

# **GLOBAL TRENDS IN INTERNATIONAL TRADE AND INTERNATIONAL RELATIONS**

**New trends in the trade of  
pharmaceuticals : the impact  
on the health sector**

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Bangkok 28-29 November  
2017**



# A2M today...



**2015-2017: RADICAL CHANGE OF THE BUSINESS MODEL OF THE PHARMACEUTICAL INDUSTRY**

**For the first time ever, a drug that cures and industrialized countries can NOT pay: the Sofosbuvir («Sovaldi from the US company: Gilead»). Price of 12 weeks treatment: 84.000 u.s. dollars**

## A2M: threats increase...



- **Pharma business model is changing: from health to financial industry**
- **1996: ARV's treat. price 100 times more than the cost**
- **2017: HCV price 1400 times more than the cost**
  
- **1996: WHO was an independant public agency**
- **2017: WHO in the hands of B&Gates and Big Pharma**
  
- **1996: generics of quemical products were accepted**
- **2017: bio-similar products are questioned...**

# Some indicators of the failure of the current R&D system/model



1. **Pharmaceutical innovation** has significantly **decreased** in recent years.
2. Lack of transparency on the real **cost of R&D**
3. **High drug prices** are blocking access

# 1. Pharmaceutical innovation has significantly decreased in recent years

Example of France.\* Important therapeutic progress 2006- 2016\*

- 2006: 22 products
- 2007: 15 products
- 2008: 10 products
- 2009: 7 products
- 2010: 4 products
- 2011: 1 product
- 2012: 0
- 2013: 0
- 2014: 5 products
- 2015: 3 products
- 2016: 1 product

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## 2. Lack of transparency on the real cost of R&D

### COST OF R&D

- IFPMA: 2.500 million US\$ (Nov. 2014...)
- LSE study (2011): 43.4 million US\$ (average)
- DNDi (Drugs for Neglected Diseases initiative):  
from **10 to 40** million Euros to improve a drug  
from **100 a 150** million Euros for a new chemical entity

# Access to medicines: Right or luxury ?

**Imperial Majesty Perfume...**



**Price: 140.000 Euros**

**Medicines...**



**at what price ???**

# At what price governments should buy the medicines they need ?



- Having determined which medicines are required, countries are faced with the challenge of determining what price they should pay.
- Governments tend to rely on one of three basic approaches: negotiation; regulation; and strategic procurement.



# *External reference pricing*



● Also known as international reference pricing, ERP is the simplest approach to price setting, using the price of a medicine in one or several countries to calculate a reference price. ERP is the most common pricing method used

- Leopold C, et al. Differences in external price referencing in Europe: a descriptive overview. *Health Policy*. 2012;104(1):50–60.
- Kanavos P, et al Differences in costs of and access to pharmaceutical products in the EU. Brussels: European Parliament; 2011



## *Cost-plus pricing*

- Cost-plus pricing: the production cost of a medicine, an agreed part of the cost of promotional expenses, and the manufacturer's profit margins (the plus).
- **Disadvantages:** lack of reliable information about the costs of R&D and margins of companies.

## *Value-based pricing:* (New trend...)



- Value-based: link the price of a pharmaceutical to the value of the product. Prices should reflect the value to the buyer rather than the actual costs of production. The question, is how to define and measure “the value” of a treatment.

## **A paradigm shift in the debate on access to medicines: 2015-2017.**



**Pharmaceutical industries wants to dissociate cost and price** arguing that the price should be related to the paying capabilities of the country or to the “value” of the medicine as compared to the potential cost of treating such as a liver transplant in the case of HCV

# A2M: 20 years of «R» evolution...

1996

1. 27.000 patients on ARVs
2. Price: of treat. 12.000 US/ year
3. WHO, MOH and few NGO's
4. NDP: a Health issue
5. A2M=Gov.will, Charity or 'luck'
6. CL for medicines = 0
7. R&D IP model: ACCEPTED
8. Pharma industry: impunity
9. Prices based in cost
10. ARV price 100 times more than the cost

2017

1. 18.000.000 M. today
2. Price: less than 100 US
3. **All** UN, Ministries, NGO's
4. NDP: health,trade,H.rigth, IP
5. A2M = RIGTH
6. More than 30 CL in 11 countr.
7. R&D model: QUESTIONED
8. Pharm:BEFORE TRIBUNALS
9. Prices based in « value »
10. Hepatites C price 1400 times more than the cost