Pharmaceutical Sector Regulation in OECD Countries

Rapid growth in healthcare expenditure is a universal issue in industrialized countries. Pharmaceutical products have been an important driver of this phenomenon: between 1998 and 2003, OECD members have seen an average real increase of 32 percent in pharmaceutical products. Cost-containment policies have thus taken a prominent position on many countries' reform agendas. They aim to tackle the inefficiencies that are commonplace in a market for pharmaceuticals that is prone to problems of moral hazard, informational asymmetries and a lack of competition at various stages.

Policymakers have a host of regulatory instruments at their disposal:

- Global budgets impose spending limits on a nationwide or regional scale. The ceiling on expenditures can either apply to certain products or groups of products or the healthcare system in its entirety.
- Prescribing budgets put a ceiling on the value of medication a physician can prescribe during a period. To enhance enforcement, overrun is financially sanctioned.
- Profit controls for pharmaceutical companies either apply to the absolute level of annual profits or their growth rate.
- External reference pricing (ERP) determines a maximum reimbursement level or market price for patented drugs. This price is based on the price of similar medication in other countries.
- Other direct price controls without explicit referencing to international prices include price negotiations, maximum prices, price freezes and the like.
- Economic evaluations require or encourage the assessment of cost and benefit to determine whether or not to include a new drug in the benefit package of national health systems or a private insurance.
- Generic reference pricing (GRP) implies that the scope to which patients are reimbursed for drug purchases depends on the price of generic drugs, i.e., drugs containing the same active substances.

Table 1

Pharmaceutical sector regulation policies in 19 OECD countries (2004)

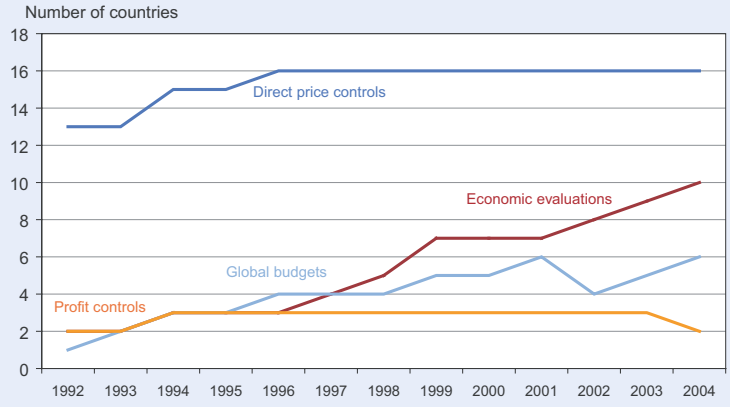
	Global budgets	Prescribing budgets	Profit controls	External reference pricing (ERP)	Price negotiations and others	Economic evaluations	Generic reference pricing (GRP)	Therapeutic reference pricing (TRP)	Generic substitution policies	Generic prescribing	Degressive pharmacy fee structures	Pharmacy chains
Australia					●	●		●	●			●
Canada					●	●	●		●			N/A
Denmark				●			●		●		●	
Finland					●	●			●		●	●
France	●				●		●		●		●	
Germany		●						●	●			●
Greece					●							
Hungary	●				●	●		●	●		●	
Italy	●				●	●		●	●	N/A	●	N/A
Japan					●					●		●
Netherlands				●				●	●			●
New Zealand	●				●	●		●	N/A	N/A		N/A
Norway				●		●	●		●	●	●	●
Portugal					●	●	●		●	●		
Spain	●		●		●		●		●	●	●	
Sweden					●	●			●		●	
Turkey				●			●		●		●	
UK	●		●			●				●	●	●
US											N/A	●
TOTAL	6	1	2	4	12	10	7	6	14	5	10	8

N/A: = not applicable or not available.

Source: Sood et al. (2009).

Figure 1

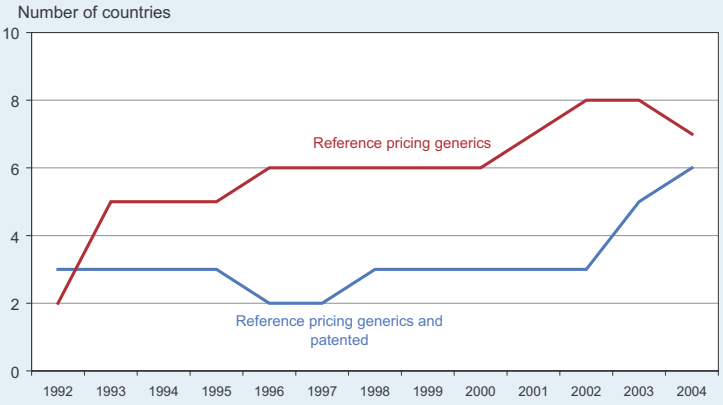
TRENDS IN VARIOUS REGULATORY MECHANISMS IN 19 OECD COUNTRIES
1992–2004



Source: Sood et al. (2009).

Figure 2

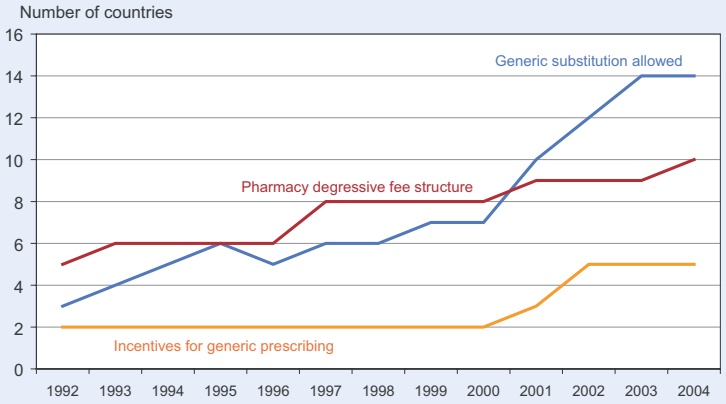
TRENDS IN REFERENCE PRICING POLICIES FOR 19 OECD COUNTRIES
1992–2004



Source: Sood et al. (2009).

Figure 3

TRENDS IN POLICIES AIMED AT INCREASING USE OF GENERIC DRUGS IN 19 OECD COUNTRIES
1992–2004



Source: Sood et al. (2009).

- Therapeutic reference pricing (TRP) imposes a reference price for both generic and patented drugs. This means that one reference price is set for products with chemically related (but not identical) active ingredients that are pharmacologically equivalent and also for products that may be neither chemically identical nor pharmacologically equivalent but have comparable therapeutic effects ("jumbo groups").
- Generic substitution policies allow pharmacists to substitute patented drugs with generics if no explicit exclusion is made on the doctor's prescription.
- Incentives for generic prescribing assign financial or non-financial benefits to doctors for substituting patented medication with generics.
- Degressive pharmacy fee structures encourage substitution with generics. The pharmacist's margin shrinks as the cost of the drug sold increases.
- Pharmacy chains' allowance is expected to lead to size-related efficiency gains and improved bargaining power towards the pharmaceutical industry.

Table 1 documents the pharmaceutical sector regulation in 19 OECD countries for 2004.

Figures 1–3 show the increasing international popularity of pharmaceutical sector regulations.

Drug price controls were the most common policy measure among OECD countries during 1992–2004. In this period, 11 additional countries adopted generic substitution policies, but the fastest growing instrument

Table 2

Percentage change in revenues following introduction of pharmaceutical regulations in 19 OECD countries, 1992–2004

	Percentage change in revenues	
	Model 1	Model 2
Profit controls	–6.3	–4.3
Budgets	–5.9**	
Global budget		–4.4*
Physician budget		–16.5***
Direct price controls	–16,8**	
Only international comparisons		–12.7***
Price negotiations and others		–17.1***
Reference pricing	1.6	
for generics		3.4
for generics and on-patent drugs		9.7**
Economic evaluation	–5.9**	–4.3
Incentives for generic use		
1 out of 3 policies for prescribing/dispensing generics	–2.8	–0.8
2 or more out of 3 policies for prescribing/dispensing generics	–4.0	–3.0

Note: For the regressions, the dependant variable was log(Revenue). The key independent variables were dummy variables for each of the regulations outlined in model 1 and model 2. Other covariates included year fixed effects, country fixed effects, exchange rates and indicator variables for whether pharmacy chains are allowed. * p<0.10 – ** p<0.5 – ***p<0.01.

Source: Sood et al. (2009).

was economic evaluation, which is now carried out in ten OECD member-states. Global budgets were imposed in another five countries, while the use of GRP and TRP, degressive pharmacy fee structures and incentives for generic prescribing also increased. The one exception to a general upward trend in regulation is direct profit control: in 2004, it was only implemented in the British and Spanish systems.

In a recent publication, Sood et al. (2009) investigate the effectiveness of these policies. As natural starting point, they test the link between regulatory regime and overall revenue generated in the pharmaceutical sector. Usage of a panel dataset of 19 OECD countries between 1992 and 2004 allows them to distinguish the revenue effects of regulation from underlying country differences and secular time trends in pharmaceutical revenue.

Table 2 presents estimation results for two model specifications. Model 1 uses broad categories of regulations, while model 2 breaks these categories down into more disaggregated classes. For model 1, significant effects on revenue are found for direct price controls, economic evaluations and budget regulation. Price controls here have the biggest impact by far, leading to an average of 16.8 percent reduction in revenues.

For model 2, the study has found that physician budgets have much more "bite" than global budgets. This appears logical, since under the former regime doctors are directly held accountable for overprescribing. Moreover, price negotiations and other forms of price controls prove more effective in reducing revenues than ERP alone.

One surprising result is the measurement of a positive association between GRP/TRP and pharmaceutical revenues. To further investigate this peculiarity, the authors have estimated a model allowing for an interaction of direct price controls and reference pricing effects. They have found that in the absence of price controls, reference pricing indeed leads to a reduction in revenue. If price controls are however already in place at the time reference pricing is implemented, its incremental effect on revenue is negligible. In fact, further analysis with fully interacted models shows that while all possible combinations of regulatory policies greatly reduce revenues, the reductive effect diminishes with each additional regulation. Introducing regulation in a mostly unregulated market like the US would therefore bring about the largest reductions.

While regulatory policies primarily target cost containment, their effects are likely to go beyond this. A number of negative dynamic impacts should be considered: lower revenues may reduce the incentive for pharmaceutical firms to invest in the development of new medication, which can delimit medical services for future generations of patients. Price controls can exacerbate market inefficiencies as they reduce competitive pressures for generic producers. The controls may also entice pharmaceutical firms to channel resources from development of new medicines into strategies to circumvent regulation.

Therefore, while pharmaceutical regulation has the potential to substantially reduce health-expendi-

tures, its net-welfare effect remains an issue of much contention.

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Reference

Sood, N. et al. (2009), "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries", *Health Affairs* 28(1), w125–37.