



EU Trade Policy & Access to Medicines

PCD workshop

Ministry of Foreign Affairs of the Netherlands, The Hague

9 June 2016

Tessel Mellema
Health Action International



Health Action International (HAI)

- Established in 1981
- Goal: improve access to affordable and quality-assured medicines and promote rational use
- Network of health care professionals, academics, public health NGOs and individuals
- European projects: monitor and research impact EU trade, intellectual property, R&D and medicines' policies

Background

- 1/3 population lacks access to essential medicines
- Price major barrier for access in LMICs
- New patented medicines priced out of reach even for high-income countries





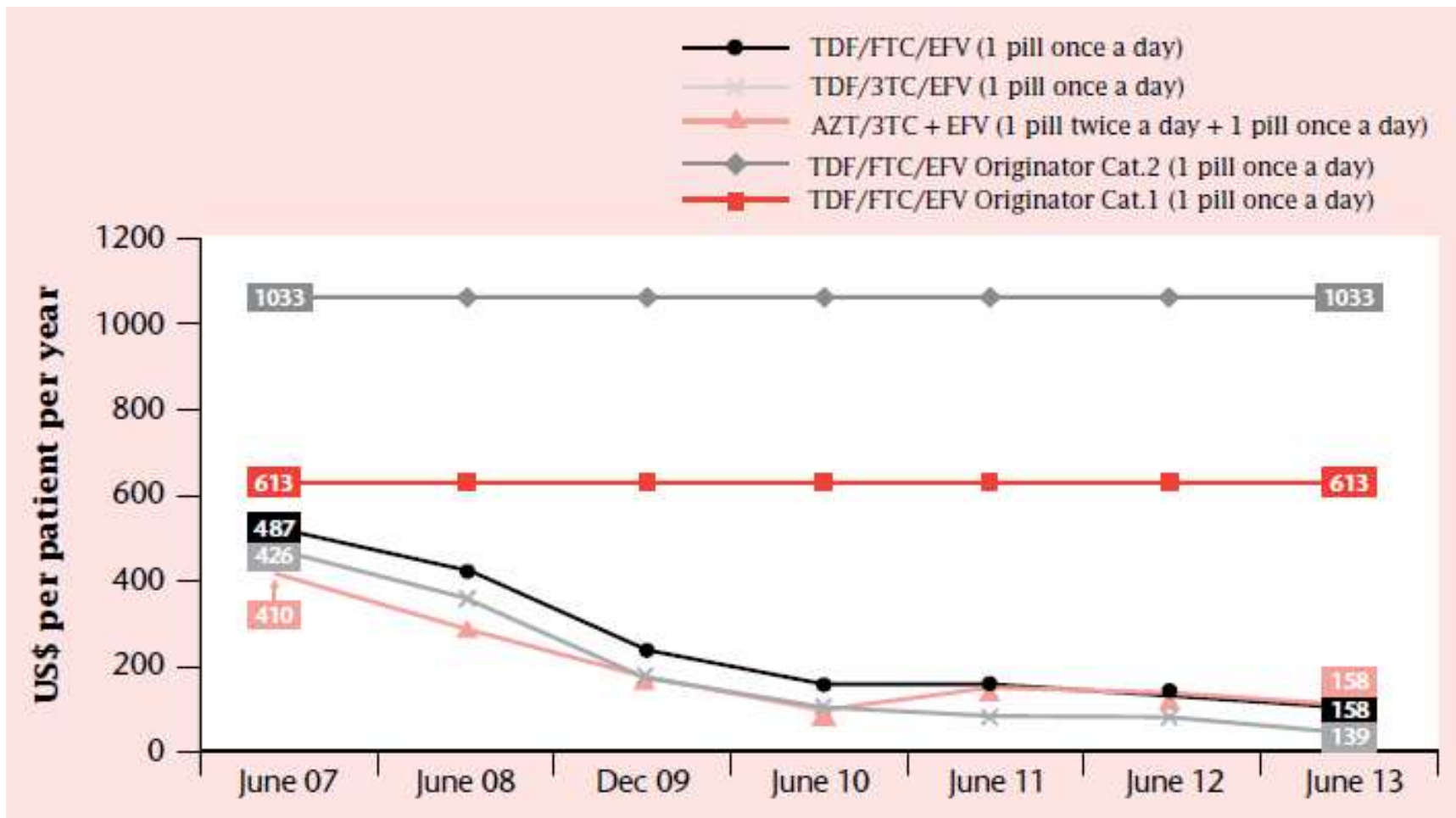
Monopoly prices patented medicines: key barrier access

Box 1 – Selected new medicines on the EML

Medicine	Disease	Disease burden	US Retail Price/Course of treatment
<u>bedaquiline</u>	tuberculosis	9 million cases in 2013	\$30,000 for 6 months
<u>sofosbuvir</u>	hepatitis C	130-150 million people have chronic HCV infection	\$84,000 for a 12 week course of treatment
<u>simeprevir</u>	hepatitis C		\$66,360 for 12 weeks
<u>imatinib</u> *	chronic myeloid leukemia	Breast Cancer: 17.6 million	\$92,000/year
<u>trastuzumab</u> *	gastrointestinal stromal early stage HER2 positive breast cancer metastatic HER2 positive breast cancer		



Generic competition brings down prices

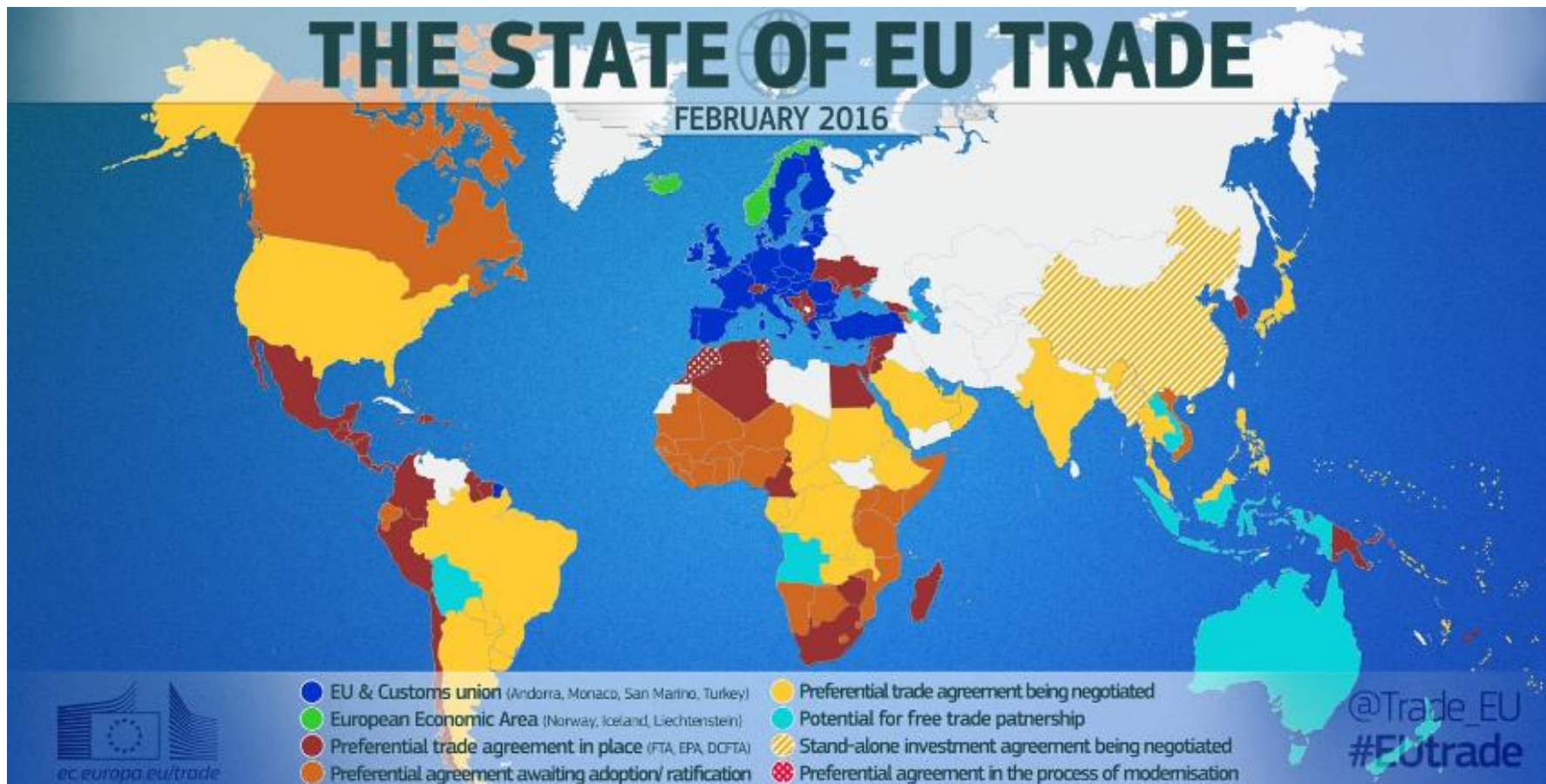


EU trade agenda since TRIPS & DOHA



THE STATE OF EU TRADE

FEBRUARY 2016



@Trade_EU
#EUtrade

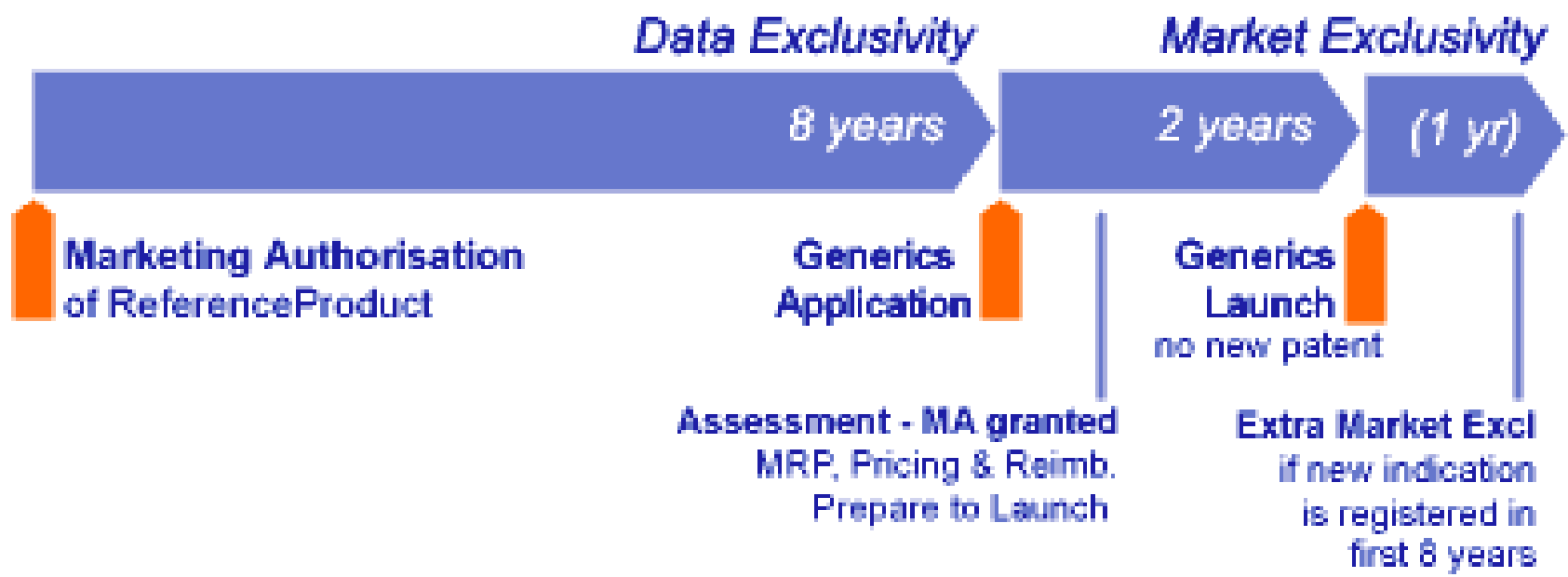


Example TRIPS-plus (I)

How the new

Data Exclusivity

affects the application of a Generic Medicine



Generic Available to Patients

8 + 2 (+1) Data Exclusivity Formula
for all Marketing Authorisation Procedures



Example TRIPS-plus (II)

Patent term extensions

- Additional protection periods to compensate for 'delays' in marketing authorisation
- Delay generic competition

Impact TRIPS plus



Table 1. Public health impacts of FTAs		
FTA	Source	Public health impact
<i>EU–Colombia FTA</i>	IFARMA prospective study commissioned by Health Action International (HAI) Europe ⁸⁸	By 2030, patent-term extensions could increase expenditure on medicines in Colombia by nearly \$280m; data-exclusivity rules could result in an increase of more than \$340m. ⁸⁹
<i>US–Jordan FTA</i>	Oxfam International ⁹⁰	Data exclusivity resulted in significant delays to the introduction of generic competition for 79 percent of medicines examined in the study. This led to price increases of between two- and ten-fold for key medicines to treat cardiovascular disease and cancer. The study estimates that the availability of generic equivalents would have reduced Jordan expenditures on medicines by between \$6.3m and \$22m between mid-2002 and 2006.
<i>US–Thailand FTA</i>	University of Bangkok prospective impact study ⁹¹	A macro-economic model measuring the impact of data exclusivity and patent extension proposals forecasted that all scenarios demonstrated a negative impact on the pharmaceutical market and access to medicines. Medicines' prices would increase by 32 percent and the domestic pharmaceutical market would contract of \$3.3m by 2027.

Bilateral pressure (I)

European Commission pressure on South Africa



Bilateral pressure (II): Colombia



- Imatinib (Glivec) effective leukemia drug (WHO EML)
- Marketed at USD16,000 p/y
GNI per capita USD 8,000
- Estimated price reduction
generics about 68-77%



CH-3903 Bern, BWM / SECO/aa

Dr
Carolina Gómez
Asesora del Despacho del Ministro
Ministerio de la Salud y Protección Social
Bogotá
Colombia

Bern, 20 May 2015

Patent of Imatinib / Glivec: Closing arguments

Dear Mrs Gómez

On behalf of the State Secretariat for Economic Affairs of Switzerland, I would like to seize the opportunity to present our views referring to an official request to declare of public interest the patent of Imatinib / Glivec. On May 18th, State Secretary and Director of the Federal Office of Public Health Pascal Strupler presented our concern to the Minister of Health and Social Protection, Alejandro Gaviria.

First, let me highlight our excellent bilateral economic relations with in particular agreements on free trade, investment protection and double taxation. Colombia is an important destination for Swiss investors with more than 16'000 jobs created locally and one out of two partners in Latin America benefiting from the Swiss Economic Development Cooperation (SECO). Switzerland and Colombia further cooperate in the fields of humanitarian aid, peace promotion and human rights.

Within the procedure of "closing arguments", I would like to present the concern of the State Secretariat for Economic Affairs of Switzerland regarding the request to the Ministry of Health and Social Protection of two Colombian NGOs and the Center for the study of Medicines of Universidad Nacional to declare of public interest the patent of Imatinib. This would be a first step to the issuance of a compulsory license by the Colombian Patent Office.

The Swiss firm Novartis has developed the beta crystal form of imatinib Mesylate creating a breakthrough, life-saving cancer medicine. No other drug comprising Imatinib was available anywhere in the world before Glivec was launched. Scientists at Novartis developed the Me-

Colombia Fears U.S. May Reject Peace Plan To Protect Pharma Profits

A leaked Colombian Embassy memo suggests the U.S. wants to preserve the high price of cancer drug Gleevec.

05/11/2016 10:47 pm ET



EU trade policy harms access to medicines



- Direct impact on access to affordable medicines by imposing TRIPS plus and bilateral pressure on countries using TRIPS flexibilities
- Growing criticism EU level of TRIPS plus protection for pharmaceuticals

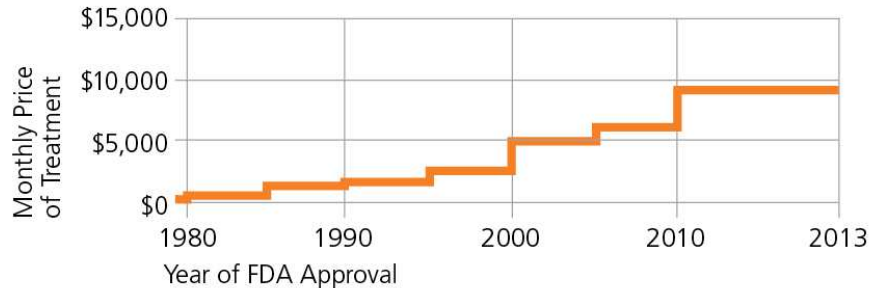


...price new medicines has exploded

- Influential oncologists: prices new patented cancer medicines '*astronomical, unsustainable and even immoral*'

Rapid Rise

Median Monthly Price between 1985-2010: **+1330%**



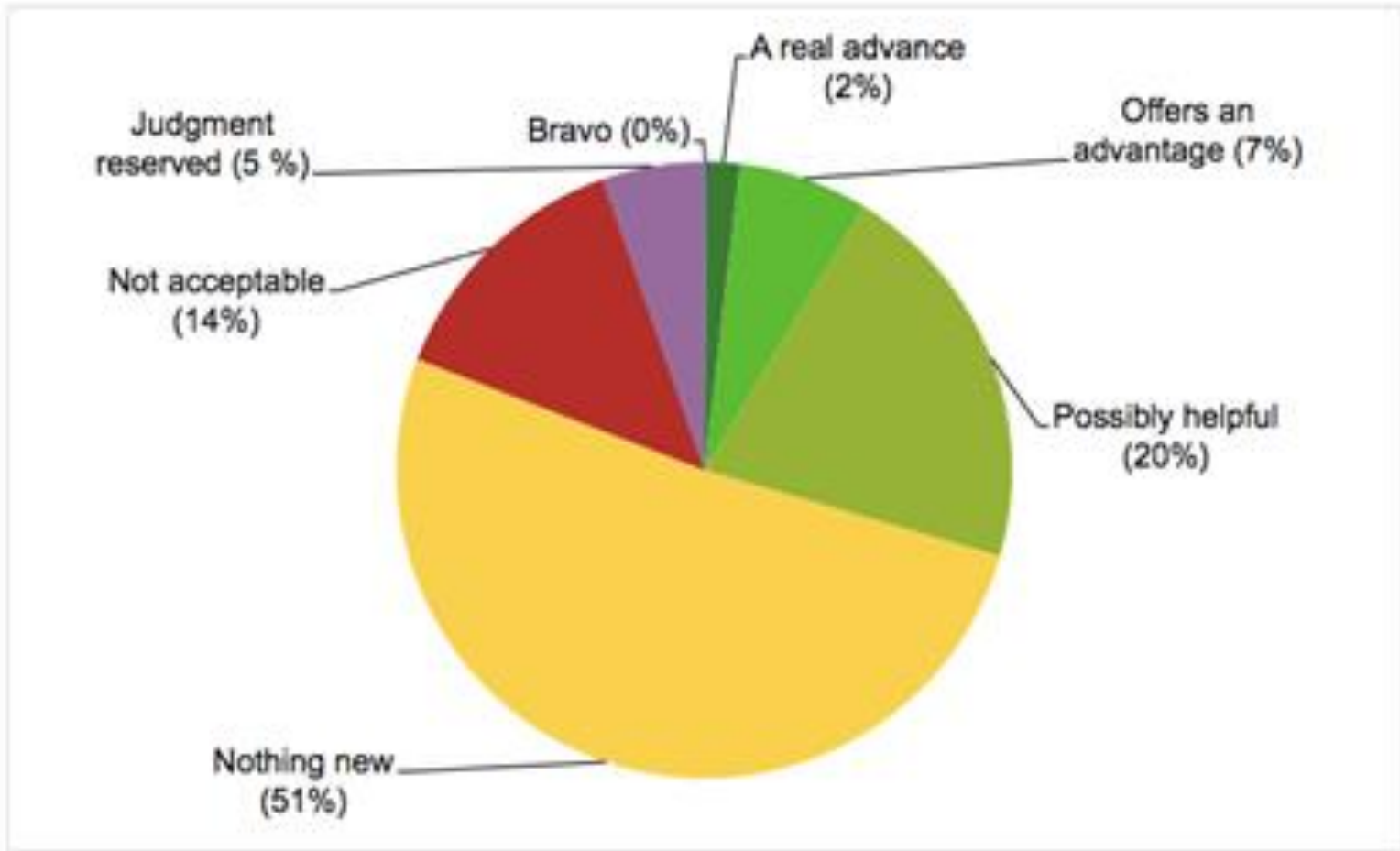
Source: Memorial Sloan-Kettering Cancer Center; 2013.

- Prices set according to the maximum of what the market is ready to pay, while the real costs of R&D remain unknown
- Companies spend more on marketing than on R&D

Prescrire's ratings 2000 to 2013

Percentages per category

N=1345



Impact current patent-driven model & need for alternatives high on political agenda



- **EU Council Conclusions pharmaceuticals**, June 2016: *Need to critically examine the impact of the current over-protection and misuse of IP and related rights for pharmaceuticals, to assure availability and affordability of medicines*
- **EP: INI report on Access to Medicines** (Oct 2016)
- **Council of Europe resolution 2015**: *to ensure accessibility of affordable and innovative medicines in the long term, the Assembly calls on the WHO to put forward alternatives to the current patent-based pharmaceutical innovation model*
- **UN High Level Panel on Access to Medicines** (report July 2016)
- **WHO**: *process to improve financing and coordinating and explore new incentives for R&D to meet global health needs*



What is needed:

Policy Coherence between EU trade, R&D and development policies

- EU trade policies need to be coherent with development goals on access to medicines
- EU trade policies need to reflect growing consensus on negative impact ever increasing levels of monopoly protection for pharmaceuticals on development of affordable and needed medicines
- Risk exporting a 'broken' IP system

EU FTA (India, MERCOSUR, Thailand)

- Develop a coherent access to medicines policy that ensures that its trade policy is consistent with its development, research and global health goals
- Not use FTAs with LMICs to introduce TRIPS-plus IP rules
- Actively support governments that use TRIPS flexibilities to protect public health
- Immediately stop targeting countries that have implemented progressive TRIPS-compliant IP policies that promote access to medicines



Thank you

tessel@haiweb.org

www.haiweb.org



EU IP and R&D policies

- Need to critically examine the impact of the current over-protection and misuse of IP and related rights for pharmaceuticals, to assure availability and affordability of medicines
 - Support EU Council Conclusions (17 June)
- Explore alternative innovation models that delink the cost of R&D from the price of the medicine to steer R&D towards priority health needs
 - Use Horizon 2020 and Member State biomedical R&D funding to explore alternative innovation models
 - Ensure that the EU takes an ambitious and progressive position in the WHO process to explore alternative incentives