

implementing delinkage

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How do we pay for R&D?

Three largest sources of funding for biomedical R&D

- Grants from governments or charities
- Profits from selling products protected by legal monopolies (patents, test data exclusivity, orphan drug exclusivity, etc)
- Orphan Drug Tax Credit (50 percent of qualifying clinical trials)

From 2004 to 2010

**private sector R&D was equal to 8.2
percent of global sales**

Year	Private sector R&D (billions of USD)	Global sales (billions of USD)	Private sector R&D as percent of global sales
2004	\$47.6	\$564.5	8.4%
2005	\$51.8	\$611.0	8.5%
2006	\$56.1	\$657.8	8.5%
2007	\$63.2	\$729.3	8.7%
2008	\$63.7	\$801.4	8.0%
2009	\$65.9	\$834.4	7.9%
2010	\$67.4	\$891.3	7.6%

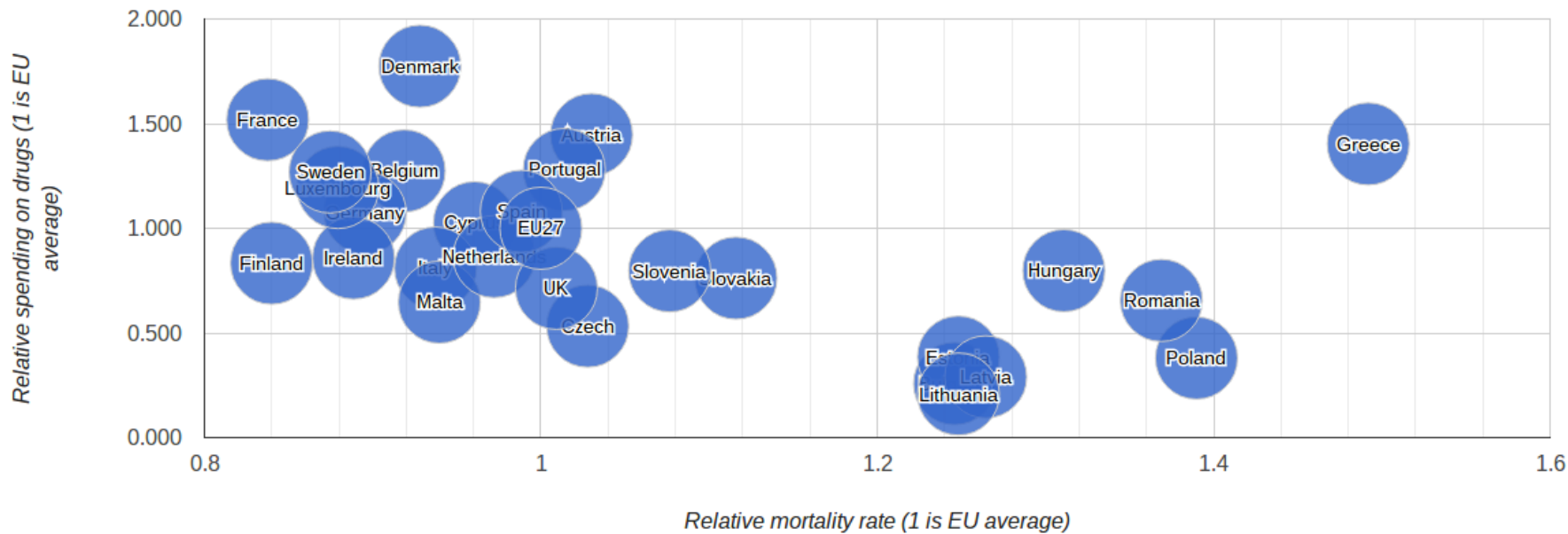
Source for R&D spending, PhRMA's 2011 Annual Industry Survey, including Figure 3, and 2013 survey, for 2005-2012 PhRMA spending. Source for sales, MS Market Prognosis, 2013

Example of cancer innovation fund

Europe, 2009

- In 2009, 1.09 percent of GDP spent on cancer treatment
- On average, 27 percent of outlays on treatment spent on drugs.
- Drug companies invest somewhere between 8 to 18 percent of cancer drug sales on R&D
- At 18 percent of drug sales, amount reinvested in R&D is less than 5 percent of cancer treatment budget.

All cancers: relative spending on drugs (per incidence), relative mortality rates



Basic idea

Eliminate monopolies on cancer drugs

Fund R&D with combination of grants, and three types of innovation prizes

- End product prizes

- Open source dividend

- Milestone prizes

Stylized example of EU market

GDP	14,303	billion Euros
Cancer treatment @ 1.1%	157.3	
Drug component @ 30 %	47.2	
R&D @ 18%	8.5	
R&D @ 8%	3.8	

EU wide Cancer innovation fund (delinkage)

- De-monopolize cancer drugs
- Put 10 percent of treatment budget (15.7 billion) into an innovation fund
- 7 billion into grants (push funding)
- 6 billion, end product prizes
- 1 billion open source dividend
- 1.7 billion, milestone prizes

Plurilateral Cancer innovation fund

One or more countries with a large enough market to induce entry by generic manufacturers create a plurilateral cancer innovation fund

Dedicate from 5 to 10 percent of treatment budget to fund innovation, through mix of push and pull funding mechanisms

Eliminate drug monopolies

Role of Europe as supplier of innovation, under delinkage model

- Greater reliance upon grants enhances role of universities and SMEs in supplying innovation
- De-Emphasis of marketing monopoly, creates more competitive opportunities for SMEs in manufacturing and distributing
- New inventions can be patented, and patents can be fully exploited in foreign countries