The role of the Regulators in the European access to medicines debate

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DISCLOSURE

EPHA receives no industry funding

I have no actual or potential conflict of interest in relation to this presentation.

High medicines' prices fuel the debate

How did we get here? Problem is systemic, not going away

- ***Exploring alternatives:*** **Future Drug Pricing Scenarios Project by Belgian and Dutch HTA agencies (First half of 2016)**
- ***Problem is global:*** **UN High-Level Panel report on access to medicines (September 2016)**
- ***No more business as usual:*** **European Parliament own-initiative report on access to medicines (March 2017)**
- ***Status quo no longer acceptable:*** **WHO Fair Pricing Forum (May 2017)**
- ***Consensus needed:*** **Round-table discussions between Health Ministers & pharma heads of Europe (2015-present)**

High medicines' prices unite governments (2015-present)

BeNeLuxA

2016: The year political correctness went out the window

Council of the EU

PRESS
EN

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Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States

"The Council of the European Union

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, that Union action, which shall complement national policies, shall be directed towards improving public health, that the Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care and allocation of the resources to them;

2. RECALLS that under Article 168(4)(c) of the Treaty on the Functioning of the European Union, the European Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products and devices for medical use;

3. RECALLS that under Article 4(3) of the Treaty on European Union, the Union and the Member States shall assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation;

4. RECALLS that under Article 5(2) of the Treaty on European Union, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein and that competences not conferred upon the Union in the Treaties remain with the Member States;

5. RECALLS that under Article 3(1)(b) of the Treaty on the Functioning of the European Union, the Union has exclusive competence in relation to the competition rules necessary for the functioning of the internal market for medicinal products;

6. STRESSES that it is fully Member States' competence and responsibility to decide which medicinal products are reimbursed and at what price and that any voluntary cooperation on pricing and reimbursement between Member States should remain Member States driven;

7. RECOGNISES that a balanced and strong, functioning and effective intellectual property environment, that is line with international commitments of the European Union, is important for supporting and promoting access to innovative, safe, effective and quality medicinal products in the European Union;

8. NOTES that the pharmaceutical sector in the European Union has the potential to be a major contributor to innovation and the health and life sciences sector, through the development of new medicinal products;

9. RECOGNISES that new medicinal products however may also pose new challenges to individuals patients and public health systems, in particular regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their post-market surveillance and patient access and affordability;

- Affordability mentioned 4 times
- Critical stance on early access schemes
- Market failures linked with pharma business strategies
- Healthy & robust competition for generics & biosimilars
- Unclear innovative value of new drugs
- Role of public funding – equitable licensing, fair return
- Intergov. collaboration
- Abuse of IP-related incentives - orphan drugs in the spotlight
- Analysis of incentives & their impact (2017-2018)

The access debate & the EMA

- A global actor & one of the successes of the EU
- Need to maintain citizens' trust in the EMA
- Critical review of the regulator dispels any mistrust
- Pioneer in clinical trials data transparency
- Technical and scientific body but its decisions have *far-reaching* economic, policy and patient safety implications

PERSPECTIVE

DRUG REGULATION AND PRICING

Drug Regulation and Pricing — Can Regulators Influence Affordability?

Hans-Georg Eichler, M.D., Hugo Hurts, M.Sc., Karl Broich, M.D., and Guido Rasi, M.D.

Public debate in the 1990s over drugs' clinical toxicity has given way to concerns about their financial toxicity. Although drug regulators aren't supposed to be

evidence standards to ensure that approved drugs have favorable benefit–risk profiles. Regulators have, for example, developed rig-

orous standards for the genera-

matically drop. Even pharmaceu-tical executives admit that this assumption is naive; companies tend to charge whatever the mar-ket will bear. Any belief in a cor-

Key themes to be addressed:

- **Where do we set the bar for approvals of new medicines in Europe?**
- **Is the EMA sending the right signals to the market?**
- **Is the EMA favoring imitation & over meaningful innovation?**
- **Are the regulators prioritizing the competitiveness of a business sector over public health needs?**
- **Relationship with pharmaceutical companies: Is the fox guarding the hen house?**

What should the EMA do (I)?

- ✓ **Be less dogmatic, less defensive**
- ✓ **Foster & encourage a dialogue with the critical voices on all issues**
- ✓ **Stop hiding behind the legislation – Enforce existing tools properly**
- ✓ **Prevent further orphanisation of pharma regulation**
- ✓ **Discourage abuse, overuse and misuse of incentives by manufacturers i.e. “rare does not mean orphaned”**

What should the EMA do (II)?

- ✓ **Be transparent and forthcoming about projects like adaptive pathways**
- ✓ **Be proactive on issues of transparency and independence – shed light into "black boxes" like pre-submission activities**
- ✓ **Collaborate with the FDA**
- ✓ **Join forces with HTA bodies but "good fences make good neighbors"**
- ✓ **Break down silos between national medicines agencies & Health Ministries**

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