Position Paper

EU collaboration on pricing and reimbursement of innovative medicines

Thanks to new scientific and technological developments and accelerated review by regulators, innovative medicines become available at a faster pace. Unfortunately, at the same time, the price of innovative medicines is rising at an unsustainable rate. The costs of new cancer drugs, for example, have doubled during the past ten years. Price setting is utterly lacking in transparency. The pharmaceutical industry – which has profit margins up to 40 percent and spends far more on marketing than on R&D – appears to have moved from ‘service driven’ to ‘profit driven’.

This situation has confronted policymakers with serious challenges, having to ensure the sustainability of healthcare systems while guaranteeing that patients can continue to benefit from innovative pharmaceutical care. The debate around affordability of innovative treatments is of special concern to hematologists. Not just because they aim to provide blood disorder patients with the best possible treatments that can save or improve their lives. Hematology is also a very research-intensive discipline, with a high success rate in delivering innovative medicines – many of which, however, are marketed at a high price, increasingly to the point of becoming unaffordable.

The European Hematology Association (EHA) acknowledges the fact that pricing and reimbursement of medicines lie within the competences of Member States. However, EHA believes that the strengthening of EU collaboration in this area is urgently needed. In particular, EHA recommends:

1. Developing a pan-European strategy to curb drug prices

In order to change the current situation – in which pharmaceutical companies maximize their profits (at much higher levels than in other industries), innovative drugs are fast becoming unaffordable, and most of basic research continues to be taxpayer-funded – there is an urgent need to lower drug prices.

EHA is a strong proponent of a pan-European strategy aimed at reducing the prices of innovative medicines, with the following key elements:

a) **Determine maximum prices** for new drugs approved for the European market. An option could be to make the European Medicines Agency (EMA) responsible for not only the registration of new medicines, but also the negotiating of fair, transparent and realistic maximum prices with the industry.

b) **Support publicly-funded trials.** PFTs will help to reduce drug prices by making the sale of approved drugs at cost price possible, by speeding up research (which will benefit from direct access to clinical trial results) and by lowering the price of post-patent biosimilars. Broad support from EU and national authorities is essential.

EHA calls upon the European Commission to make a central EU authority such as EMA responsible for negotiating maximum prices with pharmaceutical companies, and upon EU and national authorities to support publicly-funded trials, in order to curb the prices of innovative drugs.

2. Make pricing and reimbursement decisions transparent and harmonize them across EU Member States

The pharmaceutical pricing and reimbursement systems in EU countries are very complex. Each country uses different schemes and policies, adapted to its own economic and health needs. Thus, innovative treatments may be available and reimbursed in one country but not in another, resulting in major inequalities. To provide optimal care to patients, hematologists need to navigate this complex framework and be able to understand how decisions have been
taken, which criteria have been used and who has been involved. EHA therefore invites national authorities to make this information available in a more transparent and understandable manner and work with the European Commission, in the context of the EU Network of Competent Authorities for Pricing and Reimbursement (NCAPR), for the creation of a unique EU-wide database. EHA would urge Member States to make use of such a database to harmonize the outcomes of decisions taken on the national level.

EHA calls upon national authorities to develop and implement policies aimed at greater transparency on pharmaceutical pricing and reimbursement decision-making. It also invites the European Commission to develop an EU database which will help Member States make better and more harmonized decisions.

3. Extend to essential medicines the existing collaboration between Member States on procurement and negotiations

The EU Joint Procurement Agreement enables 24 EU countries to procure various medical countermeasures, such as pandemic vaccines, as a group at more advantageous conditions, including pricing. Furthermore, in 2015, Belgium, Luxembourg and The Netherlands began joint negotiations with pharmaceutical companies aimed at moderating the price of orphan drugs. In June 2016, Austria also joined this initiative.

EHA believes that, besides medical countermeasures and orphan drugs, the scope of these instruments should be extended to the purchase of other essential medicinal products. EHA urges the Slovak Presidency of the Council to discuss this possibility in the context of its ongoing work to tackle the high price of medicinal products.

EHA calls upon the Slovak Presidency of the Council to discuss the extension of the scope of joint procurement and joint negotiations at the next informal meeting of Ministers of Health.

4. Consult hematologists in Health Technology Assessment (HTA)

Member States increasingly use HTA to guide their reimbursement decisions, although this is not the only instrument employed. Hematologists are directly or indirectly involved in reimbursement decision making and/or in the implementation of such decisions and should therefore be consulted on, and actively engaged in, HTA policies and processes. This should also be the case in the framework of current EU cooperation in the area of HTA. EHA recommends using current EU instruments such as the EU HTA Network and the EUnetHTA Joint Action 3 to consolidate clear and transparent mechanisms for the involvement of relevant stakeholders, including health professionals.
Finally, EHA notes that strengthened EU cooperation in the area of HTA is needed to overcome the current fragmentation in approaches to HTA across Member States, which can lead to shortcomings in the efficient allocation of resources and even to delays in access to new medicines for patients. Promoting the development of transparent streamlined tools and processes, which facilitates the exchange of information and re-usage of joint HTA work, should be among the priorities of future EU activities in this area.

EHA calls upon the Commission and Member States to involve hematologists in HTA policies and processes both at national and EU level. It also recommends EU cooperation within the HTA Network and EUnetHTA Joint Action 3 to tackle current divergent approaches, so that patients benefit from equal assessments of innovative medicines across Europe.

About EHA

The European Hematology Association (EHA) is a not-for-profit membership organization that promotes excellence in patient care, research and education in hematology. EHA’s Annual Congress is attended by some 10,000 delegates. The association also publishes Haematologica, Europe’s primary hematology journal. Being the leading hematology organization in Europe, EHA represents the interests of the discipline, its clinicians and its scientists in Europe.

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