EUROPEAN HEMATOLOGY ASSOCIATION

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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[1]. 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[2]. Price setting is utterly lacking in transparency. The pharmaceutical industry – which has profit margins up to 40 percent[3] 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] Dutch Presidency of the EU, *Innovative and affordable medicines. Innovations for the benefit of the patient,* Discussion paper, Informal meeting of Health Ministers, 18 April 2016, p.2
[2] WHO Europe, *Access to medicines in Europe*, March 2015, p.14
[3] Amigobulls Inc., Key Financial Ratios 2015 per company on www.amigobulls.com/stocks, retrieved September 2016

1. Developing a pan-European strategy to curb drug prices
2. Ensuring full transparency, and harmonization across EU Member States, of pricing and reimbursement decisions
3. Extending to innovative medicines the existing collaboration between Member States on procurement and negotiations
4. Consulting hematologists in Health Technology Assessment (HTA)

## 1. Develop 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 negotiation of fair, transparent and realistic maximum prices with the industry. Any approach to price maximization needs to take differences in the economic situation of Member States into account.

b) **Support publicly-funded trials (PFTs).** 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.

c) **Improve market access for biosimilars.** By boosting competition, the introduction of biosimilar medicinal products helps to drive down prices, not just of the original biologic medicines but across product classes. While experiences in Europe have so far shown price reductions of 20-40%[4], we are convinced that under optimal market conditions price reductions are possible of well above 50%. The accelerated uptake of biosimilars could thus contribute significantly to increasing patient access and relieving the financial pressure on healthcare systems. Removal of obstacles to a functioning, competitive biosimilars market by European and national authorities is crucial.

In order to curb the prices of innovative drugs EHA calls upon the European Commission to make a central EU authority – such as EMA – responsible for negotiating maximum prices with pharmaceutical companies. It also calls upon EU and National Authorities to support publicly-funded trials and to ensure improved market access for biosimilars.

[4] IMS Health, *The impact of biosimilar competition*, June 2016; IMS Health, *Delivering on the potential of biosimilar medicines*, March 2016, p.7

## 2. Ensure full transparency, and harmonization across EU Member States, of pricing and reimbursement decisions

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 transparent and understandable manner and work with the European Commission, e.g. via the EU Network of Competent Authorities for Pricing and Reimbursement (NCAPR), for the creation of a unique EU-wide database that will help improve and harmonize decision-making by Member States.

> EHA calls upon National Authorities to develop and implement policies aimed at greater transparency of 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 innovative 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 lower prices. 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 innovative drugs. EHA urges the EU and Member States to consider this possibility as well as broader and stronger cooperation on procurement and pricing negotiations, in the context of ongoing efforts to tackle high medicine prices.

> EHA calls upon the EU and Member States to discuss extending the scope of joint procurement and joint negotiations.

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## 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 European 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 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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