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ACCESS OF MEDICINES AND EQUITY PRICING

Jo DE COCK, CEO NIHDI

20-11-2013

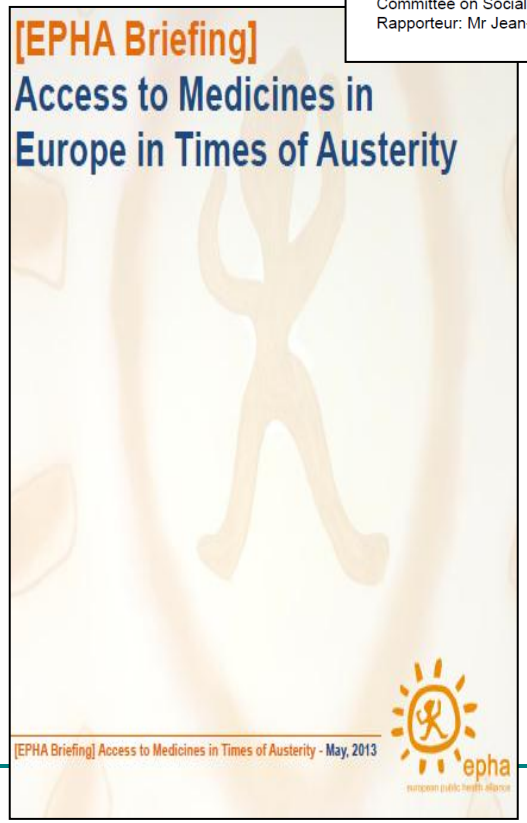
ACCESS TO MEDICINES: A MAJOR CONCERN


Parliamentary Assembly
Assemblée parlementaire
http://assembly.coe.int
COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Doc. 13225
07 June 2013

Equal access to health care

Report[1]
Committee on Social Affairs, Health and Sustainable Development
Rapporteur: Mr Jean-Louis LORRAIN, France, Group of the European People's Party



ACCESS TO MEDICINES: A MAJOR CONCERN

How to obtain greater access to medicines in recession-hit and poorer countries

1. Greater transparency about drug pricing mechanisms (by pharma and by government)
2. Transparency about—and the institution of—fair pricing policies for medicines that consider the impact on patients of new product introductions
3. Greater dialogues between all stakeholders on pricing and access of medicines
4. Greater sharing of intellectual property among pharma companies (particularly in developing countries)
5. More philanthropic (compassionate) donations of medicines to poorer and needy patients
6. Greater consideration of the impact of pharma marketing campaigns on medicine access
7. The subject of access to medicines to be handled by senior management within the pharmaceutical company

Bron: PatientView, 2013

ACCESS TO MEDECINES: ALSO A QUESTION OF SOLIDARITY

The sense of fairness and equity between Member States is being eroded. And without equity between Member States, how can there be equity between European citizens

– *State of the union, 11 sept 2012, by Jose Manuel Barroso, President of the European Commission*

ACCESS TO MEDECINES: ALSO A QUESTION OF SOLIDARITY

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leCISS
Collectif Interassociatif Sur la Santé

DOCTORS OF THE WORLD

EATG European AIDS Treatment Group

epha

hai EUROPE

SALUD por DERECHO
Right to health foundation

ACD

DECLARATION ON ACCESS TO MEDICINES

An undeniable right slipping away: recommendations to avert a public health disaster

ACCESS TO MEDECINES: ALSO A QUESTION OF SOLIDARITY

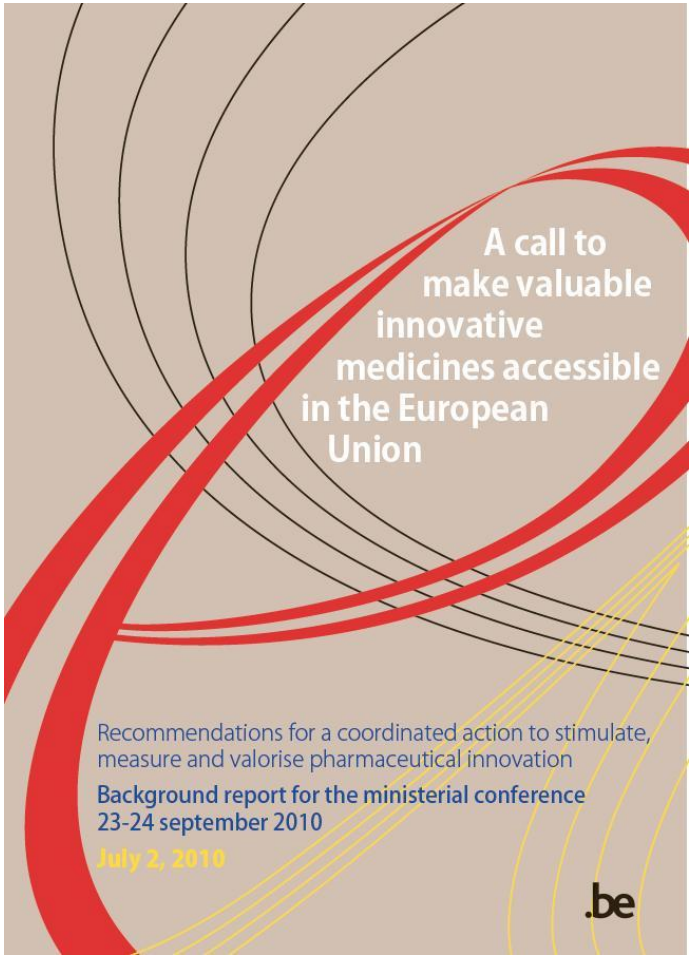
I. Evaluate the impact of fiscal consolidation measures on health and access to medicines, prevention and diagnostics

II. Transparency

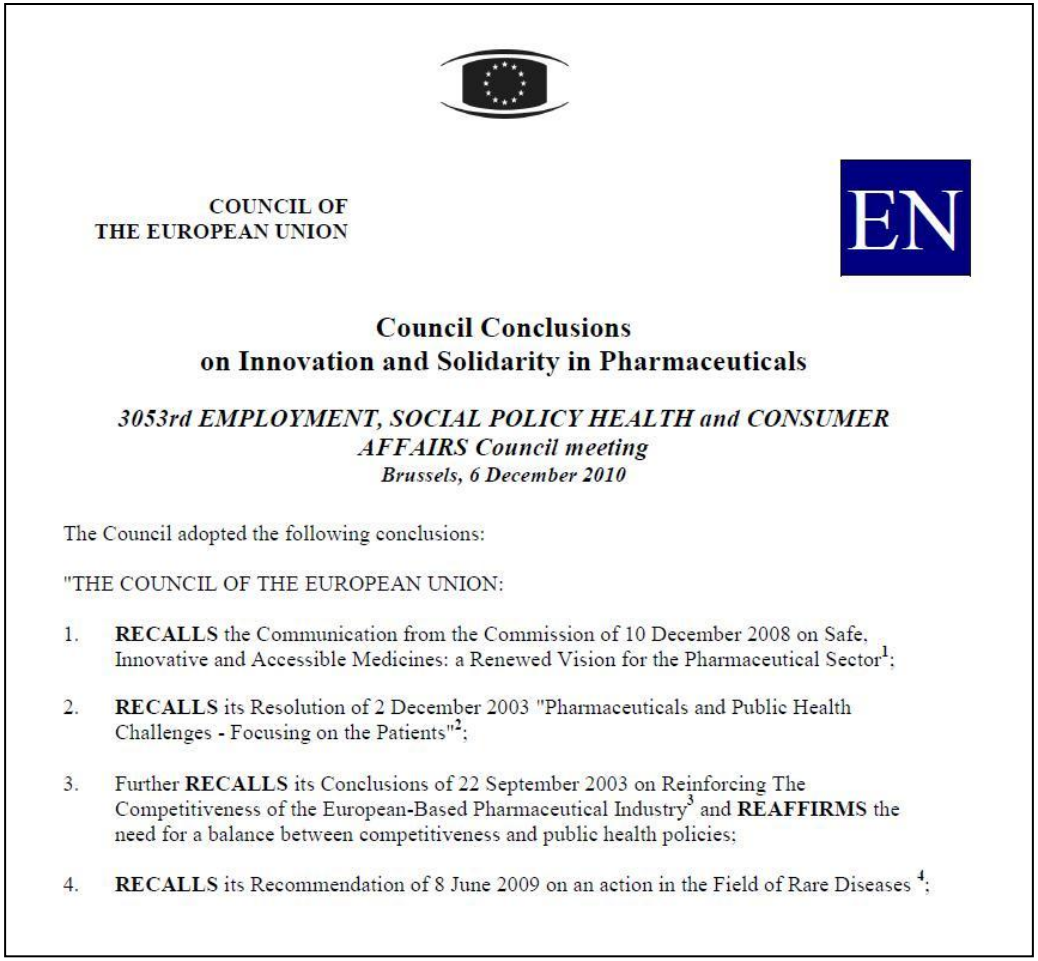
III. Cooperation at EU level

IV. New innovation models

BELGIAN PRESIDENCY 2010



COUNCIL CONCLUSIONS ON INNOVATION AND SOLIDARITY IN PHARMACEUITCALS



COUNCIL OF
THE EUROPEAN UNION

EN

Council Conclusions
on Innovation and Solidarity in Pharmaceuticals

3053rd EMPLOYMENT, SOCIAL POLICY HEALTH and CONSUMER AFFAIRS Council meeting
Brussels, 6 December 2010

The Council adopted the following conclusions:

"THE COUNCIL OF THE EUROPEAN UNION:

1. **RECALLS** the Communication from the Commission of 10 December 2008 on Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector[1];

2. **RECALLS** its Resolution of 2 December 2003 "Pharmaceuticals and Public Health Challenges - Focusing on the Patients"[2];

3. Further **RECALLS** its Conclusions of 22 September 2003 on Reinforcing The Competitiveness of the European-Based Pharmaceutical Industry[3] and **REAFFIRMS** the need for a balance between competitiveness and public health policies;

4. **RECALLS** its Recommendation of 8 June 2009 on an action in the Field of Rare Diseases [4];

COUNCIL CONCLUSIONS 6.12.2010 (NR.24)

Examine, based on the principles of solidarity, economically viable and efficient approaches to facilitate availability and access to valuable innovative medicinal products throughout the EU, while respecting the principle of subsidiarity and the competencies of Member States, e.g. on affordability and sustainability of health systems.

ACTIONS TAKEN ON THE EU LEVEL

1. Process on corporate responsibility in the field pf pharmaceuticals (esp mechanism of coordinated acces to orphan drugs, MOCA report april 2013)
   - Consensus on added value of cooperation between member states and stakeholders, supported by European Commission
   - Launching of a pilot to identify eligible drugs and initial common steps in assessment and appraisal.
   - Development of transparent value framework adding the societal value to the scientific evaluations.
   - Willingness to further discuss pricing and financial issues (e.g. differential pricing …)

ACTIONS TAKEN ON THE EU LEVEL

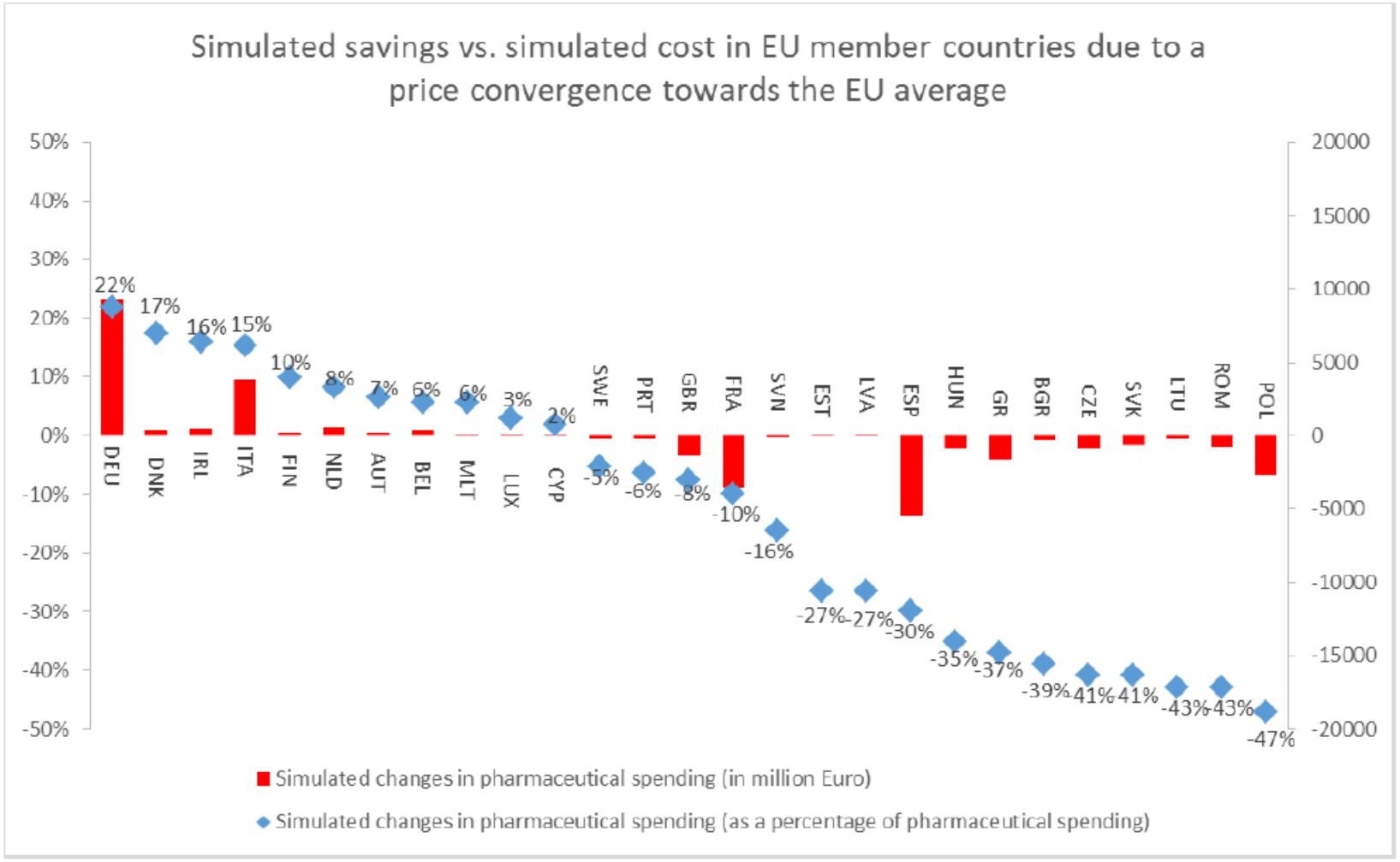
2. Reflection process “towards modern, responsive and sustainable health systems” (esp subgroep3 on costeffective use of medecines, october 2013)
   - Preparing reports on external reference pricing and policy mix for reimbursing medicinal products for I/2014. “This subjects will require further consideration not only on a technical level, but also in a more broad perspective as further debate is needed on accessibility and equity issues and related proposal on e,g, differential pricing.”
   - Propose to continue reflection of Member States and European Commission also other aspects, as availibilty, costs and safety and innovation

SOME ACTUAL FINDINGS

- Persistent differences in the uptake and diffusion of innovative medicines in Europe (IMS, October 2013)
- Higher income countries likely to obtain lower prices compared with GDP/capita (Rovira, J, May 2013)
- Delays in launching in lower income countries (Rovira, J, May 2013)
- The variation in the role of external reference pricing as one of many pricing mechanisms makes the assessment of the potential impact of a price change in one country on the price in another country difficult

  Ruggeri, K, Nolte, E, 2013)

IMPACT OF PRICE CONVERGENCE



CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

1. What is differential pricing ?

- Differential pricing implies that the manufacturer establishes different prices for pharmaceuticals, for reasons not related to costs, according to the demand elasticity: more price-sensitive countries are charged a lower price than countries that are “less” sensitive.
- The basic objective of price differentiation is to improve equality of access to innovative pharmaceuticals for unmet medical needs across Europe.

CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

farmeconomia
Health economics and therapeutic pathways
SEEd

Farmeconomia. Health economics and therapeutic pathways 2013; 14(3): 107-109

EDITORIAL

International differential pricing: easy in theory but hard in practice

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Disclosure
The authors have no conflict of interest to report

How countries pay for patented pharmaceuticals varies widely in terms of complexity of rules and processes. A pharmaceutical pricing scheme should ideally provide affordable drug access to those in need while allowing the manufacturers to receive enough profits to sustain continued technological innovation. Profit-seeking pharmaceutical companies are incentivized to set prices in a way that would maximize their revenues and sustain long term dominance of specific market segments and they understandably attempt to justify these practices as a necessity to cover their R&D investments. Health authorities, on the other hand, typically have a current budget constraint under which they have to work and have some incentive to discount the value of future innovation. While some countries have allowed "free pricing", others have introduced concepts such as "value-based pricing" or enforced rigid price controls. As one looks across various country markets, there is a range of practices that fall somewhere along this continuum.

For the current discussion, our focus is on the practice of value-based pricing – focusing on the diversity between evidence-based pricing and reference pricing approaches. We are, in particular, seeing emerging new pressures that are beginning to have an impact on some of these long-standing practices. For all practical purposes, we might remove the so-called "free pricing" countries from this thought exercise as this as a concept is a dying breed outside of the US. Similarly, we have not attempted to consider countries that

CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

2. How ? Basic assumptions
   - Fair and transparent pricing
   - Win-win situation
   - No new regulations, but soft law approach
   - No change of the legal competences of Member States on pricing and reimbursement
   - Legally “euro proof”

CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

2. How ? Elaborating a code of conduct

CODE OF CONDUCT – SOFT LAW APPROACH FOR ACCESS TO INNOVATIVE DRUGS

- VOLUNTARY BASIS, protocol agreement between INDUSTRY and MEMBER STATES

CODE OF CONDUCT – SOFT LAW APPROACH FOR ACCESS TO INNOVATIVE DRUGS

- SCOPE for the application of the principle : "VALUABLE MEDICINES"
  - High added value
  - Unmet medical need
  - Market Authorization granted

CODE OF CONDUCT – SOFT LAW APPROACH FOR ACCESS TO INNOVATIVE DRUGS

- "LIKE FOR LIKE" Principle
  - PRICING
    - Transparent Ex factory price
    - Acceptable Return On Investment
    - Confidentiality of net prices
    - Price differentiation (no IRP nor ERP)

CODE OF CONDUCT – SOFT LAW APPROACH FOR ACCESS TO INNOVATIVE DRUGS

- WEIGHING
  - Clustering of countries with similar GDP, average income per capita
  - No linking to % spent on healthcare
  - Prevalence
  - Elasticity of the demand
  - Willingness to pay (incremental and marginal value)

CODE OF CONDUCT – SOFT LAW APPROACH FOR ACCESS TO INNOVATIVE DRUGS

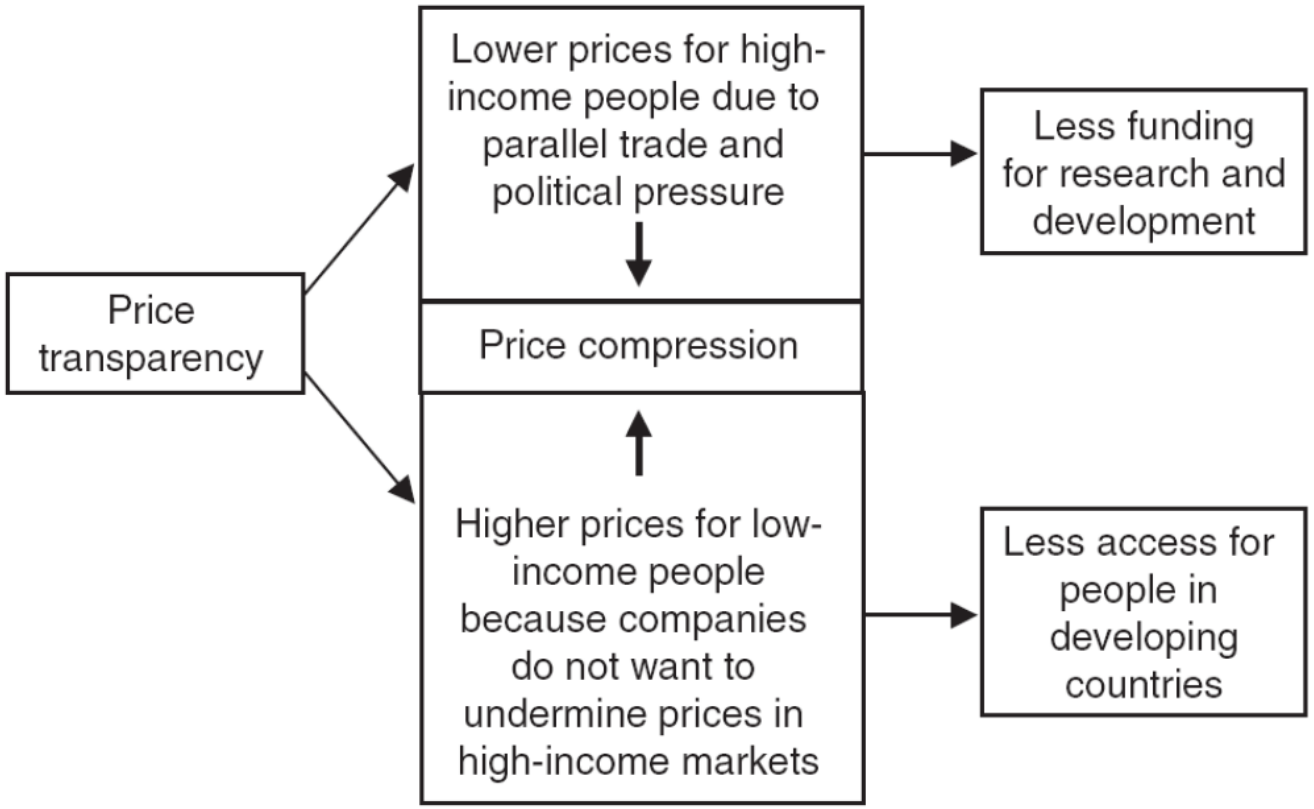
- EUROPEAN MARKET ENTRY PLAN:
  - Commitment of participating countries to apply differential pricing principles
  - Commitment of companies to launch medicines within 2 years of market access approval
- CURRENCY STABILITY : prices in EURO - 24 months fixed exchange rates
- EXTERNAL VERIFICATION BODY : independent Third Party

CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

3. Two critical succesfactors:

   - Restriction of external reference pricing
   - Limitation of parallel trade

EXTERNAL REFERENCE PRICING



Ridley DB: Pharmacoeconomics 2005; 23 (7): 651-658

EXTERNAL REFERENCE PRICING

Participating countries need to agree not to implement ERP as a method of setting prices or to limit ERP to other member states of cluster

PARALLEL TRADE

- Would lead to unwillingness of companies to step into the process, as ROI seriously reduced by parallel trade
- Introduction of possibility for public health exceptions for parallel trade

CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

Review

EXPERT REVIEWS

Differential pricing of new pharmaceuticals in lower income European countries

Expert Rev. Pharmacoecon. Outcomes Res. 13(6), 735–741 (2013)

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Pharmaceutical companies adjust the pricing strategy of innovative medicines to the imperatives of their major markets. The ability of payers to influence the ex-factory price of new drugs depends on country population size and income per capita, among other factors. Differential pricing based on Ramsey principles is a 'second-best' solution to correct the imperfections of the global market for innovative pharmaceuticals, and it is also consistent with standard norms of equity. This analysis summarizes the boundaries of differential pharmaceutical pricing for policymakers, payers and other stakeholders in lower-income countries, with special focus on Central-Eastern Europe, and describes the feasibility and implications of potential solutions to ensure lower pharmaceutical prices as compared to higher-income countries. European stakeholders, especially in Central-Eastern Europe and at the EU level, should understand the implications of increased transparency of pricing and should develop solutions to prevent the limited accessibility of new medicines in lower-income countries.

Keywords: Central-Eastern Europe • confidential pricing agreements • international price referencing • patient access • pharmaceutical pricing policy • Ramsey optimal pricing • risk-sharing

Pharmaceutical companies adjust the pricing strategy of innovative medicines to the imperatives of their major markets. The ability of payers and policymakers in a given country to influence the ex-factory price, reimbursement level and modalities of use of new prescription drugs depends on the size of the country's or region's population, the availability of established health technology assessment (HTA) capacity [1], the average income per capita and other factors [2]. Despite attempts to increase the convergence of health care systems in the EU, European countries can still develop and operate different regulation mechanisms for pharmaceutical pricing and reimbursement [3]. Diversity of pharmaceutical pricing policies is especially true for large and high-income countries, like the UK, France or Germany. To establish the price of innovative medicines in these countries, added therapeutic value, degree of innovation, profitability of manufacturers and therapeutic reference pricing play different roles.

Truly, the European pricing strategy for new pharmaceuticals is based on what is the justifiable price in top European markets [4]. This means that the ex-factory price of reimbursed innovative prescription drugs is usually 'value-based' in the most influential countries because it reflects what the countries are willing to pay. Small and lower income countries have a smaller degree of negotiating or market power to alter the pricing policy of multinational companies, although their understandable and fair intention is to buy pharmaceuticals at a lower price given their limited public and private resources as compared to higher income countries. Consequently, access to certain categories of on-patent pharmaceuticals tends to be negatively correlated with market size and per capita GDP [5].

This analysis summarizes the boundaries of differential pharmaceutical pricing for policymakers, payers and other stakeholders in lower income countries, with special focus on Central-Eastern Europe (CEE), and describes the feasibility and implications of potential solutions to ensure lower pharmaceutical prices as compared to higher income countries.

Economic principles of pharmaceutical pricing

Special features of the market for innovative pharmaceuticals have led to policy interventions,


Priority Medicines
for Europe and the World
2013 Update
World Health
Organization

CAN DIFFERENTIAL PRICING BE PART OF A SOLUTION ?

- A system of differential pricing (“equity pricing”) would be an “equitable system for true innovation while ensuring access by those who need them
- Research priorities:
  - Study mechanisms through which differential pricing could be applied to the European market;
  - Explore the prerequisites that are needed to support differential pricing
  - Evaluate the impact of external price referencing and parallel trade, in terms of availability of medicines and the affordability of medicines in European countries

Source: priority medicines report 2013

TO CONCLUDE

Access to medicines issues are complex and multifaceted. To address these issues effectively close collaboration between all relevant stakeholders is needed. While pricing and reimbursement instruments are primarily the responsibility of Member States, they are also closed linked to the realization of European policy objectives such as internal market, competiveness, research and innovation and public health.

In our opinion this means that the European Union needs to make sure that those policies are streamlined in a transparent fashion. Therefore a political debate is urgently needed, Elements as differential pricing should be part of such a debate.

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THANK YOU!