SUSTAINABLE ACCESS TO INNOVATIVE THERAPIES

BEUC response to Organisation for Economic Co-operation and Development (OECD) consultation

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Why it matters to consumers

In the past access to medicines was a challenge mainly for developing countries, while in the last 5-10 years many cases (for example, Hep C and new cancer treatments) show that also European consumers struggle to access the medicines they need. Confronted with skyrocketing prices of medicines and limited budgets governments have to make very hard choices about which treatment to reimburse and which not. This also increased consumers ‘out-of-pocket’ payments creating further inequalities among wealthy and poorer people. Action is needed to address the problem.

1. Reflecting on the last 5-10 years, what do you think have been the major changes affecting access to medicines?

In the past access to medicines was a challenge mainly for developing countries, while, in the last 5-10 years, many cases (e.g. Hep C and new cancer treatments) have shown that also European consumers struggle to access the medicines they need. Confronted with skyrocketing prices of medicines and limited budgets, governments have to make hard choices about which treatment to reimburse and which not. This also increased consumers ‘out-of-pocket’ payments creating further inequalities among wealthy and poorer people. Furthermore, the current business model of the pharmaceutical industry has shown its weaknesses by favoring the production of some medicines in commercially profitable illnesses (such as cancer) at the expense of less profitable medicines like antibiotics and vaccines vital for public health. Moreover, many new authorized drugs offer little added therapeutic value compared to existing treatments. This means that, once reimbursed, governments waste resources in medicines that do not offer real value for money. Moreover consumers are exposed to unnecessary risks as these medicines are new and have been tested only on a small group of people.

Health Technology Assessment (HTA) could be a useful tool to reward the most effective treatments. However, these assessments vary a lot among EU member states and this had led to a situation where a medicine is reimbursed in a country but not in others, creating inequalities between countries and ultimately among EU patients. In addition, the so called “personalised medicine” model has been leading to the discovery of targeted treatments which address the needs of very small populations. This model allows manufacturers to negotiate expensive prices for initially small populations; yet such price remains high also when the drug is authorized with a new indication and more patients use it. These are very expensive medicines, which are often used in combination and have a large impact on healthcare budgets. Finally, medicines shortages happen more frequently than in the past: it is then necessary to investigate the causes, sanctioned illegal practiced and increase cooperation among governments to address the problem.
2. What are the top 3 issues that must be addressed to ensure access to innovative medicines while maintaining financial sustainability of health systems?

a) **More transparency in research and development and conditionality in public funded research programs** can help governments to negotiate fairer prices which take into account the public contribution in the developments of medicines. While recognizing the crucial role of the pharmaceutical industry in fostering innovation, prices of medicines should better mirror the contribution that governments provide to the research by financing universities and research programs.

b) **Better implementation of competition rules**: fair market competition can lead to lower prices, therefore antitrust authorities should better monitor potential anticompetitive practices (such as abuse of dominant positions, pay-for-delays agreements and abuse of patent’s extensions) and prevent governments from paying artificially high drug prices.

c) **More balanced incentives**: incentives in pharmaceutical sector (particularly for orphan and pediatric medicines) need to be proportionate to the goal of encouraging innovation while ensuring financial sustainability. Stricter rules need to apply for the provision of these incentives, such as the investments actually made by manufacturers and the number of people who would benefit from the treatment.

3. Why do you think there are issues in ensuring access to innovative medicines while maintaining financial sustainability of health systems?

Despite their importance for humans ‘lives, medicines are considered as any other commodity in the market. As a consequence, manufactures set the highest prices that the market is willing to bear, very often irrespective of the real cost of their research and development, and without taking into account that patients are in a position of need and not choice. Moreover, the economic crisis has lead governments to focus on the economic recovery and growth, giving more weight to the jobs created by the pharmaceutical industry than to the impact pharmaceuticals expenditures has on public budgets.

In addition, the pharmaceutical market is very opaque. Little is known on the real cost of R&D and on the real prices of medicines that governments manage to negotiate. This is also linked to lack of political will among governments to team up and increase their negotiating power with pharmaceutical companies.

The “personalised medicines” model allows manufacturers to negotiate expensive prices for initially small populations and keep these prices high also when the drug is authorised with a new indication and more patients use it. Finally, the price of many of these promising drugs are negotiated through the so called “managed entry agreements”, for which little evidence exists over the way they improve access and at what cost.
4. What changes would you like to see happen to improve access to innovative therapies?

Governments should increase their awareness on the public spending that contributes to the R&D of medicines. They should also foresee conditionality when funding public-private partnerships and make sure there is a public return on the investment made with public money. They should also explore different R&D models, with evidence-based results to ensure access to innovative medicines. Research priorities should be defined on the basis of public health needs rather than on profitability.

In addition, governments should foster cooperation and information sharing to negotiate fairer and lower prices. Anticompetitive practices should be better monitored and discouraged through higher fines.

The legislation on orphan drugs should be revised to ensure a fairer distribution of incentives and avoid a further “orphanization” of the system.

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