BEUC The European Consumer Organisation

The Consumer Voice in Europe

Permanent Representation

B – Brussels

Ref.: BEUC-X-2016-050/IPA/cm

Brussels, 26 May 2016

Re: Access to medicines

Dear Attaché,

In view of the forthcoming meeting of the EU Health Ministers that will take place on 16-17 June, BEUC, the European Consumer Organisation, wishes to share with you its views on access to medicines.

A number of recent developments including the economic crisis, the ageing population, technological advances and new health threats present major challenges for the sustainability of European health care systems and the medicines they provide.

The price of medicines is rising year on year[1] and in light of budget constraints, public payers face difficult ethical and economic dilemmas: which treatments should be financed, should other costs (e.g. nurses, prevention) be sacrificed in order to pay for certain expensive medicines, should co-payments be introduced?

In order to guarantee patients' right to access safe and innovative medicines as well as the sustainability of health care systems we call on governments to:

- **Protect patients safety**

Patients should have timely access to treatments but ***schemes of earlier marketing authorization should not undermine patients' safety***. Fast track approval procedures of new medicines, such as the conditional marketing authorization and the ongoing European Medicines Agency pilot project on *adaptive pathways*[2], should only be used for a very limited range of medicines and ***only when there is no other available alternative***. The scope of such initiatives should be clarified and a justification for an 'early access' approval should, without exception, include an explanation of the ***unmet medical need*** in question, the extent to which the product fulfils that need, and the strength of the evidence.

…/…

[1] OECD, Health at Glance 2015. http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2015/summary/english_47801564-en?isSummaryOf=/content/book/health_glance-2015-en

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp

Bureau Européen des Unions de Consommateurs AISBL | Der Europäische Verbraucherverband
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • Fax +32 (0)2 740 28 02 •
directorsoffice@beuc.eu • www.beuc.eu • www.twitter.com/beuctweet
TVA: BE 0422 071 051 • EC register for interest representatives: identification number 9505781573-45

It is also important to ensure that both health care professionals and patients receive appropriate information about the higher risks associated with early access products. Moreover a proper post-marketing surveillance must be guaranteed. Evidence from Canada's[3] and USA[4] early access policy shows that there is ***little oversight of manufacturers' duties to confirm medicines' clinical benefits in post-marketing studies***.

- **Foster innovation by rewarding only medicines that offer an added therapeutic value**

BEUC encourages Member States to ***increase the uptake of Health Technology Assessment at national level*** and to exploit synergies at EU level in order to identify products which offer real benefits to patients. Pricing and reimbursement decisions should reward truly innovative products that bring an added therapeutic value compared to existing alternatives. Over the last decade, a very limited number of medicines approved offered a real advance in term of innovation[5] and it is urgent to reverse this trend.

- **Explore new tools for price negotiations**

New medicines entering the market (e.g. cancer drugs) are increasingly expensive – also due to the so called "orphanisation"[6] - and are eroding health budgets. The current situation is unsustainable and it is necessary to find new ways to ensure that medicines remain affordable. In this context we invite Member States to explore the possibility of joint price negotiations and to ***improve the exchange of data*** for better informed pricing and reimbursement decisions.

New methods of financing new medicines such as the so called "***managed entry agreements"*** or risk sharing schemes are being explored but ***more evidence is needed to understand whether these schemes actually do improve access to medicines and at what cost***. Concerns have also been raised about the potentially high administrative costs, the lack of transparency, the danger that public payers could end up funding a part of private drug development[7] and the misleading effect these schemes have on the external reference pricing (ERP) system[8].

- **Promote a healthier competition in the pharmaceutical sector**

Ensuring fair market competition can lead to lower prices. For example generic medicines entering the market in 2014 drove the price of originators prior to patent expiry down by 61%[9].Anticompetitive strategies and pay for delay agreements should be discouraged with a better enforcement of competition rules – including dissuasive penalties - in order to facilitate the entry of generic medicines on the market. Patent incentives such as supplementary protection certificates, data exclusivity and market exclusivity should be reconsidered in order to avoid abuses at the expense of medicines affordability.

…/…

[3] Lexchin,J.(2007).Notice of compliance with conditions: a policy in limbo. *Healthcare policy*, *2*(4), 114.
[4] http://www.gao.gov/products/GAO-16-192.
[5] Stopping the spiral of exorbitant prices, La Revue Prescrire,November 2014. http://tacd-ip.org/wp-content/uploads/2014/11/EU-Parliament-12-November-2014-TA-version-finale-Teresa-Alves.pdf
[6] Gagnon MA "New drug pricing: does it make sense?" Prescrire Int 2015; 24 (162): 192-195.
[7] Adamski, J. et al. (2010). Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. *BMC health services research*, *10*(1), 153. http://www.biomedcentral.com/content/pdf/1472-6963-10-153.pdf
[8] Espín, J., Rovira, J., & García, L. (2011). Experiences and impact of European risk-sharing schemes focusing on oncology medicines. http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/Experiences%20and%20impact%20of%20European%20risk-sharing%20schemes.pdf
[9] IMS Institute. The role of generic medicines in sustaining health,2015.

- **More effective and transparent R&D**

A relevant part of R&D is largely subsidized with public money. This occurs through tax incentives, through research provided by public institutions and through public private partnerships such as the Innovative Medicines Initiative[10]. Greater transparency is needed on the public and private funding for research to ***avoid that taxpayers pay twice for the same product, first with R&D incentives for the industry and then paying a high price for the medicine***.
Public and private research priorities should be better defined according to public health needs[11]. In the current model, pharmaceutical companies have more incentives in investing on medicines granting them the highest possible profit rather than on those which offer real innovation, as the scarcity of new effective antibiotics shows.

- **Address the problem of medicines shortages at EU level**

Medicines stock-outs are hitting European pharmacies leaving patients unable to access medicines they need in a timely way. Shortages concern cancer therapies, antibiotics and vaccines – all of which require timely administration and strict adherence. While some of these drugs can be substituted, others cannot. A comprehensive response to drug shortages is needed at the EU level, particularly because they can put Member States in direct competition with one another for sufficient medicines supplies, and ultimately risk the continuity of patient care[12].

We are confident that the Council meeting will offer a good opportunity to openly discuss these challenges and put forward possible solutions.

For more information, please find here our position paper on access to medicines and here a factsheet summarizing the key issues.

We thank you in advance for your consideration and remain at your disposal for further discussing this important matter.

Yours sincerely,

Ilaria Passarani
Head of the Health and Food Department

[10] https://www.imi.europa.eu/
[11] http://www.who.int/medicines/publications/essentialmedicines/en/
[12] Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A. (2015). A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian, French and the European Union's Perspectives. PLoS ONE 10(5): e0125691. doi: 10.1371/journal.pone.0125691.