HEALTH AS THE REAL WINNER

Presidency Conference on options to provide better medicines for all

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What can we do to ensure that patients have the medicines they need?

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Today, here in Bulgaria, in other parts of Europe, and in many places all over the world, thousands of people suffer and die prematurely because they have no access to the medicines they need.

The balance between the interests of Pharmaceutical companies and the interests of the Patients and the Population has been broken. We pay exaggerated prices for medicines that have a much lower cost of production. This is unfair.

We have to act firmly to strengthen the balance in the pharmaceutical systems in the EU and its MS (Council Conclusions 17 / 6 / 2016)

What can governments do? (1/7)

- Know the numbers & negotiate according to actual (not inflated) costs.

Expenses and comparative savings if the medicines are paid at the generic price and the research is financed directly by public institutions, EU-28 (€ million)

	Current pharmaceutical expense	Alternative Model
Sales at EFP paid by patients or Health Systems	165,862 *	
Spending at the price of generic or biosimilar	64,952	64,952
R&D expenses	26,595 *	26,595
Extra-protits for companies	74,315	
Possible savings for patients and taxpayers		**74,315**

Margin for negotiation

* EFPIA, The pharmacetutical industry in figures, key data 2017. EU-28

Value based price vs. Transparency of R&D costs and expected return on investment

"But equally important is the need to change the rhetoric about what constitutes a fair and sustainable price for all- and that must start with transparency of R&D costs and expected return on investment rather than just discussion of value. **In the end, there is no value in a medicine that is too expensive and sits on the shelf**".

Sarah Garner, Andrew Rintoul, Suzane Hill. WHO

https://link.springer.com/article/10.1007%2Fs40273-017-0567-4

What can governments do? (2/7)

- Improve their bargaining power
  - Transparency / information on costs & prices
  - Coordinate with other countries (joint procurement, etc.)
  - Prepare for using Compulsory / Mandatory Licence, and use it when necessary
  - Consider manufacturing through private non-profit companies or public companies
  - Strengthen EMA and HTA (independent from industry)

What can governments do? (3/7)

- Recover public investment in R&D
  - European funds: Horizon 2020, IMI, European Clinical Trials network
  - National funds: grants, prizes, tax-credits, research developed in public centers, etc.

What can governments do? (4/7)

- Increase public investment in R&D (EU-level strategy)
  - The resources would come from a Discount on sales of medicines *, destined to finance
    - Public research institutes, networks and platforms: Basic research, clinical trials' networks, … (AMR, Cancer, health promotion, disease prevention), research prizes and awards, etc.
    - DNDi-like initiatives
    - Public funding of regulatory bodies and agencies (EMA, HTA, etc.)
    - Public funding of Scientific societies, patients associations, etc.
    - Public funding and control of Real World Data / Big Data frameworks

* (10%-20% of total sales at EFP in the EU-28 equals € 16,5 billion - € 33 billion)

What can governments do? (5/7)

- Ensure competition
  - Have an assessment of exercise of market power in price negotiations (EXPH)
  - Avoid and combat violation of Art 101 and 102 of the TFEU
    - Imposing abusive prices (Aspen case)
    - Limiting markets (evergreening, pay for delay, etc.) (Avastin-Lucentis case)
    - Applying differential pricing (confidential agreements on Hepatitis C treatments)
  - Avoiding cartels (originator and generics companies)

What can governments do? (6/7)

- Increase the proportion of generics and biosimilars
  - Accelerate approval and reimbursement agreements
  - Promote rational prescription through education and appropriate incentives
  - Inform patients
  - Guarantee effective competition (avoid cartels)
  - Reduce copayments

What can governments do? (7/7)

- Monitor access (and excess): information systems.
  - Impact of copayments on access
  - Impact of high prices on access
  - Inadequate prescription (antibiotics…)
  - Drug Adverse Effects

I have faith in the future…

But, to gain a better future, we have a lot of work to do. And we have to work together.

Different institutions have proposed measures to ensure that patients have access to the medicines they need; for example:

- UN SG's HL Panel on access to medicines report, 14 September 2016

http://www.unsgaccessmeds.org/final-report/

- European Parliament resolution, 2 March 2017, on EU options for improving access to medicines

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0061+0+DOC+XML+V0//EN

- WHO Executive Board, 142 / 14 Rev.1. January 2018. Actions recommended. Plan of action on public health, innovation and intellectual property

http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_14Rev1-sp.pdf

-EXPH (Expert Panel on effective ways of investing in health) (2018). Opinion on innovative payment models for high-cost innovative medicines. 17.1.2018

https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_innovative_medicines_en.pdf