

The Consumer Voice in Europe

## BEUC RESPONSE TO PRELIMINARY OPINION ON 'ACCESS TO HEALTH SERVICES IN THE EU'



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This BEUC response was developed in reaction to the [Preliminary Opinion](#) on *Access to health services in the EU* by the Expert Panel on Effective ways of investing in health. Our response only addresses those chapters of the Preliminary Opinion that relate to BEUC's work on health.

## **An introduction to access to health services in the European Union**

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In addition to the data presented in this chapter, BEUC would like to highlight that important insights into patient access to healthcare 'on the ground' in member states can be gathered through consumer surveys. According to survey results published by members of The European Consumer Organisation (BEUC) in September and October 2015, many European consumers struggle to pay for the health services they need. Altroconsumo reports that 46% of Italian households gave up health care because they could not afford to pay for it.<sup>1</sup> At the same time, 1 in 5 Belgian households cannot afford to pay their medical bills, according to a survey by Test-Achats/Test-Aankoop.<sup>2</sup> Results from OCU indicate that Spanish households now pay 58% more for their medicines in than in 2010.<sup>3</sup> A survey of Portuguese consumers in 2014 showed that 39% of respondents did not buy a medicine over a 3-month period because they could not pay for it.<sup>4</sup>

### **1. Financial resources are linked to health need**

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BEUC agrees with the main challenges and policy responses identified in this section.

### **2.3 Services are affordable for everyone – Policy recommendations**

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BEUC agrees with the main challenges and policy responses identified in this section. In particular, BEUC supports EU action to study not only financial hardship at the household level, but also the impact of recent policy changes on (risk of) poverty. Changes to pharmaceutical pricing and reimbursement policies in the wake of the financial crisis shifted the financial burden of medicines to patients through increasing user fees, out-of-pocket payments, or other means. Recently, BEUC's Dutch member, Consumentenbond has expressed concerns that higher up-front healthcare costs (called 'eigen risico') in the Netherlands will be a barrier to patients seeking care they need (<http://t.co/phzRthYJdr>). BEUC recommends EU action in this field to gather standardized, comparable data from across the EU to examine the impact of these and other policies on consumers' health and general wellbeing. This information is essential to understanding and addressing health inequalities fuelled by health and other policies.

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<sup>1</sup> Altroconsumo. *Sanità cara: gli italiani rinunciano alle cure*. 22 Sept 2015. <http://t.co/6PubsY5tAM>

<sup>2</sup> Test Achats-Test Aankoop. *Un ménage belge sur cinq incapable de payer ses soins médicaux*. 30 Sept 2015. <http://t.co/exHhOJKBBY>

<sup>3</sup> OCU. *OCU denuncia que el gasto en medicamentos ha crecido en un 58% en los hogares*. 30 Sept 2015. <http://bit.ly/1JGf6hc>

<sup>4</sup> DECO Proteste. *Farmácias*. In the June 2015 volume of Test Saude.

### 3. Services are relevant, appropriate and cost-effective

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BEUC supports the development and use of disinvestment strategies when new medicines have shown to have limited value for patients, in order to free up the health budget for other, proven therapies.<sup>5</sup>

We highlight two additional areas where evidence-based approaches fall short of expectations to make health services and goods relevant, appropriate and cost-effective. One reason for over-medicalisation is weak primary health care and a lack of coordination between those services with social services provided at the local level in order to prevent disease, improve health literacy and healthy behaviours. Another area that should be explicitly addressed in the report is external pressure from the pharmaceutical or health technology industry on decisions and specifically decisions to reimburse products. In spite of the growing number of tools to aid reimbursement decisions, examples show these processes have been sidestepped, dedicating scarce healthcare resources to unproven therapies. Pressure from manufacturers has led governments to abandon the standard 'value for money' assessments and hastily reimburse some medicines.<sup>6</sup> Past experience with anti-virals for H1N1 flu show that excessive pressure on European governments can see large quantities of medicines purchased in the absence of convincing evidence that they work. This practice not only depletes drug budgets but diverts funds away from other proven treatments.<sup>7</sup> Decisions not to reimburse medicines for certain conditions have also been overturned owing to media attention and public opinion, sometimes guided by drug makers.<sup>8</sup>

#### Policy responses

BEUC agrees with the policy responses listed in this section. As concerns the priority-setting processes for health technology assessment (HTA) to inform coverage decisions, we recall that the Council of Europe recommends that member states consider limiting reimbursement to only those medicines with a proven added therapeutic value compared to existing alternatives.<sup>9</sup> Decisions not to reimburse a medicine may not be acceptable by some even if the medicine lacks sufficient evidence of its added value. BEUC recommends that reimbursement authorities foster consumer trust by involving a balanced representation of stakeholders in the priorities set for reimbursement policy and by publishing the rationale and outcome of all pricing and reimbursement decisions. These steps may help foster public understanding and acceptance of reimbursement decisions.

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5 WHO. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. 2015 <http://bit.ly/1MKEAIN>

6 Van Herck, P., Annemans, L., Sermeus, W., & Ramaekers, D. (2013). Evidence-based health care policy in reimbursement decisions: lessons from a series of six equivocal case-studies. *PloS one*, 8(10), e78662.

7 Van Herck et al. 2013. See point ii. DOI 10.1371/journal.pone.0078662

8 De Redactie. Viktor krijgt Soliris binnenkort terugbetaald. (2013) <http://bit.ly/1kwiUNo>

9 Council of Europe. Resolution 'Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?' (2015). See point 6.2.2.3 in the Resolution. <http://bit.ly/1YQIz4C>

It should be mentioned in the report that that one way to address over-medicalisation and to promote health and wellbeing is by strengthening primary health care and coordinating those services with social services provided at the local level in order to prevent disease, improve health literacy and healthy behaviours. In addition, consumer participation at different levels of health management is important for a person-centered health care.<sup>10</sup> To improve the efficient and appropriate use of medicines, adherence to clinical pathways and guidelines should not only be monitored but also enforced through the introduction of incentives.

## 6.1 Medicines

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BEUC agrees with the main concerns raised in this chapter and wishes to add the following comments. The growing number of 'me too' medicines that are barely more effective than their competitors, are drawn to the market by the current R&D model and this should be mentioned in the report. Only 3% of new medicines licensed in France in 2014 offered a real advance for their approved indications.<sup>11</sup> Similar trends have been observed in Germany and the Netherlands.<sup>12</sup> Although the me-too approach can create some price competition, it doesn't tend to lead to price reductions in practice<sup>13</sup> and can detract investments from new areas of research. Price negotiations would benefit from greater price transparency. Publishing contracts between drug manufacturers and government buyers can increase the quality and extent of competition from other bidders, allowing governments to purchase medicines on the best terms.<sup>14</sup> BEUC supports pooled procurement pilots and the public disclosure of the evidence they generate.

Medicines availability and/or drug shortages were not addressed in this chapter despite the fact that 66% percent of European hospital pharmacists surveyed in 2014 reported shortages on a daily or weekly basis. 75% of respondents reported negative impacts on patient care.<sup>15</sup> Shortages can be caused by one or a combination of problems in manufacturing (i.e. shortage of raw materials), distribution and supply (i.e. parallel trade), or economics (i.e. financial crisis or marketing strategies).<sup>16</sup> The fact that there is no harmonized definition of drug shortages in the EU makes it difficult to monitor and report the problem in a comparable way.

### Policy responses

BEUC supports the policy responses listed here and wishes to add several comments. The Innovative Medicines Initiative is a fora where socially responsible licenses can be piloted for medical products that have benefited from EU funds. Using cost-effectiveness analysis in coverage decisions is in line with the recommendations of the Council of Europe for

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10 World Health Organization. World Health Report 2008 'Primary Health Care'. <http://bit.ly/1HcdkKo>

11 La Revue Prescrire. New drugs and indications in 2014. *Rev Prescrire* February 2015; 35 (376): 132-136. <http://bit.ly/1Amp61o>

12 WEMOS. Position paper 'Added Therapeutic Value: European citizens should get their money's worth'. (Sept 2014) <http://bit.ly/1WCAQ9>

13 Hollis, A. Me-too drugs: is there a problem. *WHO report*. (2004). <http://bit.ly/1I9qhec>

14 Hudson, A., Kenny, C., Poortman, C., Initiative, C. S. T., Taggart, C., Coldham, L., ... & Savedoff, W. Publishing Government Contracts: Addressing Concerns and Easing Implementation. <http://bit.ly/1XSDN3W>

15 European Association of Hospital Pharmacists. Report 'Medicines shortages in European hospitals' (October 2014). <http://bit.ly/1ub2BSZ>

16 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. <http://bit.ly/1bYZ9tg>

member states to consider limiting reimbursement to only those medicines with a proven added therapeutic value compared to existing alternatives.<sup>17</sup> Information sharing and pooled purchasing power can lead to more effective and accountable healthcare spending. Consumers support the exchange of information about discounted medicines prices and pooled procurement mechanisms for medicines at the EU level.<sup>18</sup> Improved information and data collection requires systematic pan-European studies on the direct and indirect costs of medicines for patients, especially those living with high-burden diseases, to identify where inequalities lie and how to address them.

In terms of how the EU can support member states, although there are many welcome proposals for medicines development in this section, further attention can be given to EU action for medicines affordability and availability. For example, efficient resource use is supported by sharing and assessing evidence of medicines' added therapeutic value through EUnetHTA. The continuity of EUnetHTA beyond Joint Action 3 can be reinforced by establishing an EU-level joint committee of multi-disciplinary experts who are independent and adequately resourced to discuss the concept of 'added therapeutic value', exchange information and conduct HTAs.<sup>19</sup>

The European Parliament can promote access to medicines through EU-wide action on the added therapeutic value of new and existing medicines, and support the introduction of greater price transparency. Concerning EU action on drug shortages, a starting point is to define drug shortages and identify ways EU member states can work together to prevent and address shortages by forming an EU-level working group. The European Parliament can support this work by calling for an investigation of drug shortages in Europe to gather information about their frequency, and the causes and possible solutions.

## 6.2 Medical devices

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BEUC agrees with the main challenges and policy responses identified in this section and wishes to add the following comments. Access to medical devices requires more and better clinical data, gathered wherever possible through randomized controlled trials, for purchasing and use of safe and cost-effective devices. The EUnetHTA can be supported to assess medical devices selected according to transparent criteria and promote the exchange of information about devices' added value between member states.

More information about access to safe and effective medical devices is available can be found in BEUC's position paper ([http://www.beuc.eu/publications/beuc-x-2013-031\\_ipa\\_medical\\_devices-beuc\\_updated\\_position-final.pdf](http://www.beuc.eu/publications/beuc-x-2013-031_ipa_medical_devices-beuc_updated_position-final.pdf)).

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17 Council of Europe (2015). See point v. <http://bit.ly/1YQIz4C>

18 Karel Jooker. Prijszetting geneesmiddelen: Een remedie tegen euroscepticisme [Medicines price setting: A remedy for euroscepticism] (Feb/Mar 2015). In Test Gezond, published by Test Achats-Test Aankoop.

19 Towards a harmonised EU assessment of added therapeutic value. Study commissioned by the European Parliament's ENVI Committee. June 2015. <http://bit.ly/1BhYiQn>

## 7. People can use services when they need them

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BEUC recommends building the evidence base of health literacy in the EU by involving stakeholders such as European consumer organisations, which publish reader-friendly, timely and relevant health information in their publications and websites.

## 8. Services acceptable to everyone

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BEUC recognises the potential for developing e-Health systems for greater information and service continuity. E-health will help make health systems more responsible to patients' needs when several challenges have been addressed in its development, in particular: the guarantee of patients' informed consent for storage and sharing of personal data; a legal framework for data protection; the optimal interoperability of eHealth systems within and between EU member states; the introduction of a system of redress and compensation in case of privacy breaches. More information can be found in BEUC's position on eHealth (<http://www.beuc.eu/publications/2011-00399-01-e.pdf>).

### Ensuring equitable access

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BEUC supports how the report has highlighted the challenges and proposals for access to medicines for patients. In particular, this report is appropriately focused on the challenges for accessing all medicinal products, not only new, expensive medicines. Moreover, we do concur that doing more for patients does not necessarily equate to spending more. Many challenges to consumers' access to medicines can be addressed through objective and evidence-based decision making for efficient health spending.

Efficiency in health spending begins with good health governance. This report should generally recognise the importance of transparency, the resolution of conflicts of interest and accountable decision making in priority setting and decision making at the local, national and EU levels. In line with this approach, the Council of Europe has recently stressed that absolute transparency of the links between the pharmaceutical industry and all health sector players and that those with a conflict of interest be excluded from 'sensitive decision-making processes' in its report 'Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?'.<sup>20</sup>

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20 Council of Europe (2015). See point v. <http://bit.ly/1YQIz4C>



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