AFFORDABLE AND INNOVATIVE MEDICINES

BEUC comments to the European Commission preliminary report of the Pharmaceutical Sector Inquiry

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Summary

BEUC welcomes the Commission sector inquiry as an important effort to ensure that European consumers actually benefit from innovative and affordable medicines.

Following the findings of the inquiry we encourage the European Commission and the Member States to take concrete actions, namely:

- Reconsider the Commission proposal on information to the general public on prescription medicines;
- Further investigate the spending on promotional activities and the impact on medicines’ prescription and consumption;
- Reward real innovation;
- Improve the patents system;
- Increase transparency;
- Move competence on medicines from DG ENTERPRISE to DG SANCO.
BEUC welcomes the Commission sector inquiry as an important effort to ensure that European consumers actually benefit from innovative and affordable medicines. The preliminary report provides a unique overview of the situation of competition in the pharmaceutical sector as well as a considerable amount of information, facts and figures. Unfortunately the findings of the report confirmed our concerns about the problems affecting the pharmaceutical sector, in particular with regard to the lack of innovation and the delay of entry of generics into the market.

Following the results of the inquiry, we identified concrete actions to be taken at EU and national level that can contribute to improve the current situation.

1. **More R&D, less marketing**
The results of the inquiry highlight that pharmaceutical companies spend only 1.5% of their turnover on basic research intended to identify potential new medicines (17% on R&D as a whole) and 23% of their turnover on marketing activities directed to health professionals. In addition, we learned from the report that the number of employees in marketing departments is twice - and in some cases three times - the number of those working in R&D. These figures are not justified, especially considering that the demand for pharmaceuticals is rather rigid, that doctors should base their prescription exclusively on the individual patients’ needs and that the doctor-patient relationship should not be influenced by any marketing techniques. We recommend that the pharmaceutical industry refocuses its efforts on its core public health role, which is to develop new medicines to meet patients’ needs. That is the reason why we oppose the proposed amendments to the pharmaceutical legislation\(^1\) which would allow pharmaceutical companies to spend even more money on activities other than R&D, namely on direct-to-consumer communication strategies. The main goal of these communication strategies is to boost sales and this will ultimately lead to a higher health care expenditure (in terms of higher prices for medicines, higher medicines consumption, higher consumers’ payments, higher public budgets expenditure and higher costs of monitoring for the competent authorities) but not to better medicines and health care.

2. **Further investigate the spending on promotional activities and their impact on medicines’ prescription and consumption**
We encourage the Commission to further investigate the marketing techniques used by the companies and look more in depth at advertising to health professionals, advertising to consumers of over the counter medicines (OTC), disease awareness campaigns and their impact on medicines consumption. It is also essential to look at the financing of continuing medical education (CME) and medical research as well as at post marketing studies. Furthermore, it is

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important to better examine the distribution chain (wholesalers and pharmacies) whose specificities might magnify the effects of anticompetitive behaviours and penalise the sale of generic medicines.

3. Reward real innovation
The report shows that for 40% of the medicines in the sample selected for the investigation, originator companies launched so called second generation/follow on medicines, what we actually call “Me-too” medicines. These medicines hinder innovation, increase prices and do not offer any added therapeutic benefit. This phenomenon is due to the fact that health regulatory agencies only ask from a new medicine to be effective and safe but not more effective than what it is already being used for the same condition. They just have to show that they are better than nothing. To encourage real innovation we consider imperative to change the legislation and require that in clinical trials companies compare their new medicines with the best current treatment instead of with a placebo.

4. Improve the patents system
The protection of intellectual property rights is intended to promote innovation, to the mutual advantage of companies and society. Pharmaceutical companies’ quotes in the report acknowledge that they use/abuse of patent strategies to delay the entry of generics on the market and that they do so to generate additional revenue. These practices (and combination of practices) to extend patents, especially the so called “ever greening” and the “patent clusters”, are clearly anti competitive, prevent the entry of generics into the market, result in higher expenditures for consumers and for Europe’s health care systems, and should not be allowed.
Any abuse of the patent system and any abuse of a dominant market position should be prosecuted. To ensure a deterrent effect sanctions should be proportionate to the profits obtained by the illegal practices.

To have high quality patents and true innovation we call for a stricter application of the patent rules, including the introduction of stricter criteria for the list of medicine properties eligible for patent.

Finally, we support the establishment of an EU patent system and the creation of a European Patent Court. This will ensure clarity, consistency and legal certainty, will reduce administrative burden and litigation costs for companies, resulting in a faster access to new and more affordable medicines for consumers.

5. Increase transparency
In order to guarantee all European consumers access to the same medicines in all Member States we consider it essential to make the centrally authorised procedure mandatory for all medicines (Regulation 726/2004). It would be also important that the national medicines agencies and the EMEA supervise settlements agreements.
For the sake of transparency and to address the issue of patent clusters we encourage the EMEA and the national competent authorities to publicly disclose the patent expiration date of the medicines they authorise as well as the number of patents for each product.

Regarding pricing and reimbursement we call for a better implementation of the Transparency Directive (Directive 89/105/EEC). Pricing and reimbursement procedures should be independent and any undue external intervention should be prosecuted. To improve transparency of prices we also invite the Commission and the Member States to further investigate the real costs of developing a new medicine and the public and private financing of the research. Development costs are often used to justify high medicines prices, but we want to ensure that consumers benefit from good value for money. We also want to ensure that R&D efforts, especially those publicly funded, are oriented towards patients needs (including neglected diseases) and not focused on developing blockbuster medicines.

6. Transfer competence on medicines from DG ENTERPRISE to DG SANCO

Medicines are not like any other product as they save people lives and add benefit to everyone’s health but pharmaceutical companies are like any other company and their goal is to make money. This explains why the pharmaceutical sector is so unique and needs to be carefully regulated. It also explains why it is so important to find a better balance between companies commercial interests and general public health interests, i.e. the interest of millions Europeans who are actually waiting for a new medicine to treat their disease, for a new effective medicine that can improve their quality of life. To achieve this, and to ensure that European pharmaceutical policies are considered from a health perspective, we call for competence on medicines to be transferred from the DG ENTERPRISE to DG SANCO.

Conclusion

Following the findings of this important inquiry we encourage the European Commission and the Member States to take concrete actions and punish unethical practices. We hope that the findings of this inquiry will serve as inspiration for a review of the regulatory framework to ensure consumers access to medicines with a well understood safety profile, a clear therapeutic value and affordable prices.