HAI Provides EU Member States with Recommendations that Promote Therapeutically Advantangeous and Affordable Medicines

(HAI letter to European Union Health Attachés and Ministers prior to their meetings to discuss Council conclusions on pharmaceuticals | 3 June, 2016 | Download PDF)

Dear Attaché,

Medicines are a key component of patients' treatment. Yet, in the European Union (EU), the increasingly high price of medicines and shrinking public healthcare budgets are jeopardising affordable access to needed medicines. Moreover, despite strong intellectual property (IP) protection and continued strengthening of additional market monopolies in the EU, there has been a striking lack of development of truly innovative medicines that address priority health needs.[i]

The failure of the current biomedical research and development (R&D) model can no longer be ignored. The Dutch Presidency of the Council of the EU correctly described the problem of the current over-protection and misuse of IP rights, calling for a better balance between rewarding innovation and the affordability of healthcare. This call for action was strongly supported by many public health organisations.[ii]

Within the context of the upcoming adoption of Council conclusions on pharmaceuticals, Health Action International (HAI) urges health ministers from all EU Member States to support ambitious measures that promote the development of therapeutically advantageous and affordable medicines.

The current patent system excessively rewards patent holders while creating high costs to society. In Europe, on top of the 20-year patent protection period, additional market exclusivity, data exclusivity, and supplementary protection certificates delay price-lowering generic competition. The practice of 'evergreening', which refers to the numerous ways in which pharmaceutical companies use the law to extend their patent monopoly protection, is an example of the industry's focus on extending protection and retrieving revenues from existing products. Another area of concern is orphan drugs, which benefit from supplementary protection and are often high priced.[iii]

The EU should therefore **critically examine the societal impact of the abuse and misuse of IP rights** for pharmaceuticals and put in place appropriate measures to redress current imbalances. It is also important to perform **effective monitoring of anti-competitive practices** that aim at blocking or delaying generic competition and apply

dissuasive sanctions.

Furthermore, alternatives to a patent-based system are needed to stimulate therapeutically valuable innovation. By implementing **needs-driven, open models of innovation** that embrace delinking the cost of R&D from the price of the medicine, governments can steer R&D towards priority health needs. This model would also enable governments to stimulate rational marketing and fair use of results, and enable affordable medicine prices.

There is also an urgent need to prevent EU taxpayers from paying multiple times for their medicines, as they already pay for public funding and infrastructure for (early) research, and through various tax and other incentives. This could be achieved by attaching binding conditions to public funding of biomedical R&D (such as through Horizon2020). Such conditions could ensure **public access to all research results and a better reflection of the share of public funding received** in the price of medicines developed down the line.

The current information asymmetry between payers in EU Member States and the pharmaceutical industry on R&D costs and prices is a major problem. EU Member States should **better track the amount of public funding** that has contributed to the development of health technologies, including tax incentives and structures for basic research.[iv] The real costs of the private share of R&D remain unknown and estimates from the industry and independent analysts vary greatly.[v] Member States can use their combined market position to **pressure companies to disclose the private share of R&D costs**. Increased transparency on the actual prices paid for medicines is also needed to empower payers in price negotiations and ensure more affordable treatment.[vi] The **EU should support price transparency** by establishing a centralised, publicly available database with information on actual medicine prices, including discounts and rebates.

Health technology assessment (HTA) is an important tool for the sustainability of healthcare systems. **Cooperation on HTA at the EU level should strive to find synergies that enhance the quality of assessments and preserve high standards**. Reimbursement should be confined to medicines of added therapeutic value, and affordable prices are needed to enable universal access. **Joint price negotiation and procurement schemes** at regional and national levels can contribute to more affordable medicine prices. We highly recommend increased voluntary joint initiatives in this area, such as the pilot launched by the Belgian and Dutch governments.

Low regulatory standards get in the way of genuine therapeutic innovation, leading to the pursuit of marginal outcomes and a ‘me-too’ mentality.[vii] Regulators should **request comprehensive, meaningful data (such as relevant clinical outcomes and comparative trials against best available treatment) to inform decisions on marketing authorisation**. The so-called ‘adaptive pathways’ paradigm is not an adequate solution to improve access to safe medicines of added value. Because of inherent concerns on patient safety, **early approval of medicines should be confined to situations of true unmet medical needs**. Regulators should be strict in demanding that companies comply with pharmacovigilance commitments and apply sanctions if they fail to do so. This is

particularly relevant in the context of early approval, where patients are exposed to higher risks.

Finally, to enable independent assessment and strengthen informed decision on treatment, clinical trial data must be made publicly available. **Information on medicine safety and efficacy data should never be considered commercially confidential, or a trade secret**. The new EU Clinical Trials Regulation must be implemented in ways that maximise data transparency. Likewise, the recently adopted EU Trade Secrets Directive should be implemented in a way that will not hamper governments' disclosure obligations or public access to information that is crucial for protecting people's health.

For more information or to discuss these points further, do not hesitate to contact us.

Sincerely,
Tessel Mellema and Ancel.la Santos Quintano
Policy Advisors, Health Action International

ENDNOTES

[i] Revue Prescrire (2011) 'New drugs and indications in 2010: inadequate assessment; patients at risk', Revue Prescrire 20(115):105–110. See also : Revue Prescrire February 2015; 35 (376): 132-148; Prevue Prescrire February 2005; 25 (258) 139-148.

[ii] http://haiweb.org/publication/civil-society-urges-member-states-support-dutch-eu-presidencys-vision-access-affordable-medicines/.

[iii] Gagnong MA (2015). New drug pricing: does it make any sense?. Prescrire International, Volume 24 N° 162

[iv] Submission by Mazzucato, Science Policy Unit, University of Sussex, to the United Nations High-Level Panel on Access to Medicines. Feb 2016. http://www.unsgaccessmeds.org/inbox/2016/2/28/mariana-mazzucato.

[v] See, for example, the presentation, New Drug Pricing: Does It Make Any Sense?, by Marc-André Gagnon, Assistant Professor in Public Policy at Carleton University (Ottawa, Canada). (Video in French available on www.prescrire.org). Translated from Rev Prescrire June 2015; 35 (380): 457-461; http://www.dndi.org/2013/media-centre/press-releases/dndi-rd-model/; http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study; http://www.pharmamyths.net/files/Biosocieties_2011_Myths_of_High_Drug_Research_Costs.pdf

[vi] A recent article in *The Lancet Oncology* highlighted the risk of overpaying for medicines caused by a lack of information on real prices paid (including discounts). Vogler et al.

(2015). Cancer Drugs in 16 European Countries, Australia and New Zealand: A Cross-country Comparison Study. *The Lancet Oncology*. Vol 17, No.1, p.39-47.

[vii] Fojo T, Mailankody S, Lo A. Unintended consequences of expensive cancer therapeutics – the pursuit of marginal indications and a me-too mentality that stifles innovation and creativity. The John Conley lecture. JAMA Otolaryngol Head Neck Surg 2014;140:1225-36.