Sustainable access to innovative therapies

HOPE response to OECD online consultation

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European Hospital & Healthcare Federation

Reflecting on the last 5-10 years, what do you think have been the major changes affecting access to medicines?

In Europe, from one to almost two third of pharmaceuticals in monetary terms are prescribed in hospitals. In the budget of hospitals their share has been increasing in the recent years, with the growth of expensive molecules being higher than the growth of overall health expenses or GDP. There are many more new "innovative" drugs coming (in particular in immunotherapy) although it is difficult to get a clear view of what is in the pipeline. Apart from the financial consequences, there has been, is and will be major impacts of innovative products on hospital organisation. In some countries, there are national systems for prioritizing. Some hospitals are anticipating the arrival of "innovative" medicines with tools to calculate their impact, with specific financial envelops, and with appropriate investment etc. But most are not able to do so.

What are the top three (3) issues that must be addressed to ensure access to innovative medicines while maintaining financial sustainability of health systems?

New medicinal products pose new challenges regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability, their post-market surveillance and patient access and affordability. There is clearly an issue with the opacity of price mechanisms, price setting based not on the transparency in R&D costs and traceability, leading to treatment rationing unethical and ineffective from a public health perspective.

Another growing concern is the regulatory schemes for the earlier marketing authorization of medicines with less comprehensive data. The incentives in this specific legislation need to be balanced between different goals: encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact. Circumstances should be avoided that are created to encourage inappropriate market behavior of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit patients' access to new medicines for unmet medical needs. There is an increasing trend of marketing authorization of new medicinal products for small indications, including, in some cases, the authorization of a single product for 'segmented' patient groups within a disease area and the authorization of one substance for several rare diseases. Companies may seek very high prices while the added value of some of these products is not always clear. There is a clear correlation between patent monopolies and the affordability and accessibility crisis.

As far as the European Union is concerned, the 17 June 2016 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States are coming in this context at an appropriate time.

Legal tools exist to increase universal access to treatment by promoting generic competition such as patent opposition and compulsory licence, Stability agreements between governments and the bio-pharmaceutical industry, Managed entry agreements for new medicines, Adaptive pathways, Out-come-based reimbursement, Innovative pricing and funding models. Some countries have developed their own models.

Why do you think there are issues in ensuring access to innovative medicines while maintaining financial sustainability of health systems?

HOPE welcomes further development of exclusively Member States driven voluntary cooperation between relevant authorities and payers from Member States, including cooperation within groups of Member States, that share common interests in relation to pricing and reimbursement of medicinal products and to explore possible areas in which such voluntary cooperation can contribute to higher affordability and better access to medicinal products.

A special attention should be given to the access to medicines for patients in smaller Member States, as mentioned in the June 2016 declaration of Sofia of Health ministers of central and eastern Europe on ensuring adequate access to pharmaceutical products at sustainable and affordable prices.
HOPE is participating to the European initiatives leading to exchanging HTA-methodologies and assessment outcomes through EUnetHTA and the HTA Network as already foreseen under the Joint Action EUnetHTA. It is clear however that financial impact and pricing must be addressed separately from the HTA and that the applicability of HTA results need to be assessed by national health systems.

What changes would you like to see happen to improve access to innovative therapies?

This overall issue raises for hospitals the question of innovation, the question of hospital financing methods, but also the question of better targeting what is reimbursed or not. More work needs to be done on prescriptions, on the risks linked to the lack of scientific evaluation and on the negotiation of the price at an early stage. The responsible for hospitals at national level should take a growing role in the existing mechanisms for the evaluation of innovative drugs, needing a dedicated financing; this is true also for medical devices by developing HTA in hospitals. Moreover, hospitals may not all be fully optimal on the daily management of clinical trials, on the inclusion of ambulatory care patients and their follow up after hospitalisation, on the return of information to healthcare professional. Registers are not perfect because of the lack of motivation and financing. There is then a need to rethink strategies, financing and investment of research; a need to rethink as well the internal organisation of hospitals following the introduction of innovation and not only of innovative medicines.

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HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.