. Timing for access from EMA authorisation was 521 days on average - far beyond the 180 days envisaged in the Transparency Directive. This is despite having list prices which, by agreement between industry and the State, are externally referenced and limited to an average of a basket of 14 Members States since 2016 (including the UK, until recently).

Irish authorities carry out demanding Health Technology Assessments (HTAs) of nearly all proposed new medicines. Suppliers commonly offer discounted prices after the HTAs. However, even when a price is agreed, significant delays of even a year have occurred before a decision is made to provide and reimburse a medicine.

The root cause of recent delays in Ireland has been insufficient funding and a structural absence of appropriate multi-annual budgeting to manage medicines expenditure. No new funds were provided from the Exchequer in 2020 for new medicines. Budget 2021 corrected that, with a welcome €50 million allocation. A reduction of IP rights for orphan medicinal products or any other product would have made a negligible or no impact on achieving timely access within the benchmark of the Transparency Directive. In industry-State negotiations, it has never been suggested that it would.

Access, pricing and funding are linked. They should be addressed in their own terms. From experience in Ireland, the best way to enable the equitable and timely provision of medicines is by an open, outcome-focused negotiation between industry and the State on pricing, funding and efficient processes to evaluate new medicines, with competition in a sustainable off-patent market. Reducing IP rights is not an appropriate proxy for an access-pricing-funding discussion that addresses root causes and aims to deliver new medicines to patients. We do not see the IIA proposals as a

reliable way to achieving that outcome. The proposals are not grounded in the practicalities of access, pricing and funding interactions between national authorities and medicines providers.

As a member state of the European Union that hosts the manufacturing base for the European and global supply of many medicines, we are strongly of the view that further investment and production of new medicines and therapies in Europe is unlikely to be helped by a European policy to reduce or weaken IP rights for medicines.

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