Feedback of the European Social Insurance Platform (ESIP)

to the Evaluation roadmap/Inception Impact Assessment on the revision of the EU pharmaceutical legislation

27 April 2021

ESIP, representing statutory social health insurers in the EU, UK and Switzerland, welcomes the Commission's intention to revise the pharmaceutical legislation. Increasingly high prices of medicines, sometimes coupled with low levels of evidence at time of market authorisation, create pressure on healthcare budgets, consequently hindering access to innovative medicines for patients.

The current legislative framework should be revised particularly in the following areas:

- It is essential to include a common definition of unmet medical needs (UMN) in the EU pharmaceutical legislation targeted to 'high' unmet medical/public health/societal needs. The definition must be consistently cross-referenced in the EU legislation. It should build on a common understanding of UMN and agreed quantifiable criteria. Quantification of UMN is possible in terms of burden of disease, the absence or existence of satisfactory treatment options and the possible benefit of a new technology over standard of care.
- ESIP acknowledges the intention to simplify the EU pharmaceutical legislation particularly to promote the swift market entry of generics and biosimilars. Reducing the regulatory burden on manufacturers needs to fully preserve regulatory standards. Fast-track procedures for new technologies must be limited to specific eligibility criteria and subject to the same high standards of quality, safety and efficacy.
- The existing framework of incentives, based on intellectual property rights, relies on the economic success of the medicinal product concerned. This leads to a concentration of investment in markets (at territorial and product level) with higher return on investment and to increased prices of patented products, often not justified by R&D costs or by international thresholds for cost-effectiveness ratios. ESIP supports options to link rewards to reinforced obligations to make products available in all EU countries within a restricted timeframe and to ensure transparency of R&D costs. These obligations should be combined and conditionality clauses introduced to ensure public return on public investment when public funds are used for R&D. A revision of the system of incentives – and eligibility criteria – should restore the balance between innovation, affordability and sustainability. Alternative incentives models should be further explored and promoted. Facilitated access to an effective repurposing framework would also encourage companies, in particular generic and biosimilar companies, to apply for the authorisation of new indications/therapies developed under off-label use by public institutions. This would benefit patients and enhance competition. However, care should be taken that indication slicing and possible "orphanisation" is avoided.

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- In addition, to promote competition of generics and biosimilars, the Commission could also consider developing a database of patents and SPC expiries by (new) indication. The database should be accessible to public health authorities and generic and biosimilar manufacturers, promoting faster market entry of competitor products, thus increasing affordability.
- When adapting the legislation to innovative ways medicines are developed and evidence is generated, randomised controlled trials should remain the gold standard; real-world data should be used primarily as a source of complementary evidence. Evidence requirements for informed pricing & reimbursement decisions should be taken into account from the outset.
- Finally, to make the pharmaceutical supply chain more resilient, ESIP supports reinforced obligations regarding supply, transparency of stocks and early notification of shortages and withdrawals. Mandatory sanctions, including financial, should be introduced for producers (and wholesalers/suppliers) that fail to comply with their obligations under Articles 81 and 23a of Directive 2001/83/EC.

ESIP's members look forward to expanding on this feedback in the future consultations.

You can find the submitted response on the European Commission's website here.