Law

Feedback from: Association of European Cancer Leagues (ECL)

Feedback reference
F2242732

Submitted on
27 April 2021

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User type
Non-governmental organisation (NGO)

Organisation
Association of European Cancer Leagues (ECL)

Organisation size
Micro (1 to 9 employees)

Transparency register number
19265592757-25 *(http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=19265592757-25&locale=en)*

Country of origin
Belgium

Initiative
Revision of the EU general pharmaceuticals legislation *(/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en)*

ECL welcomes the opportunity to contribute to the revision of the general pharmaceutical legislation.
Across the legislative changes in the health space, it is essential to remember that health is a public good and should not be discussed as a marketing item.

ECL's keywords: conditionalities, transparency, and cross-border collaborations.

Firstly, to address unmet medical need (UMN), gaps in science need to be filled as essential research questions are not investigated. Patients play a pivotal role in steering non-commercial and commercial R&D towards those areas that need new health technologies to prevent, detect, cure, or stabilise a disease. It should be logical to include patients' voice in the discussions on defining criteria to assess UMN.
Public, academic and non-profit research should be supported with HORIZON Europe and the EU4Health Programme to address UMN, with the objective of extending their role from basic research to market-ready products. This would ultimately increase competition for commercial developments.

Simplification: It does not mean cutting corners in scientific assessments. Simplification should mean making communication channels more transparent and avoid duplications. This should apply also in the monitoring of medicine and medical device supplies, making use of existing tools such as the i-SPOC systems to firstly prevent shortages and then minimise the disruption should a shortage occur.
Incentives: These should be accompanied by conditionalities and within a system of rewards & sanctions to cover scientific gaps, drive research in areas that currently do not have treatments, guarantee the provision of medicines, foster transparency on R&D costs and the costs required to put a medicine on the market. Public funds for research should come with conditions to make drugs affordable and available, for example by making use of socially responsible licensing and periodically assessing if targets are reached. Personalised treatments should not lead to proliferation of orphan designations that may not bring real added value. To address affordability, revoking

market exclusivity when a medicine has generated sufficient RoI should be explored.

Future-proofed legislation: It is essential to establish a sustainable system that can still be in place in the next years. Personalised medicine is a vital area for patients, but EU legislation cannot establish an unsustainable ecosystem for governments, otherwise personalised medicine would only be accessible to some, widening inequalities among the EU Member States. The introduction of generics and biosimilar needs to be fostered to increase competition and minimise monopolies.

Skyrocketing prices create an unsustainable system. Even if the new therapies might bring added value to patients (which should be assessed with joint clinical assessment to identify real innovation in treatment of complex diseases, such as cancer) these need to be affordable or they will never reach patients. There should be a clear justification behind a price: besides bringing added value for patients, there should be a reasonable relationship between the cost of bringing the product to market and the price, price should be predictable and cost-effective. In addition, a fair pricing process should be created together with other stakeholders. By echoing the response of EFPN, the Commission should investigate the (marketing) tactic of withdrawing off-patent drugs and reintroduction of similar medicines with a new indication and much higher price.

Collaboration: EU Member States face common challenges (e.g. aging population, economic distress, new unaffordable medicines coming into the market, Covid-19). It comes naturally to strive for cross-border collaboration and perform horizon scanning when assessing and negotiating medicines. Healthcare systems are under the competence of national governments, but the EU should take the lead and support regional initiatives, like BeNeLuxA.

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