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Affordability of Medicines a Top Priority for EHA: Toward a Fair Pricing Model for Innovative Medicines

Hematology, as we all know, is a highly innovative discipline that continues to generate new insights that carry the promise of revolutionizing diagnosis and treatment of blood disorders, potentially saving and improving the lives of patients suffering from even the rarest of illnesses. However, access to new treatments is at risk because of the steep, often excessive prices of those new drugs that do reach the clinic.

The looming unaffordability of innovative medicines as a result of high prices poses a threat to both patient access and the sustainability of health care systems. In the current system of market exclusivity granted by patent rights drug manufacturers are primarily driven by recouping research and development costs and offering sizable profits to shareholders, often resulting in hefty price tags for medicines (particularly those with orphan designation). With increasingly strained health care budgets, even in wealthier countries, this causes limitations on the purchase and reimbursement of innovative medicines. In markets deemed too small—in terms of patient population size or purchasing power—an expensive medicine may not be made available at all.

Although many of them affect only small numbers of people, the importance of treating blood disorders is clear. An estimated 80 million people in Europe suffer from a hematologic disorder (malignant or nonmalignant). In addition to the considerable physical and psychological burden, the economic cost is substantial, estimated by 2 European Hematology Association (EHA)-commissioned studies published in *The Lancet Haematology* at €23 billion a year across the European Economic Area (the 28 European Union-countries plus Switzerland, Norway, and Iceland).[1]

Yet, as new therapies are being developed at a rapid pace and the study of blood is contributing significantly to break-through innovations in other disciplines such as oncology, the benefits for patients and society as a whole are limited by soaring drug prices. Although data on R&D spending and on pricing and reimbursement mechanisms are scarce, a recent study by US hematologists–oncologists Vinay Prasad and Sham Mailankody offered a clear indication of the wide gap between actual R&D costs and the price at which a new drug is sold. Based on their analysis of ten cancer drugs approved by the FDA in the years 2006–2015, the median cost of developing a single cancer drug was $648 million; the median revenue after approval of a drug $1,658,4 million.[2] Although health care systems vary across the continent, in Europe too authorities are challenged by the high prices of innovative drugs. Current business models based on long-lasting patents and rendering high profits and high prices are no longer tenable, negatively affecting all partners in the chain from drug development to patient treatment, including, ultimately, the pharmaceutical industry.

Time for a new business model

The findings of Prasad and Mailankody are in line with the conviction held by the European Hematology Association's Task Force on Fair Pricing that rapidly rising prices of new drugs—in hematology perhaps more than in any other medical discipline—are primarily a product of

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perverse incentives in current pricing models. Although it is only natural for companies to pursue a healthy profit, it is clear that profit levels in the pharmaceutical industry far exceed those in other sectors and certainly exceed what is acceptable from a public health point of view—especially in light of the large sums of public funding that go into health research, effectively making taxpayers pay for their medicines twice.

What is needed, in our view, is a new economic model for the development of innovative medicines and for bringing them to the market. A model that offers a better balance between public and private interests, that is, transparent and involves all stakeholders. It goes without saying that for any new business model to be successful it needs to be beneficial for all involved: patients must have access to the best available, affordable care; hematologists should be able to deliver the best possible treatments; industry needs to be rewarded for developing, manufacturing and marketing high-quality drugs with a reasonable profit margin; and national health systems have to be able to procure and reimburse medicines without busting public finances.

EHA Task Force on fair pricing

What can EHA do to help curb medicine prices? After identifying "pricing" as a top advocacy priority, the EHA European Affairs Committee last year established the Task Force on Fair Pricing to provide direction and take action.

Having concluded that the fundamental problem lies in the dysfunctionality of current business models, the Task Force set out to gather a working group of leading European health economists who will be assisting EHA in developing the guiding principles for new business models. The case for a new pharmaceutical pricing model was also made, convincingly and emphatically, at the EHA annual congress in Madrid last June, where Prof Richard Sullivan (King's College London), Andrew Rintoul (WHO) and Dr h.c. Peter Kapitein (patient advocate and Task Force member) spoke at a session dedicated to pricing.

More can and must be done. An option would be to make a central EU authority responsible for determining maximum prices for new medicines approved for the European market. There should be no automatic market access for European Medicine Agency-approved drugs unless a reasonable price can be negotiated. More options will be explored; however, any approach to price maximization would need to take differences in the economic situation of countries into account.

EHA also calls upon national and EU authorities to support publicly funded trials (PFTs). These would make the sale of approved drugs at cost price possible, speed up research (by offering direct access to trial results), thus helping to reduce drug prices.

Biosimilars

Promoting the acceptance and uptake of biosimilars is another important element in the Task Force's pricing strategy. Because biosimilars tend to be considerably less expensive than the reference biological medicine to which they offer an alternative, they have the potential to widen patient access and force down prices. Although so far price reductions on the European market remain relatively limited—mostly 20% to 30%[3]—we are convinced that under optimal market conditions, price reductions of well over 50% are realistic.

Increased uptake of biosimilars requires trust and awareness among professionals and patients. EHA is prepared to actively endorse biosimilars, develop education tools, and support biosimilar companies willing to introduce their drugs against fair and substantially reduced prices.

Alliances

Naturally, EHA will not be able to make a sufficiently big impact on its own. Participation in alliances that are active on pricing and the broader issue of access to medicines, such as the European Public Health Alliance, and ongoing contacts and alignment with other stakeholders—including the European Parliament which, through the Cabezón Report,[4] has firmly placed these issues on the political agenda—are therefore essential complementing activities.

Ultimately, all phases of and all actors in the "pricing chain" should be subject to critical review and revision. In the current situation too many "incentives" are clearly counterproductive, resulting in prices that are far from fair and that threaten patient access to newly developed and promising drugs, even in those (wealthy) countries where availability has so far hardly been an issue. Prices of innovative hematology drugs must go down, substantially—for the sake of patients, doctors, payers, and health care systems. EHA is determined to play its part, in close collaboration with all other stakeholders, including the pharmaceutical industry, in keeping life-saving and life-enhancing medicines affordable and accessible. The right treatment available to patients across Europe, no matter how rare their blood disorder, at a price that is fair to patients, manufacturers and tax payers—that is what we would call priceless.

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