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Why are the prices of new medicines so high and what can we do about it? (F8)

Blog entry

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Why are the prices of new medicines so high and what can we do about it? (F8)

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One issue that keeps emerging in health care meetings between decision-makers and stakeholders is the high prices of new medicines with the EU council stating that the [pharmaceutical strategies create financial pressure](#). The moderator of the Innovative Medicines session in the European Health Forum Gastein started by asking the audience a very timely question: Is it acceptable and fair that vital and innovative medicines are so upscale? The view is rising that price levels are not sustainable, blaming manufacturers for unethical leverage of patient needs. This has been attributed to the monopolistic power that has been provided to them due to national and international patent rules, causing many payers and patient advocates concluding that the current pharmaceutical R&D and pharmaceutical policy model needs replacing. Not a change of tools, but a change in rules.



Elias Mossialos, Els Torreelle, Richard Bergström, Karin Kadenbach, Ri De Ridder

There is a real decision-making problem due to the use of [inadequate evidence](#) from the very start of the regulatory pathway, starting from licensing decisions during marketing authorisation, continuing to pricing and reimbursement decisions in Health Technology Assessment (HTA), to [treatment selection decisions between clinicians and patients](#). Funding of R&D investments does not seem to follow disease burden as several important disease areas are [underfunded](#), whereas estimates from the German HTA agency IQWiG suggest that approximately 65% of new drugs have no (quantifiable) added benefit. One of the [unintended consequences](#) of the pursuit of marginal indications or “Me-Too” drugs is that it stifles innovation and creativity.

However is this an issue for which we should only blame the pharmaceutical industry and manufacturing companies or the regulators and competent HTA authorities as well? And why is the price of some new medicines so high? Some experts say that the current situation of highly expensive medicines is due to the fact that we, society, have given industry the right to set prices as high as the market can bear.

Another line of criticisms relates to the fact that the pharmaceutical industry acts as a pure financial institution according to which R&D spending does not reflect real R&D investment but financial [speculation](#) as in the case of the Hepatitis C treatment Sovaldi. Or that society ends up [paying twice](#) for new medicines, first in the form of basic research and then again for marketed products at point of care, as Nobel Prize winner *Joseph Stiglitz* has *indicated*.

If this situation exists, then why do HTA agencies keep covering the reimbursement of such products? In the EU, at least, the mode of evaluation has so far been based on illustrating “value-for-money” through the use of economic evaluations such as cost-effectiveness analysis (CEA). Industry could argue that the use of incremental cost effectiveness ratios (ICERs) has been directing the negotiation procedures at HTA level and even shaping their clinical development programs. The pricing landscape has been set following CEA arguments because this is what payers have so far been asking for.

Manufacturers need to be given the right signals clearly. Value preferences of decision-makers and the appropriate stakeholders should be incorporated in a transparent and constructed way early on in the product life-cycle of new medicines in order to influence appropriately their development, regulation, coverage and use. Requiring comparative evidence at marketing authorization, as part of adaptive pathways together with the use of network meta-analyses, [could be used](#) to generate real world evidence on comparative effectiveness. This should take place while aiming to streamline evidence needs between licensing and HTA in different countries.

There is a “wrong balance” in the area of pharmaceuticals, and blaming only the pharmaceutical industry might be naive. Escalating and unsustainable prices of new medicines is not just a health policy or even a human rights issue but also reveal industrial policy goals which should not be ignored. There is a political game that relates to keeping manufacturers within national, supranational and continental boundaries. Should we use medicines as vehicles of economic growth or as public goods?

Collectively EU countries can form the biggest collective monopsony power in the world and they should bring it together, aiming to become informed and intelligent buyers, not lousy ones. However the starting point of negotiations should not be set unilaterally but rationally, based on evidence and societal value preferences.

*The views are reflecting keynote presentations from Elias Mossialos (Professor of Health Policy and Director of LSE Health at the London School of Economics and Political Science) and Els Torreele (Director of Access to Medicines and Innovation at the Open Society Foundations), followed by a panel discussion with Richard *Bergström* (Director General of the European Federation of Pharmaceutical Industries and Associations), Ri De Ridder (Director General of the National Institute of health and Disability Insurance) and Karin Kadenbach (Member of the European Parliament) which took place in the Innovative Medicines session on Thursday 29 September 2016 as part of the European Health Forum Gastein.

This Blog was written by the **Young Gasteiner Aris Angelis**

