The Access to Medicines debate in Europe

Particularities & latest developments

Access to Medicines in the Baltics, Health Projects, Riga, 13 October 2017

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The Access to Medicines debate in Europe today…

…Is a new debate & a harsh new reality

- Unprecedented level of attention across Europe
- Test for social cohesion & social justice
- High prices = top barrier, top concern
- High prices = Systemic problem, not going away
- National (&EU) policy makers urgently looking for solutions
- Access restrictions = the new norm
- …while patients are used as a funding mechanism for a business model

2016: The year that political correctness went out the window

"Future Drug Pricing Scenarios Project" commissioned by Belgian & Dutch HTA agencies - 4 Scenarios against T.I.N.A.:

a) Needs-oriented Public-Private Partnerships

b) Parallel Drug Development Track

c) Pay for Patents

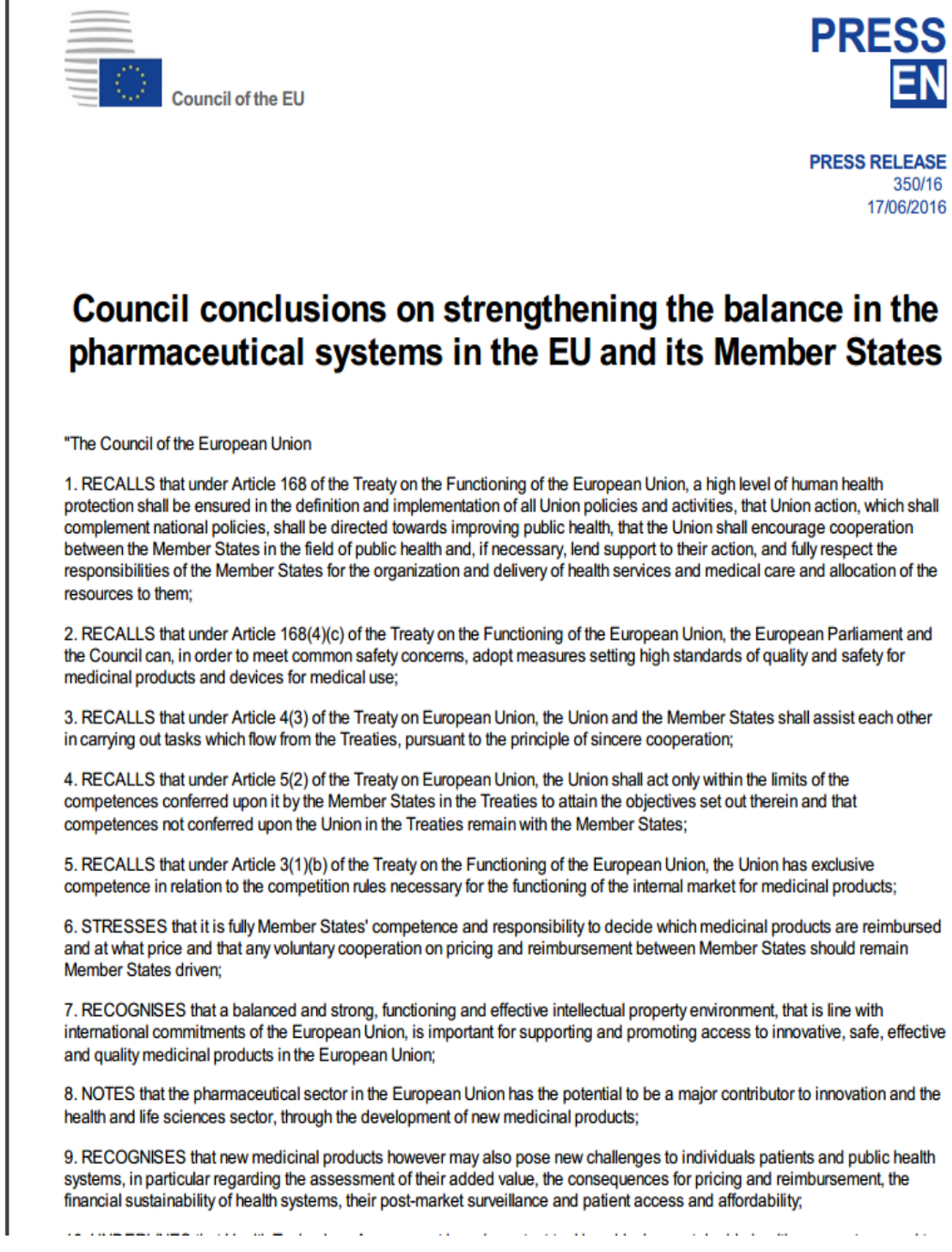
d) Public Good from A to Z

<u>No more lip-service</u>: UN High-Level Panel Report on Access to Medicines:

- **"Review and assess proposals…for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies"**

EU govs. try to work together: BENELUXA, the Valletta Declaration

2016: The year that political correctness went out the window



Council of the EU

PRESS
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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**
- **Abuse of IP-related incentives - orphan drugs in the spotlight**
- **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**
- **Analysis of incentives & their impact (2017-2018)**

Attempts to divert the attention away from the real issues by:

Talking about *value, outcomes & innovative* payment methods

- **Justify high prices on theoretical preventive savings**
- **No change of the "sky is the limit" business model**
- **No impact assessment of new payment schemes**

Talking about *faster & earlier* access - The Adaptive Pathways school of thought

- **Lowers evidentiary requirements, puts patient safety at risk**
- **Speed over science > Disincentive for real innovation**
- **Trojan horse: Deregulation by stealth**
- **Shifts development risk onto health care systems**

Talking about *"personalized"* medicines

- ***Everyone wants to be an orphan* a.k.a. the nichebuster business model, not necessarily for unmet medical needs**

What needs to be done?

- ✓ New rules of the game & news tools VS piecemeal solutions
- ✓ Push the envelope but don't ignore ongoing policy developments
- ✓ Critical review of the top EU regulator – prevent further regulatory capture
- ✓ Keep access schemes as the exception
- ✓ Make the case for a review of IP-related incentives
- ✓ Prevent further orphanisation & consolidation of the *nichebuster* business model

What needs to be done? (part II)

- ✓ Map role of public support at national level
- ✓ Increase public funding – attach conditionalities
- ✓ Highlight role of competition law
- ✓ Joint negotiations + international collaboration + more solidarity = reduce info asymmetry + harder for industry to play the system
- ✓ Transparency of prices, transparency in share of public funding, transparency in production & R&D costs
- ✓ Secrecy undermines govs' leverage
- ✓ Robust HTA system > top quality & Good Fences make Good Neighbors

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