PhRMA PROJECT ON GOVERNMENT INTERVENTIONS IN PHARMACEUTICAL MARKETS IN OECD COUNTRIES

Overview of Government Interventions in OECD Countries

July 1, 2004

THE BOSTON CONSULTING GROUP

CONTEXT FOR THIS MATERIAL

These slides summarize selected findings of a Boston Consulting Group study commissioned by PhRMA and conducted between April and May 2004. The objective of the study was to evaluate the impact of pharmaceutical cost controls in non-U.S. OECD markets on the U.S. consumer and economy, and to inform the U.S. policy debate in the context of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003

Our study drew on four main strands of research:

- **A detailed review of the approaches taken by cross-cutting sample of OECD countries to controlling drug costs: Canada, France, Germany, Japan, Poland, Spain, the United Kingdom and the United States**
- **A survey of the extensive literature including academic studies and reports**
- **A detailed analysis of primary data from IMS for a set of drug classes (including anti-diabetics, anti-psychotics, statins, and select anti-cancer agents)**
- **Series of interviews with pharmaceutical executives**

(1) List of countries in sample: U.K, Germany, France, Spain, Poland, Canada, Japan, U.S.
Note: In this document, we use the term "OECD" to refer to OECD countries excluding the United States

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Introduction

Country profiles

- U.K.
- Germany
- France
- Spain
- Poland
- Japan
- Canada
- U.S.
- Overview of all other OECD countries

Definitions

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STUDY FOCUSED ON A SAMPLE OF COUNTRIES

Case study countries

- **United Kingdom**
- **Germany**
- **France**
- **Spain**
- **Poland**
- **Canada**
- **Japan**
- **United States**

<u>Including U.S.</u>, together represent

- **75% of OECD GDP**
- **80% of OECD health care spend**
- **65% of OECD population**

<u>Excluding U.S.</u> together represent

- **61% of non-U.S. GDP**
- **65% of non-U.S. OECD health care spend**
- **51% of non-U.S. OECD population**

Note: GDP is PPP adjusted. Population estimate is from 2002. GDP data is 2001. Health care spend is 1998 data
Source: OECD statistics

OECD GOVERNMENTS EMPLOY A RANGE OF INTERVENTIONS TO CONTROL DRUG COST

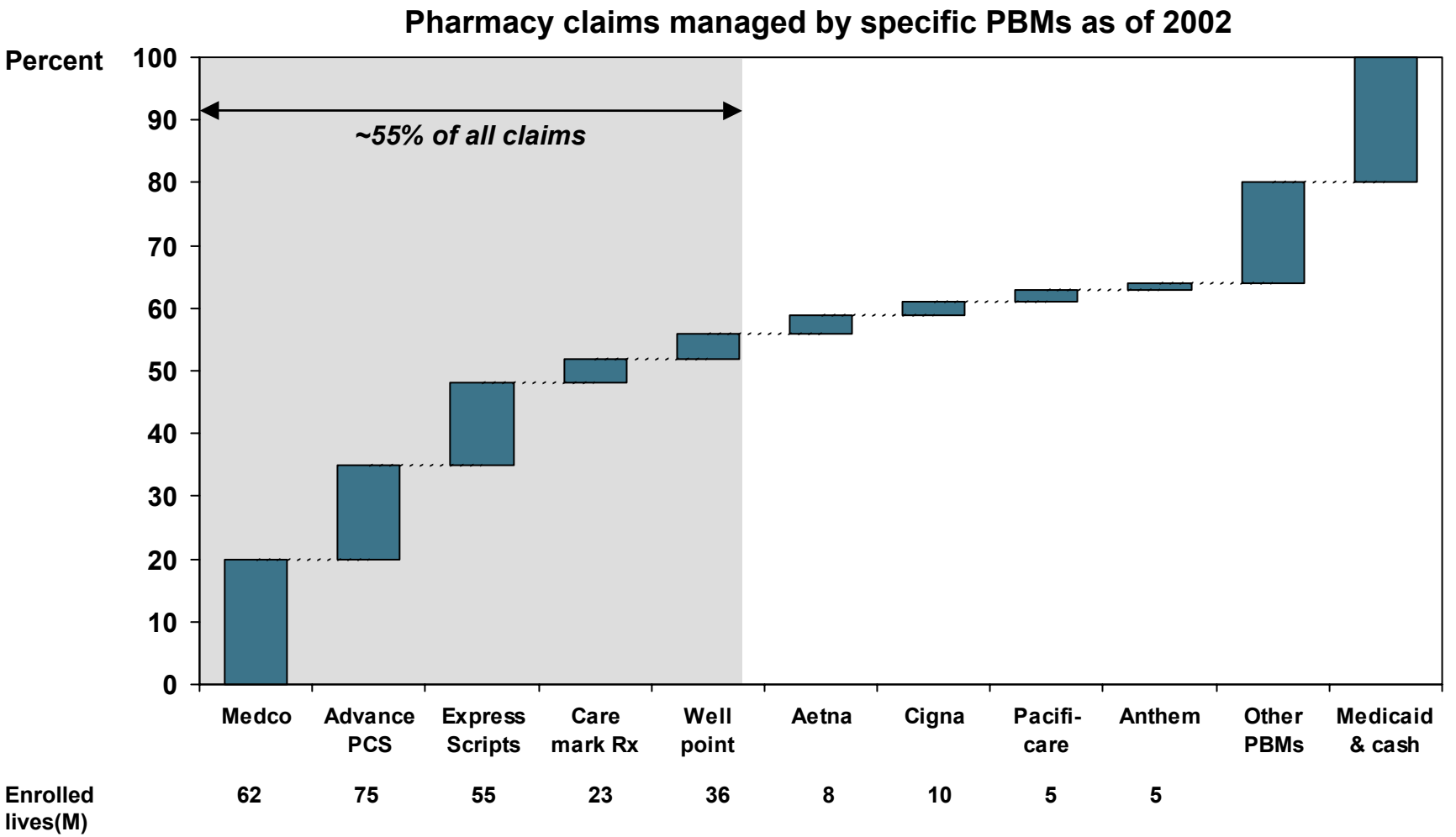
	Price controls	x	Volume controls	=	Spending controls
Supply	• Cost plus pricing • Pharmacoeconomic criteria • Molecule/class reference pricing • Cross-country reference pricing • Mandatory rebates • Price cuts/price freezes		• Marketing spend limits • Product volume caps		• Profit controls • Revenue controls
Demand	• Co-payments/co-insurance • Generic substitution incentives		• Prescribing guidelines • Positive/negative lists • Formularies • Parallel import dispensing targets/incentives		• Physician Rx budgets • Physician healthcare budgets

Note: Molecule/class reference pricing: pricing/reimbursement the same for drugs with same active ingredient or therapeutic benefit; Mandatory rebates: one-off discounts or 'voluntary' contributions to budget deficits; Positive lists similar to formularies; formularies can be used to steer prescribing among reimbursable drugs; All definitions in back-up

U.S. PRIVATE PAYERS USE BROAD ARRAYS OF TOOLS TO MANAGE DRUG COSTS

Target	Drug cost management levers	Description
Manu-facturers	• Concentration of buying power (e.g., PBMs)	• Pool drug purchasing volume to increase negotiating leverage
Physicians	• Formularies • Prior authorization • Physician incentives/capitation • Generic substitution • Counter-detailing • Disease management • Step therapy	• List of preferred drugs • Pre-approval for specific high cost branded drugs • Allowable monthly budget per patient • Physician notified of generic alternative • Plan-sponsored info on value/cost • Protocol and treatment guidelines • Initial therapy with least expensive option
Enrollee	• Co-insurance • Tiered co-pays • Mail-order substitution • Script limits • Covered lowest-cost drug	• Patient cost sharing • Co-pay increases with drug cost to payer • Encourage use of mail-order to lower cost • Monthly limit on total scripts per patient • Only lowest-cost drug covered; all other drugs available only at patient expense

PHARMACY BENEFIT MANAGERS HAVE SIGNIFICANT LEVERAGE IN U.S. MARKETPLACE



Note: Enrolled lives may be distorted due to double counting across company reporting
Source: Wachovia Securities; BCG analysis

GOVERNMENT INTERVENTIONS CONTINUE TO PROLIFERATE

Tools currently used by governments to manage drug costs in their state health insurance systems

			U.K.	Germany	France	Spain	Poland	Japan	Canada
SUPPLY	Price	• Cost plus pricing							
		• Pharmacoeconomic criteria							
		• Molecule/class reference pricing							
		• Cross-country reference pricing							
		• Mandatory rebates							
		• Price cuts/price freezes							
	Volume	• Marketing spend limits							
		• Product volume caps							
	Spending	• Profit controls							
		• Revenue controls							
DEMAND	Price	• Co-payments/co-insurance							
		• Generic substitution incentives							
	Volume	• Prescribing guidelines							
		• Positive/negative lists							
		• Formularies							
		• Parallel import dispensing targets/ incentives							
	Spending	• Physician Rx budgets							
		• Physician healthcare budgets							

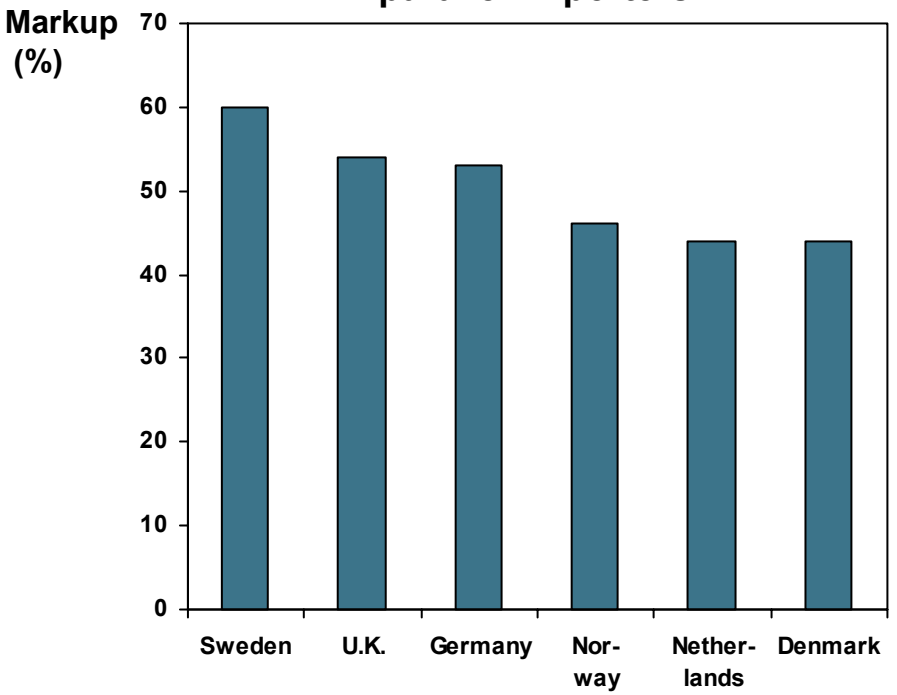
Date of initial implementation: 1970s-1980s | 1990s | 2000s

Note: Analysis is summary of individual country studies. Please see following slides for sources used in each country

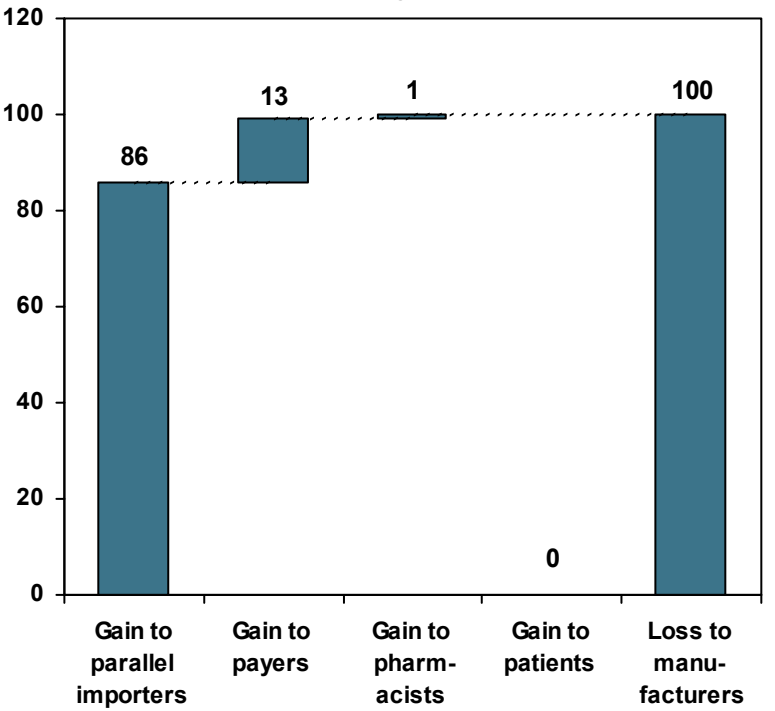
INTERVENTIONS LEAD TO UNINTENDED NEGATIVE CONSEQUENCES (I)

Example: Primary Benefit of Parallel Trade Is Value Shift to the Channel

Average mark-up of parallel importers



Distribution of parallel trade money flows

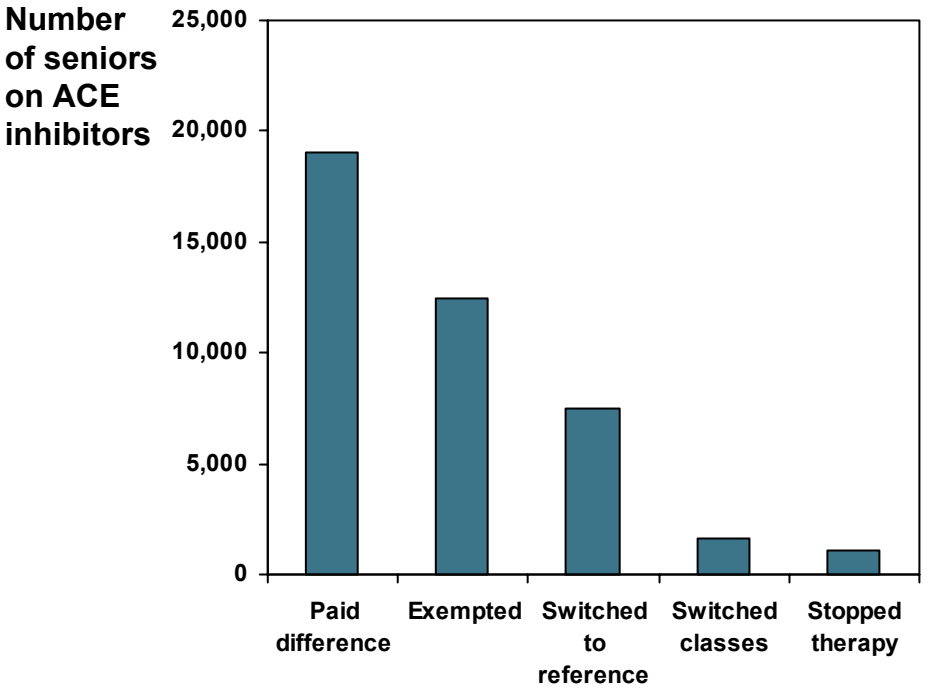


Source: LSE Health and Social Care, January 2004, Special Research Paper: The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States – a Stakeholder Analysis

INTERVENTIONS LEAD TO UNINTENDED NEGATIVE CONSEQUENCES (II)

Example: Reference Pricing in British Columbia

Use of ACE Inhibitors for Seniors Following Reference Price Implementation



Health Outcomes Worsened for Patients who Switched or Stopped Therapy

Rate of hospitalization increased 19% in the two months following implementation for those who switched to reference drugs

- **Longer term, this rate fell to a 3% increase (note that some patients also switched drugs again)**

Patients who stopped therapy also experienced a higher rate of mortality in 12 weeks following implementation

Note: health outcomes examples were not all statistically significant; increased costs to health plan as a whole were not estimated

Source: Fraser Institute, 2002, Public Policy Sources Occasional Paper: The Fantasy of Reference Pricing and the Promise of Choice in in BC's Pharmacare

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INTERVENTIONS IN UNITED KINGDOM

	Price controls	x	Volume controls	=	Spending controls
Supply	• Cost plus pricing • Pharmacoeconomic criteria • Molecule/class reference pricing • Cross-country reference pricing • Mandatory rebates • Price cuts/price freezes(1)(2)		• Marketing spend limits • Product volume caps		• Profit controls • Revenue controls
Demand	• Co-payments/co-insurance • Generic substitution incentives		• Prescribing guidelines • Positive/negative lists • Formularies • Parallel import dispensing targets/incentives		• Physician Rx budgets • Physician healthcare budgets

1970's - 1980's
1990's
2000's

(1) Price cut in 1993 and 1999; price freeze in 1993
(2) Price caps set on generics in 2000; modified in 2004

Sources: U.K. Department of Health (http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/fs/en); "United Kingdon – Pharmaceutical Pricing and Reimbursement Policies," LSE study on healthcare, http://pharmacos.eudra.org/F3/g10/p6.htm; ABPI

THE UNITED KINGDOM PHARMACEUTICAL CONTROLS (I)

Drug type	Regulating body	Market intervention
Branded National Health Service (NHS) licensed drug[1]	Department of Health in consultation with ABPI[2]	• Pharmaceutical Price Regulation Scheme (PPRS) negotiated every 5-6 years • The PPRS is an agreement between the Department of Health and ABPI on prices and profits • Initial launch prices of products with new active substance marketing authorization and line extensions relating to such products not controlled, subject to profits being below Margin of Tolerance (MOT); price increases need permission • 1999 PPRS allows 17% Return on Capital (ROC) for level 1 (price increases) and 21% for level 2 (analysis of Annual Financial Returns) • MOT of up to 140 percent of level 2 ROC • Prices increased or decreased depending upon companies performance in relation to ROC targets; alternatively, profits over MOT to be repaid or price increases delayed • Price allowance for R&D from 17 percent and 20 percent of the value of NHS sales • Additional 0.25 percent allowed for NHS home sales above £0.5M per year for each in-patent molecule up to limit of 12 molecules

(1) Drugs licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA)
(2) Association of the British Pharmaceutical Industry
Sources: U.K. Department of Health (http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/fs/en); "United Kingdon – Pharmaceutical Pricing and Reimbursement Policies," LSE study on healthcare, http://pharmacos.eudra.org/F3/g10/p6.htm; ABPI

THE UNITED KINGDOM PHARMACEUTICAL CONTROLS (II)

Drug type	Regulating body	Market intervention
Generics (52 percent of Rx by volume)	Department of Health	• Until 2000, there were no price controls on generics • Price 'turbulence' in 1999 led to implementation of maximum price scheme in 2000 • Maximum prices were set based on average November 1998 –January 1999 prices • Price control system modified in 2004
All Rx	Primary Care Trusts (PCTs)	• Sets practice area prescription budgets • Prescribing guidelines at local level including generics promotion and volume control of drugs
	National Institute of Clinical Excellence (both independent and part of NHS)	• Decides best practice health guidelines including for medicines • Appraises 20-30 NMEs per year for cost effectiveness and effectively sets prices on these drugs
Negative lists	Department of Health	• Blacklist of drugs that cannot be prescribed by GPs on the NHS • Greylist of drugs which may only be prescribed by GPs on the NHS to patients of a description specified and for the purpose specified
OTCs/private prescriptions	N/A	• No price controls

Sources: U.K. Department of Health (http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/fs/en); "United Kingdon – Pharmaceutical Pricing and Reimbursement Policies," LSE study on healthcare, http://pharmacos.eudra.org/F3/g10/p6.htm; ABPI

TIMELINE OF PHARMACEUTICAL CONTROLS IN UNITED KINGDOM (I)

1957	• Voluntary Pricing Regulation Scheme which became the Pharmaceutical Price Regulation Scheme (PPRS) • PPRS agreements reached in 1961, 1964, 1969, 1972 and 1978 which reflect agreement between U.K. government and Association of British Pharmaceutical Industries (ABPI)
1984	• "Selected list" (negative list) extended in 1992
1986	• New PPRS agreement
1988	• Prescribing Analysis and Cost System (PACS): Physicians given detailed information on volume and cost of prescriptions in order to control their prescribing behavior
1990	• GP fund holding (~40 percent of GPs), budget includes Rx costs
1991	• Indicative Prescribing Scheme (IPS): Each physician given a prescribing benchmark
1990-92	• Pharmaceutical prices frozen

Sources: U.K. Department of Health (http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/fs/en); "United Kingdon – Pharmaceutical Pricing and Reimbursement Policies," LSE study on healthcare, http://pharmacos.eudra.org/F3/g10/p6.htm; ABPI

TIMELINE OF PHARMACEUTICAL CONTROLS IN UNITED KINGDOM (II)

1993

- **2.5 percent price reduction on all prescription pharmaceuticals and a three year freeze at that level**
- **New PPRS agreement**

1999

- **Latest PPRS agreement: Prices lowered by 4.5%; Comparison of each company's profits to maximum ROC in the U.K. (17-21%); profits above the cap are paid directly to the NHS**
- **Allowances made for R&D within the prices paid by NHS of 17% to 20%**
- **NICE set up to set best practice health guidelines including for medicines and to appraise some NMEs for cost effectiveness and set price based on pharmacoeconomic analysis**
- **Some unbranded drug prices controlled by Department of Health after public consultation**

Sources: U.K. Department of Health (http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/fs/en); "United Kingdon – Pharmaceutical Pricing and Reimbursement Policies," LSE study on healthcare, http://pharmacos.eudra.org/F3/g10/p6.htm; ABPI

TIMELINE OF PHARMACEUTICAL CONTROLS IN UNITED KINGDOM (III)

2000 – 04

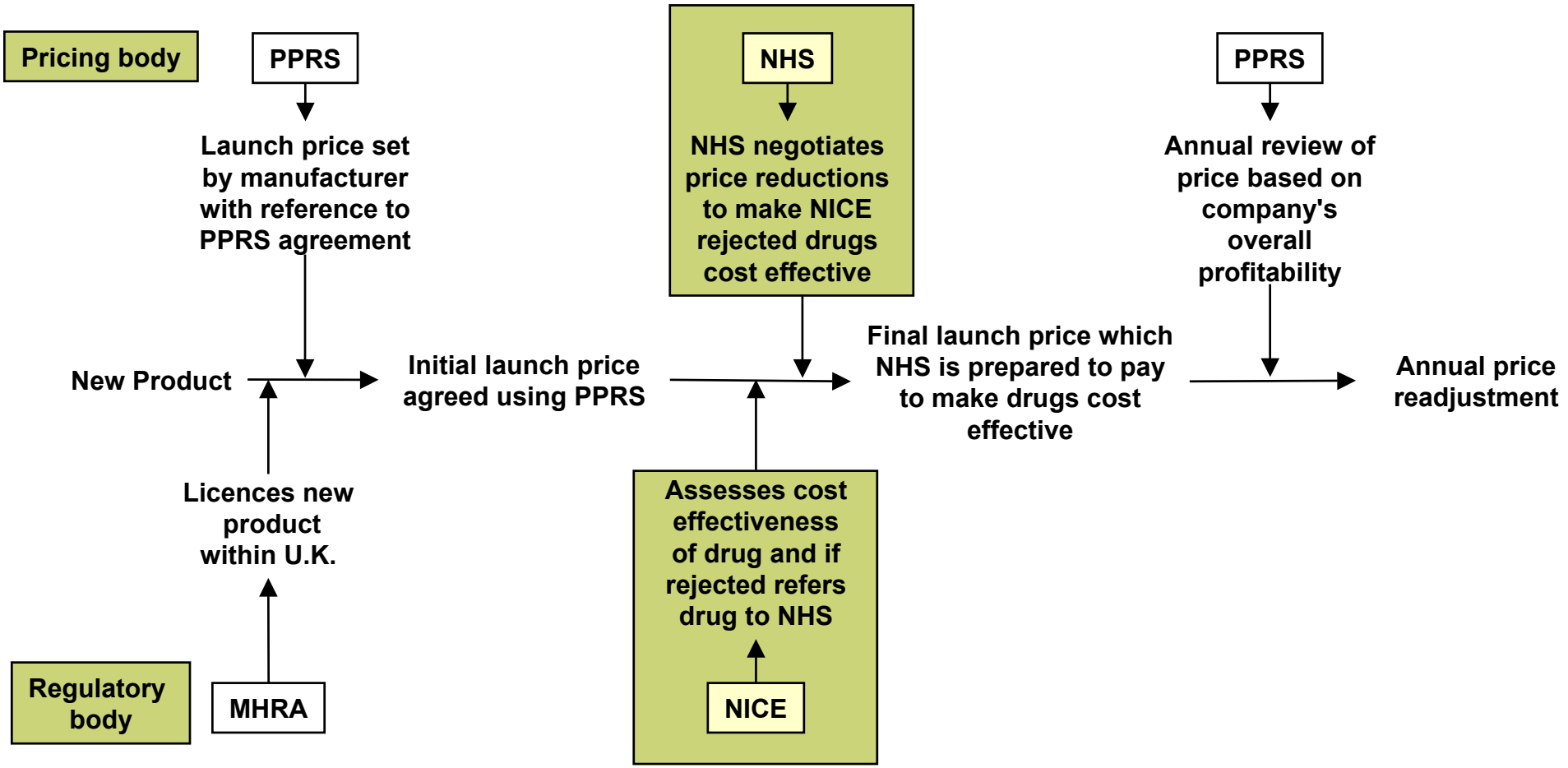
- **Maximum prices set based on average November 1998 – January 1999 prices**
- **Primary Care Trusts (PCTs) to set practice prescribing budgets**
- **More than 50 percent of GPs are fund holders (have approximately 10 percent less spending on pharmaceuticals than non-fund holding practices)**
- **New PPRS being negotiated in 2004**
- **Generic price control system to be modified in 2004; free pricing allowed subject to restrictions on price increases; generic prices have to be lower than originator brand price**

Other

- **Pharmacies reimbursed by NHS through prescription drug fee at NHS price and allowance fee for dispensing costs**
- **Claw back system promotes parallel imports: Pharmacists negotiate rebates with wholesalers and profits are restituted to the NHS; profits determined on an average basis through inquiries, therefore pharmacies have an incentive to obtain higher margins through parallel imports**
- **Flat co-payments except for exempt categories of patients and conditions**

Sources: U.K. Department of Health (http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/fs/en); "United Kingdon – Pharmaceutical Pricing and Reimbursement Policies," LSE study on healthcare, http://pharmacos.eudra.org/F3/g10/p6.htm; ABPI

UNITED KINGDOM USES PHARMACOECONOMIC EVALUATION TO GUIDE PRICING NEGOTIATIONS



Note: PPRS - Pharmaceutical Price Regulation Scheme; NHS – National Health Service; MHRA – Medicines and Healthcare Products Regulatory Agency; NICE – National Institute for Clinical Excellence

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INTERVENTIONS IN GERMANY

	Price controls	x	Volume controls	=	Spending controls
Supply	• Cost plus pricing • Pharmacoeconomic criteria(1) • Molecule/class reference pricing(2) • Cross-country reference pricing • Mandatory rebates(3) • Price cuts/price freezes		• Marketing spend limits • Product volume caps		• Profit controls • Revenue controls
Demand	• Co-payments/co-insurance(4) • Generic substitution incentives		• Prescribing guidelines • Positive/negative lists • Formularies • Parallel import dispensing targets/incentives		• Physician healthcare budgets

1970's - 1980's
1990's
2000's
Under discussion

(1) Being implemented in July 2004, with the creation of the Institute for Quality and Economics in Health Care (IQWG)
(2) The reference price is the maximum that can be reimbursed
(3) Mandated rebates on drugs not covered by reference pricing – 6% in 2003 and 16% in 2004
(4) Co-payments were abolished for products covered by reference prices in 1993, but were re-introduced again in 1994

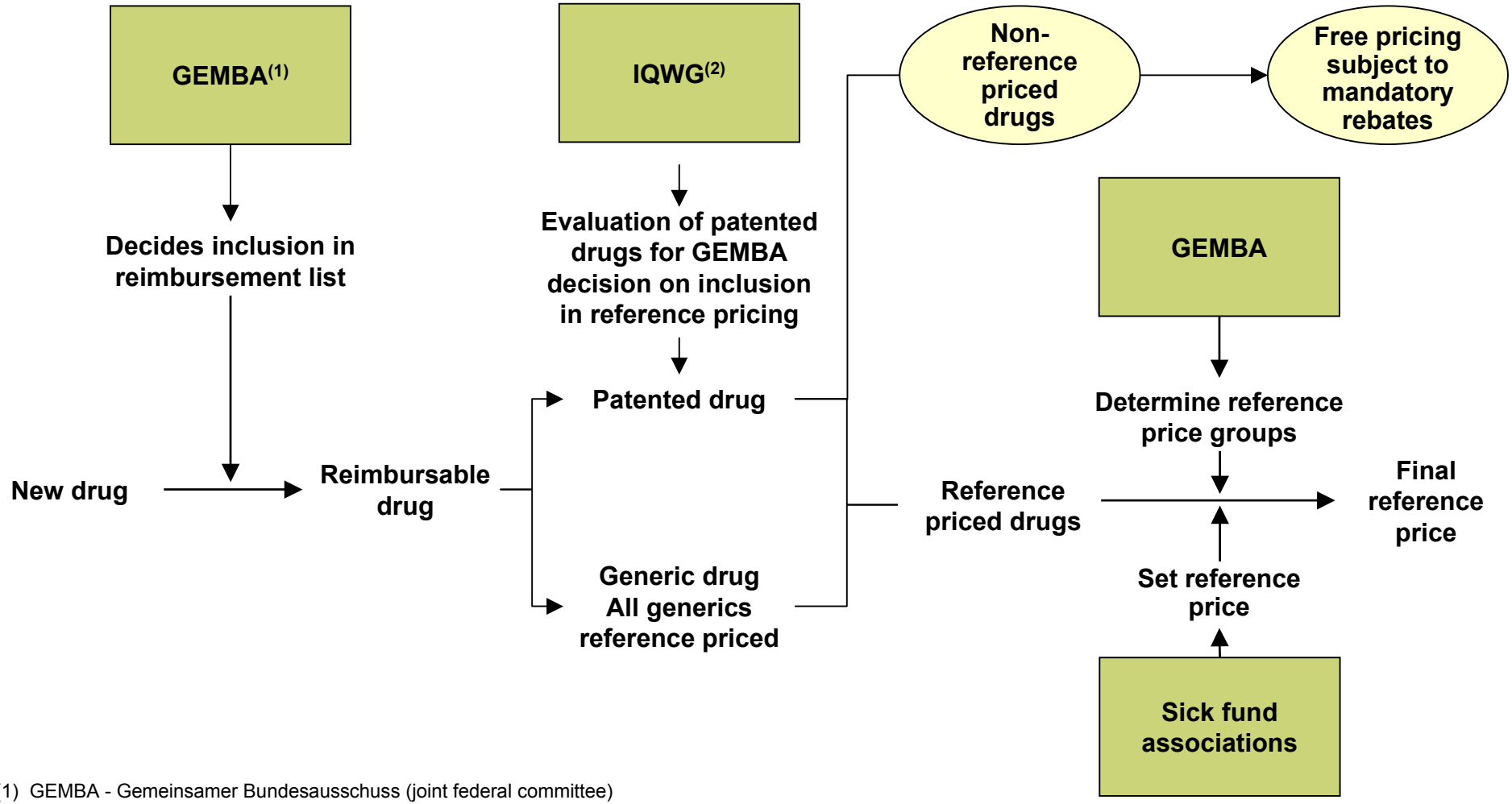
Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

GERMAN PHARMACEUTICAL CONTROLS

Drug type	Regulating body	Market intervention
Reimbursed patented drugs	GEMBA (1) and IQWG(2)	• Innovative and therapeutically beneficial new patented drugs not subject to price control via reference pricing • Inclusion of patented drugs in reference pricing depends on GEMBA evaluation; actual evaluation to be performed by IQWG after July 2004 • Reimbursed drugs covered by statutory Health Insurance • Reimbursement prices set for categories of comparable products and revised annually • Categories defined by GEMBA based on similarity of effect/active ingredient • New reference price line calculation (from regression analysis) to be based on difference between the cheapest and most expensive drug
Generics	GEMBA	• Decides whether or not to include in negative list • If reimbursable, all generics are subject to reference pricing

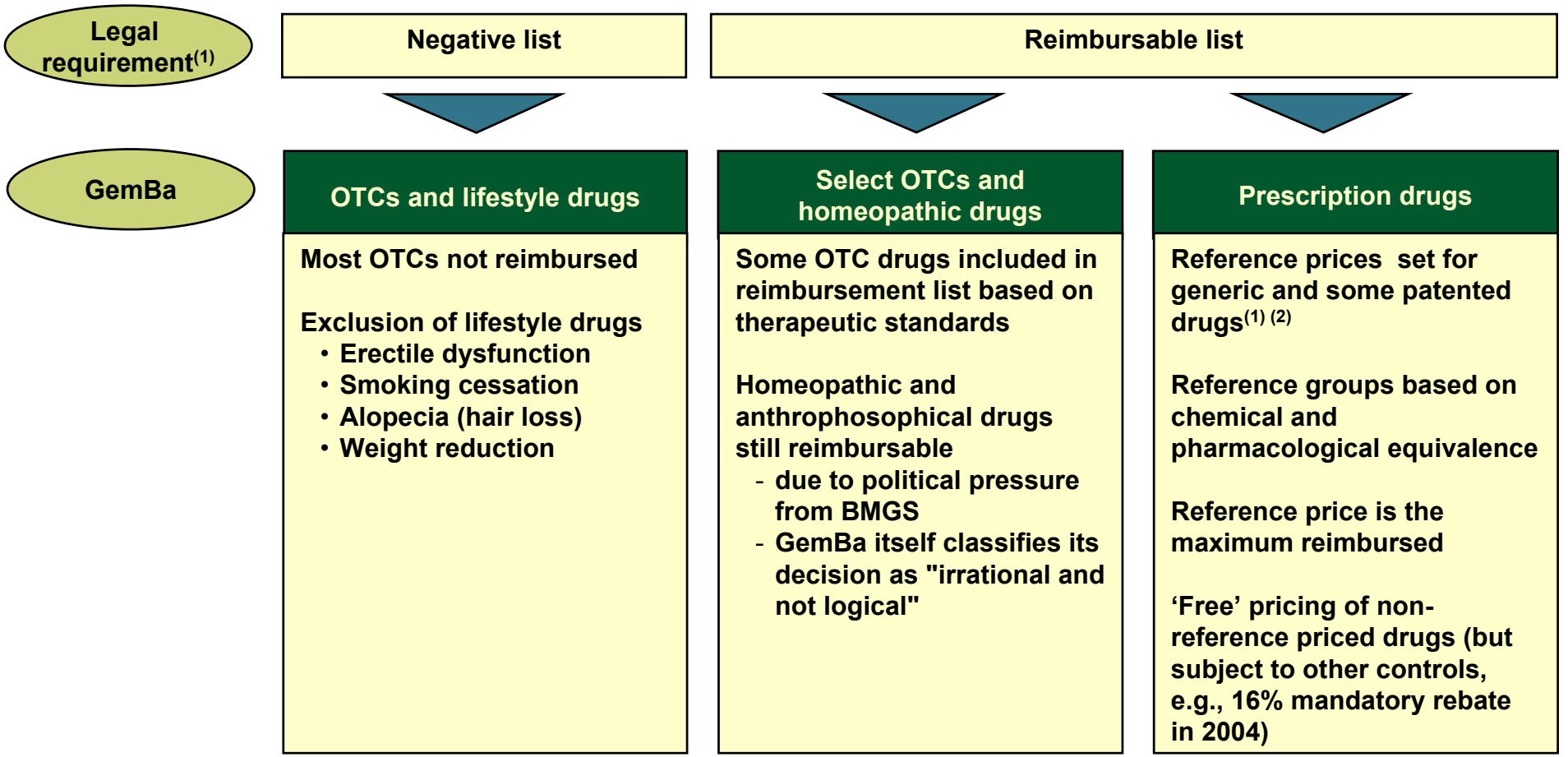
(1) GEMBA - Gemeinsamer Bundesausschuss (joint federal committee)
(2) Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen - Institute for Quality and Economics in Health Care
Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

GERMANY USES MOLECULE/CLASS REFERENCE PRICING TO CONTROL DRUG PRICES



(1) GEMBA - Gemeinsamer Bundesausschuss (joint federal committee)
(2) Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen - Institute for Quality and Economics in Health Care
Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

GEMBA DETERMINES WHICH DRUGS GO INTO NEGATIVE AND REIMBURSABLE LISTS



(1) In 1997, reference priced products accounted for a 63.2% share of the market for prescription drugs and produced savings of ECU 1.6 billion, equivalent to a 7.5% share of the market for prescription drugs (Source: "Policy Relating to Generic Medicines in the OECD," National Economic Research Associates, Study carried out on behalf of the European Commission

(2) According to latest healthcare reform law (GMG), select patented drugs may be subject to reference pricing based on IQWG evaluation

Sources: GemBa, German Association of Research-Based Pharmaceutical Companies (VfA), Press

REFERENCE PRICE SETTING A TWO STEP PROCESS
GEMBA and Sickfund Associations Involved

Definition of comparable drug groups

GemBa defines comparable drug groups based on chemical and pharmacological equivalence

Hearing with pharma companies before and after group definition

Selection has to be approved by BMGS(1)

Can be applied to patented drugs with no evident therapeutic benefit

- **Minimum of 3 comparable drugs needed to form group**
- **If first drug in group is off patent; non-patented drugs can be included in grouping, which leads to lower reimbursement levels**

Reference price (RP) setting

Sickfund associations set reference prices

New reference price-setting based on the difference between the cheapest and most expensive drug

- **Price calculation for different dosages and pack sizes based on regression analysis**
- **Only products with a minimum 1% market share used for determining regression line**

Reference prices updated annually to reflect market changes

Hearing with pharma companies after reference price calculation

(1) BMGS - Ministry of Health and Social Security (Bundesministerium für Gesundheit und Soziale Sicherung)

Source: "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004; "German price controls backed by ECJ," World Markets Research Centre Limited, 17 March 2004; "Reference pricing for drugs – is it compatible with U.S. healthcare," P. Kanavos and U. Reinhardt, Health Affairs – Vol. 22, No. 3; German Institute of Medical documentation and Information (DMDI, http://www.dimdi.de/en/amg/fbag/index.htm);BCG studies

GERMAN REFERENCE PRICE-SETTING TO CHANGE IN 2004 WITH NEW HEALTHCARE REFORM LAW

Previous system

Three levels of drug groups for reference pricing

- **Level 1: drugs with same active ingredient and bioavailability, if therapeutically relevant**
  - **e.g., metformin**
- **Level 2: drugs with pharmacologically and therapeutically comparable active ingredients, in particular chemically related agents**
  - **e.g., alpha-rezeptorenblockers**
- **Level 3: drugs with therapeutically comparable effects, in particular combination drugs**
  - **e.g., antidepressants**

Reference prices set based on bottom third of price range

All patented drugs excluded

New system

Basic methodology remains similar

Reference prices set based on difference between the cheapest and most expensive drugs

Some patented drugs could be included based on pharmacological analysis by IQWG

New reference groups added(1)

- **Proton Pump Inhibitors**
- **Angiotensin-2-Antagonists**
- **Statins**
- **Triptanes**
- **Alpha-Glucosidase-Inhibitors**

(1) Does not imply that patented drugs within group will be included in reference pricing; some patented drugs may be included based on evaluation by IQWG

Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004; German Institute of Medical documentation and Information (DMDI, http://www.dimdi.de/en/amg/fbag/index.htm)

EXAMPLE OF GERMAN LEVEL 1 REFERENCE PRICING IN 2003

Most Drugs are Priced Below the Reference Price

Reference price-setting steps

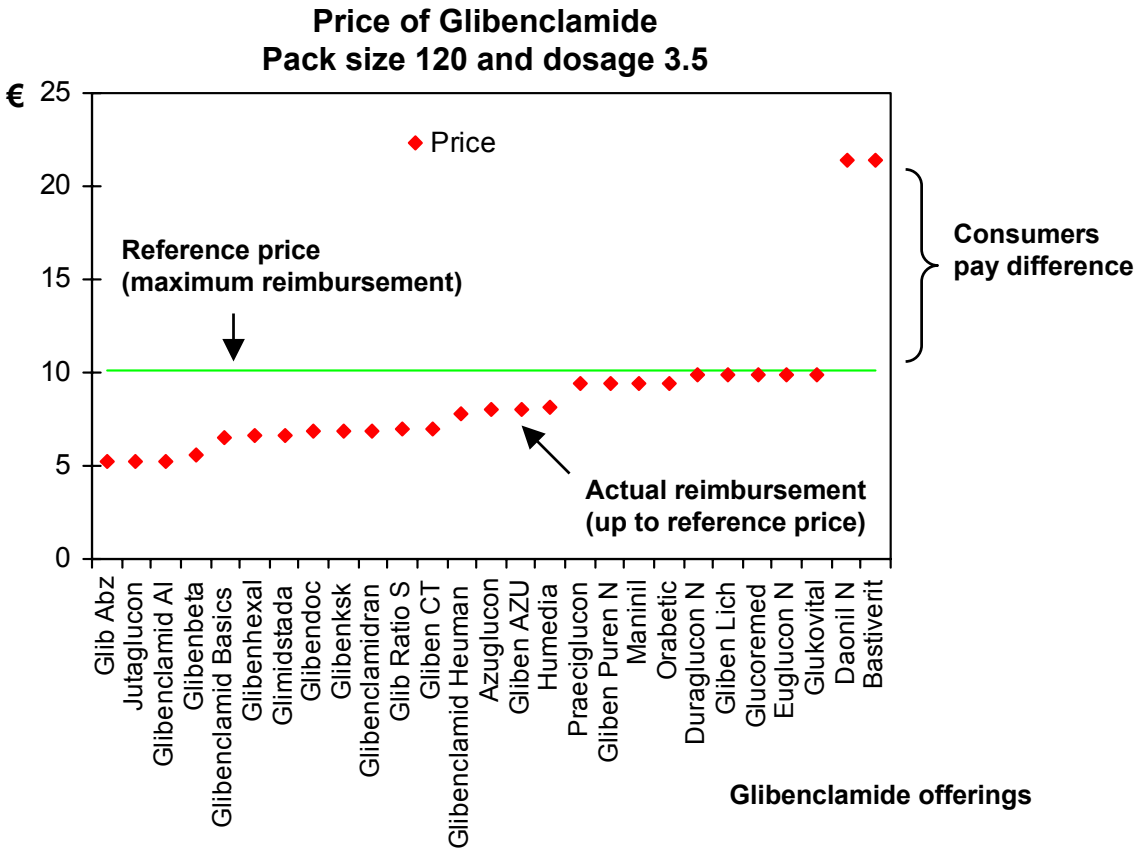
Standard package (dosage and pack size) determined

Reference price for standard package set by sickfund associations based on bottom third of price range

Reference prices for other pack sizes and dosages set relative to reference price for the standard package based on the regression equation

Relative price = *a* x dosage + *b* x pack size

Coefficients *a* and *b* derived based on actual pharmacy retail prices of all packages



Note: This is based on reference prices in 2003. Patented drugs were not included in reference pricing. Inclusion of some patented drugs in reference price setting is being introduced in 2004; the new system is supposed to take effect with the setting up of IQWG in July 2004

Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004; German Institute of Medical documentation and Information (DMDI, http://www.dimdi.de/en/amg/fbag/index.htm)

GERMAN LEVEL 2 AND LEVEL 3 REFERENCE PRICING

Reference price-setting steps

Price setting method from level 1 modified to account for drugs with different active ingredients in level 3 (and level 2) groups

Simple dosage replaced by active ingredient equivalent (WAF) factor in the regression equation

WAF defined as dosage/ equivalent factor (AF),

where AF = Average daily dose (ADD) active ingredient to be compared/ADD active ingredient used as reference for comparisons

Calculating the active ingredient factor (WAF)

Esample: The tranquilizers oxazepam and lorazepam, with oxazepam being the reference for comparison

Step1: Calculating the AF

Oxazepam: ADD = 30 mg; AF = 30/30 = 1

Lorazepam: ADD = 2mg; AF = 2/30 = 0.067

Step 2: Calculating the WAF

a) WAF of oxazepam with dosage 10mg = dosage (10) / AF (1) = 10

b) WAF of lorazepam with dosage 1mg = dosage (1) / AF (0.067) = 15

Note: This is based on reference prices in 2003. Patented drugs were not included in reference pricing. Inclusion of some patented drugs in reference price setting is being introduced in 2004; the new system is supposed to take effect with the setting up of IQWG in July 2004

Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004; German Institute of Medical documentation and Information (DMDI, http://www.dimdi.de/en/amg/fbag/index.htm)

TIMELINE OF PHARMACEUTICAL CONTROLS IN GERMANY (I)

1983	• **Negative list** • **Health Care Reform Act: grouping by therapeutic category for reference pricing**
1993	• **Drug budgets (spending caps) for office-based physicians: Federal Physicians Association liable for first DM 280 million cost overrun; pharmaceutical industry liable for remainder up to DM 560 million** • **Price cuts and two year price freeze from January 1993**
1994	• **Spending caps (introduced in 1993) set by region** • **Flat co-payments re-introduced; co-payments based on pack size**
1996	• **No drug receiving marketing authorization after 1995 will be reference priced until its patent expires**

Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm

TIMELINE OF PHARMACEUTICAL CONTROLS IN GERMANY (II)

1997	• **Sick funds reduced existing reference prices by an average of 7.9%** • **Switched to annual price revision from a quarterly system**
1998	• **Extended reference pricing to 15 more groups of substances** • **Reference prices not to be higher than the highest price in bottom third of price range** • **Regionally set drug spending caps (introduced in 1993) replaced by doctors' practice-specific prescribing guidelines**
1999	• **Re-introduced regional spending caps**

Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm

TIMELINE OF PHARMACEUTICAL CONTROLS IN GERMANY (III)

2000 – 04	• **Mandated rebates on drugs not covered by reference pricing; rebate increased from 6% in 2003 to 16% in 2004** • **Parallel import quotas introduced at pharmacies, increased quota from 5.5% in 2002 to 7% in 2003** • ***Aut idem* law in 2000 encourages generic prescription by doctors** • **Reference prices reintroduced for some patented drugs in 2004 as part of Statutory Health Insurance Modernization Act (GMG)** • **New reference price line calculation to be based on difference between the cheapest and most expensive drug** • **De-reimbursement of some drugs in 2004** • **Increased co-payments for medicines from January 2004**
Future	• **Institute for Quality and Economy in the Health Care System (IQWG) to be set up in July 2004** • **IQWG will classify new products based on innovativeness and therapeutic benefit; this analysis will determine whether a new product is subject to reference pricing**

Sources: LSE study on healthcare in Germany, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

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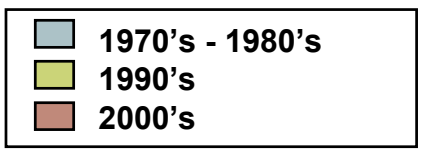
INTERVENTIONS IN FRANCE

	Price controls	x	Volume controls	=	Spending controls
Supply	• Cost plus pricing • Pharmacoeconomic criteria • Molecule/class reference pricing(1) • Cross-country reference pricing(1) • Mandatory rebates (2) • Price cuts/price freezes		• Marketing spend limits • Product volume caps		• Profit controls • Revenue controls
Demand	• Co-payments/co-insurance • Generic substitution incentives		• Prescribing guidelines • Positive/negative lists • Formularies • Parallel import dispensing targets/incentives		• Physician Rx budgets • Physician healthcare budgets



(1) The reference price is the reimbursement price
(2) Pharmaceutical industry required to make a one-off contribution of FFr 2.5 billion (U.S.$490 million) towards the healthcare budget deficit in 1996 and 100 million euros (U.S.$120 million) in two installments in April 2004 and April 2005

Sources: "France – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

FRENCH PHARMACEUTICAL CONTROLS

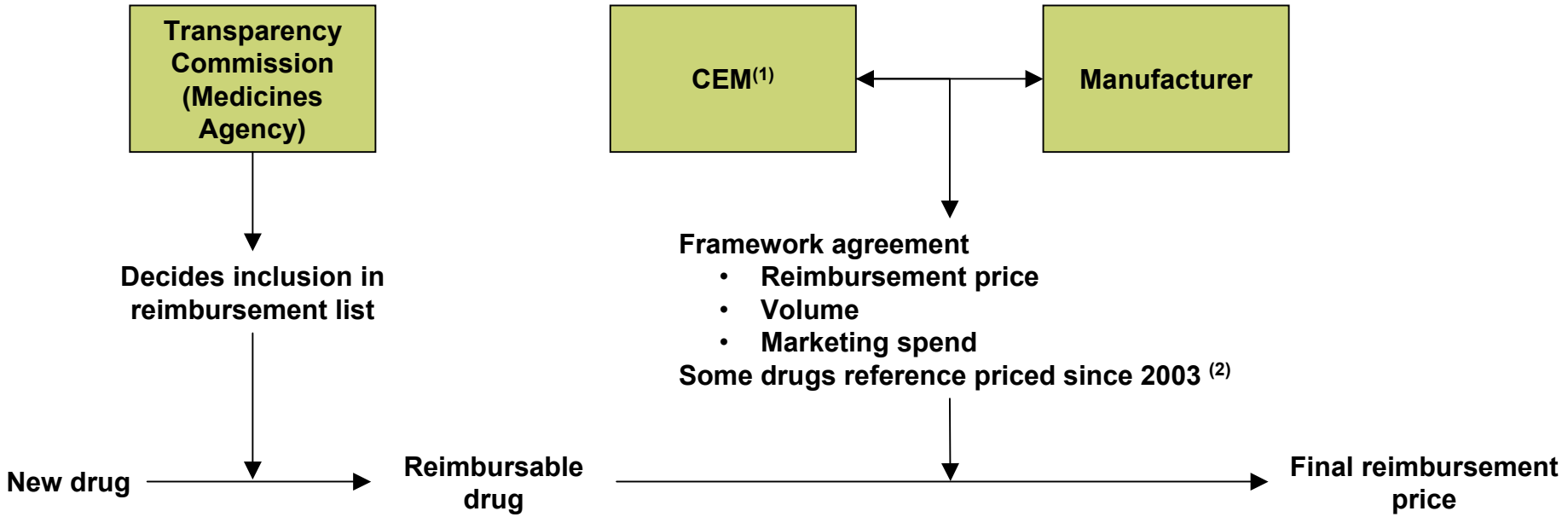
Drug type	Regulating body	Market intervention

Reimbursed patented drugs	Transparency Commission	• Decides inclusion of drug in reimbursed list
		• Reimbursement price negotiated with CEM(1) based on an overall framework agreement
		  • Negotiated every 4 years but monitored at least twice every year (after the 4th and 8th months)
		  • Price from framework agreement depends on
		  - technical review by Transparency Commission that assigns drug to one of 5 categories based on innovation, therapeutic benefit and impact on public health; called Service Médical Rendu (SMR) rating
		  - reference price checks with other EU countries
		  - agreement on price*volume – price reduction or cash penalties for exceeding marketing and volume limits
		  • Marketing spend limited by tax calculated from marketing spend over sales ratio
		  • Pharma companies encouraged to offer generics as part of framework agreement
		  • Molecule/class reference pricing introduced in 2003-04

(1) Comité Economique du Médicament

Sources: "France – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

FRANCE EMPLOYS "FRAMEWORK AGREEMENTS" WITH PHARMA COMPANIES TO GOVERN PRICING



(1) Comité Economique du Médicament

(2) Reference pricing (molecule/class) introduced for products with generic substitution rate of 10-45% in 2003; to be extended to products with generic substitution rate of less than 60% in 2004; France also checks prices in other countries while setting the reimbursement price

Sources: "France – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resources, March 12, 2004

TIMELINE OF PHARMACEUTICAL CONTROLS IN FRANCE (I)

1970s	• Pricing of drugs based on a number of factors such as the utility, manufacturing costs, sales forecasts, prices in other EU countries, treatment costs, R&D in France and nationality of manufacturer
1991	• Tiered co payment levels for reimbursable drugs: 0%, 35%, 65%, 100% • Taxes on promotional expenses by pharma companies • Special tax (2.5% of sales) was imposed on the industry
1993	• CEM set up to negotiate framework agreements with pharmaceutical companies
1994	• Price regulation by state replaced by framework agreements • SNIP agreement between the pharma industry and the government, setting a global ceiling on pharma spending, caps on pharma promotion and pricing of new products; agreements with individual companies on pricing, factoring in sales volumes, R&D expenditure, etc. • Co payment rates raised from 30% to 35% and 60 to 65%

Sources: "France – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

TIMELINE OF PHARMACEUTICAL CONTROLS IN FRANCE (II)

1995	• **Companies subject to a variable tax on reimbursable products**
1996	• **Pharma industry asked to make a FFr 2.5 billion (U.S. $490 million) "contribution" towards the healthcare budget deficit in 1996**
1999	• **Pharmacists allowed to substitute generics for branded products** • **Limit set on growth rate of drugs sold in pharmacies to 2%**
2000 – 04	• **Drug pricing re-evaluated, leading to price decreases; select drugs also de-listed** • **Reference pricing introduced for products with generic substitution rate of 10-45% in 2003; to be extended to products with generic substitution rate of less than 60% in 2004** • **Reduced reimbursement rate from 65% to 35% on 617 products that have "weak" or "moderate" SMR rating** • **Promotional tax on pharmaceutical industry increased in 2004** • **Industry to make one-off payment of 100 million euros (U.S. $120 million) in two installments in April 2004 and April 2005**

(1) Comité Economique du Médicament

Sources: "France – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "International Review of Pharmacoeconomic, pricing and reimbursement news in the second half of 2003," Decision Resourses, March 12, 2004

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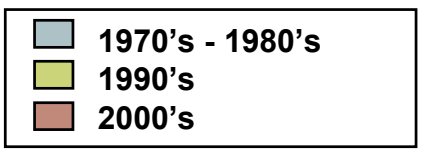
INTERVENTIONS IN SPAIN

	Price controls	x	Volume controls	=	Spending controls
Supply	• Cost plus pricing • Pharmacoeconomic criteria • Molecule/class reference pricing(1) • Cross-country reference pricing(1) • Mandatory discounts • Price cuts/price freezes		• Marketing spend limits • Product volume caps • Incentives to market generics		• Profit controls • Revenue controls
Demand	• Co-payments/co-insurance • Generic substitution incentives		• Prescribing guidelines • Positive/negative lists • Formularies • Parallel import dispensing targets/incentives		• Physician Rx budgets • Physician healthcare budgets



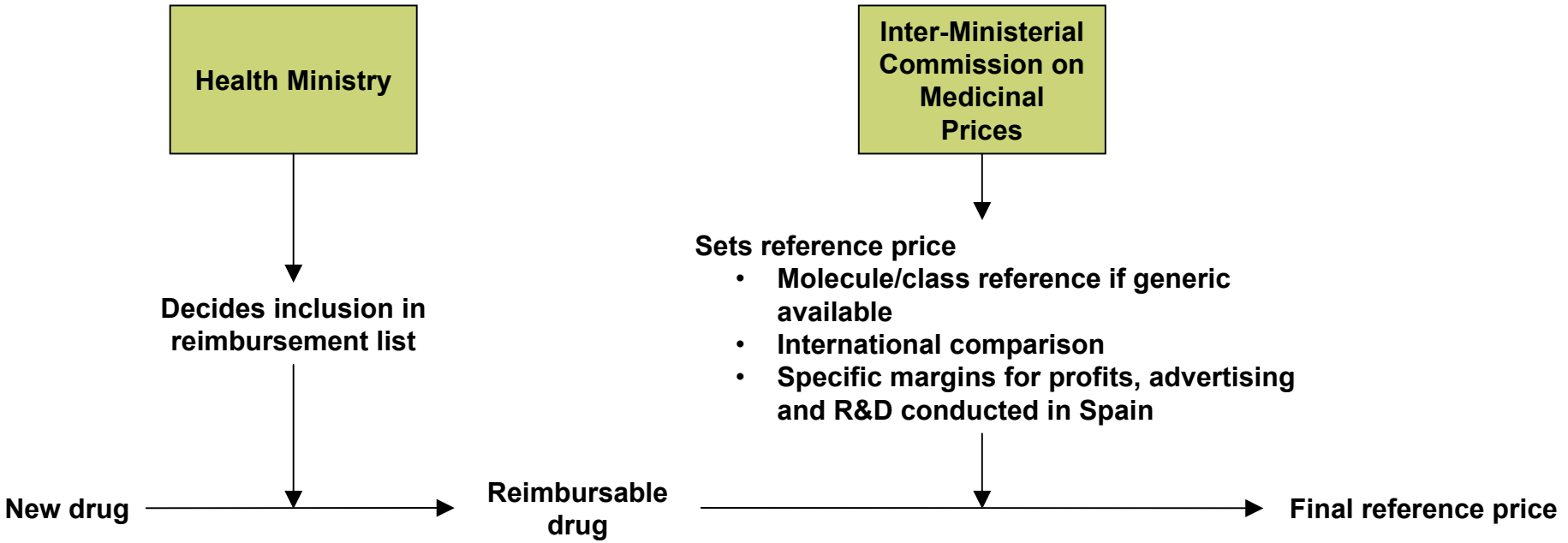
(1) Reference price is the maximum price reimbursed by the social security system
Sources: "World Pharmaceutical Market Spain," Epsicom Business Intelligence February 14, 2003;
"Pharmaceutical regulation in Europe," Parlos Kanavos, Harvard Medical School; "Spain – Pricing and Reimbursement of Pharmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

SPANISH PHARMACEUTICAL CONTROLS

Drug type	Regulating body	Market intervention
Reimbursable prescription drugs	Interministerial commission on medicinal prices	• Price control through negotiation on a cost-plus basis, taking into account expected sales and allowing specific margins for profits (12-18% of allowable costs), advertising (12-16% of allowable costs) and R&D conducted in Spain • Where generic available, prescription drugs classified by active ingredient to set reference price • Reference price is the maximum price reimbursed by the social security system • Each formulation and pack size has a fixed reference price calculated as follows - average price of all the cheapest products holding a 20% market share and which are at least cheaper 10% cheaper than the originator product • Pharmacists obliged to substitute drugs that exceed reference price with bioequivalent generics, unless patient pays difference • International price comparisons for active ingredient when difficulties arise in assessing transfer price of a molecule
New non-reimbursable products	NA	• No price regulation

Sources: "World Pharmaceutical Market Spain," Epsicom Business Intelligence February 14, 2003;
"Pharmaceutical regulation in Europe," Parlos Kanavos, Harvard Medical School; "Spain – Pricing and Reimbursement of Pharmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

SPAIN EMPLOYS REFERENCE PRICING AND CONTROLS ON MARKETING SPEND



Sources: "World Pharmaceutical Market Spain," Epsicom Business Intelligence February 14, 2003; "Pharmaceutical regulation in Europe," Parlos Kanavos, Harvard Medical School; "Spain – Pricing and Reimbursement of Pharmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

TIMELINE OF PHARMACEUTICAL CONTROLS IN SPAIN (I)

1990	• **Medicines Law: direct pricing for each product taking into consideration manufacturing and R&D costs, estimates of volumes and value of sales, and the prices in other European countries** • **3% reduction in the prices of most drugs and price freeze until 1996**
1994	• **Pharma companies limited to annual sales increases of 7%, pay back profits to government if they exceed limit** • **Introduction of co-payment levels – 40% in general and 10% for chronic illnesses**
1996	• **Pharma companies must pay the government back a percentage of their profits on annual sales growth over 2.6%**
1997	• **Introduced proposal for reference pricing** • **Medicines Agency created**
1998	• **834 drugs in 39 therapeutic groups removed from reimbursement list**

Sources: "World Pharmaceutical Market Spain," Epsicom Business Intelligence February 14, 2003;
"Pharmaceutical regulation in Europe," Parlos Kanavos, Harvard Medical School; "Spain – Pricing and Reimbursement of Pharmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

TIMELINE OF PHARMACEUTICAL CONTROLS IN SPAIN (II)

2000

- **Reference pricing system takes effect; reference prices initially set for 42 ingredients covering 114 products under 590 presentations (280 branded and 310 generic)**
- **In early 2000, government estimated that retail price of medicines had been cut by 11% over the previous four years**
- **Government imposes discounts on pharmacies billing over the national average of Ptas 55 million (U.S. $365,000) per year, intended annual savings of Ptas 500 million (U.S. $3.2 million)**
- **Pharmacists' mark-up on generics increased from 27.9% to 33% of retail price**

2002

- **Reference prices extended to 17 additional compounds covering 28 products in 183 presentations**
- **2002 pharmaceutical plan proposes to introduce tighter regulations regarding visits to healthcare professionals by pharmaceutical company representatives and the sponsorship of scientific meetings by pharmaceutical companies**
- **Medical visas for high-priced drugs (some 125 drugs require prior approval before being prescribed under the national health system)**

Sources: "World Pharmaceutical Market Spain," Epsicom Business Intelligence February 14, 2003;
"Pharmaceutical regulation in Europe," Parlos Kanavos, Harvard Medical School; "Spain – Pricing and Reimbursement of Pharmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

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INTERVENTIONS IN POLAND

	Price controls	x	Volume controls	=	Spending controls
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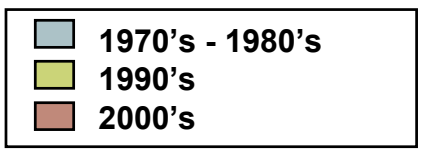


(1) The reference price is the reimbursement price

Sources: "World Pharmaceutical Market Poland," Epsicom Business Intelligence July 15, 2003; "Poland – Health Care, Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; PhRMA memorandum on Pharmaceutical issues in Poland; "National Trade Estimate Report on Foreign Trade Barriers (NTE)," PhRMA, 2003

POLISH PHARMACEUTICAL CONTROLS (I)

Drug type	Regulating body	Market intervention
Reimbursed domestically-produced prescription drugs (largely generics)	Ministry of Finance and Ministry of Health	• Prices set annually on the basis of input costs plus 20% mark-up • Domestically produced Rx are 70% of all domestic pharmaceutical production (prescription and non-prescription) • Average prices 20-50% of EU price
Reimbursed imported medicines (largely branded)	Ministry of Finance, manufacturer and Ministry of Health and Social Welfare	• Importers faced same wholesale margin of 11% until 2001 as local producers, which put them at disadvantage as they had to cover both wholesale and import costs with same margin • 2001 law replaced this system but was not implemented as government was using this to negotiate price cuts • Registration of original products takes twice as long as local copies of products still under EU patents • Higher co-payments as reference price depends on price of local substitutes • Annual revision • No new drugs have been added to the reimbursed list in the last five years

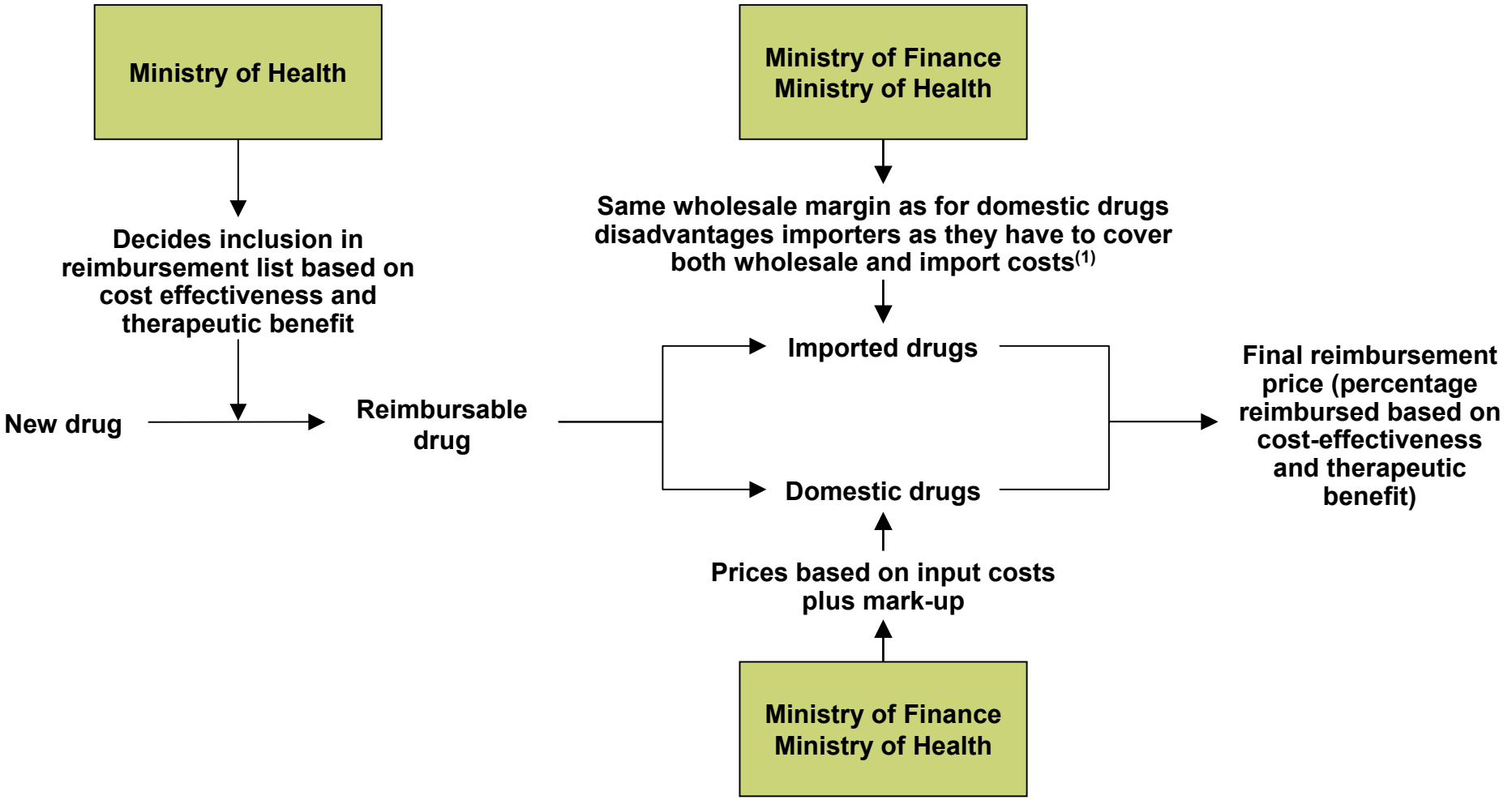
Sources: "World Pharmaceutical Market Poland," Epsicom Business Intelligence July 15, 2003; "Poland – Health Care, Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; PhRMA memorandum on Pharmaceutical issues in Poland; "National Trade Estimate Report on Foreign Trade Barriers (NTE)," PhRMA, 2003

POLISH PHARMACEUTICAL CONTROLS (II)

Drug type	Regulating body	Market intervention
Hospital drugs	Ministry of Health	Ministry of Health sets maximum price; hospitals can negotiate prices below the maximum price
All reimbursed drugs	Ministry of Health, based on recommendation by a Drug Management team with representatives from ministries of health, finance and economy	Evaluation criteria to be eligible for reimbursement • Inexpensiveness • Commonly known by doctors • Essential for therapy • Cost-effective and beneficial for overall therapy • Commonly used (not restricted to one small group of patients) • Generally the price of cheapest drug in category reimbursed
Non-reimbursed medicines (domestic and imported)	NA	No price control

Sources: "World Pharmaceutical Market Poland," Epsicom Business Intelligence July 15, 2003; "Poland – Health Care, Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; PhRMA memorandum on Pharmaceutical issues in Poland; "National Trade Estimate Report on Foreign Trade Barriers (NTE)," PhRMA, 2003

POLISH SYSTEM TENDS TO FAVOR DOMESTICALLY-PRODUCED DRUGS



(1) Margin discrimination against importers removed legally in 2001; however implementation problems continue

Source: "World Pharmaceutical Market Poland," Epsicom Business Intelligence July 15, 2003; "Poland – Health Care, Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; PhRMA memorandum on Pharmaceutical issues in Poland; "National Trades Estimate Report on Foreign Trade Barriers (NTE)," PhRMA, 2003

TIMELINE OF PHARMACEUTICAL CONTROLS IN POLAND (I)

1996
- Reimbursement act lists drugs in four categories
  - basic list obtainable on co-payment of 0.5% of minimum monthly wage
  - second supplementary list reimbursed at 70%
  - third list of less effective drugs reimbursed at 50%
  - fourth list of drugs supplied free in hospitals to treat chronic illness

1997
- Ministry of Finance (MOF) increases prices of domestic pharmaceuticals by an average of 12%, in line with inflation

1998
- Number of reimbursable drugs reduced

1999
- Drugs can only be reimbursed if prescribed by doctors participating in the national health insurance system
- Appearance of restrictive local formularies; although declared illegal, they have an impact on prescribing by doctors

2001
- Pharmaceutical pricing law updated, margin discrimination against importers replaced; however there were implementation problems
- MOF raises prices of domestic pharmaceuticals by 19%, well above the inflation rate
- Number of reimbursable drugs reduced and some products moved to categories with higher co-payments

Sources: "World Pharmaceutical Market Poland," Epsicom Business Intelligence July 15, 2003; "Poland – Health Care, Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; PhRMA memorandum on Pharmaceutical issues in Poland; "National Trade Estimate Report on Foreign Trade Barriers (NTE)," PhRMA, 2003

TIMELINE OF PHARMACEUTICAL CONTROLS IN POLAND (II)

2003	• **Ministry of health introduced maximum prices for hospital drugs; hospitals can negotiate prices below this maximum price**
Other	• **Difference in the way prices are set for domestic and imported drugs likely to violate EU regulations** • **State drug spending has tripled over past few years, but state's share of total volume has declined; about 60% of medicines sold in Poland covered by the reimbursement system**

Sources: "World Pharmaceutical Market Poland," Epsicom Business Intelligence July 15, 2003; "Poland – Health Care, Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; PhRMA memorandum on Pharmaceutical issues in Poland; "National Trade Estimate Report on Foreign Trade Barriers (NTE)," PhRMA, 2003

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INTERVENTIONS IN JAPAN

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Supply	• Direct price control • Pharmacoeconomic criteria • Molecule/class reference pricing(1) • Cross-country reference pricing(1) • Mandatory rebates • Price cuts/price freezes (2)		• Marketing spend limits • Product volume caps		• Profit controls • Revenue controls
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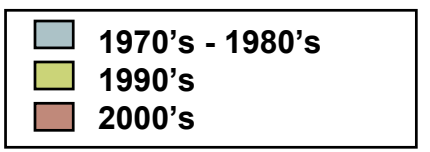


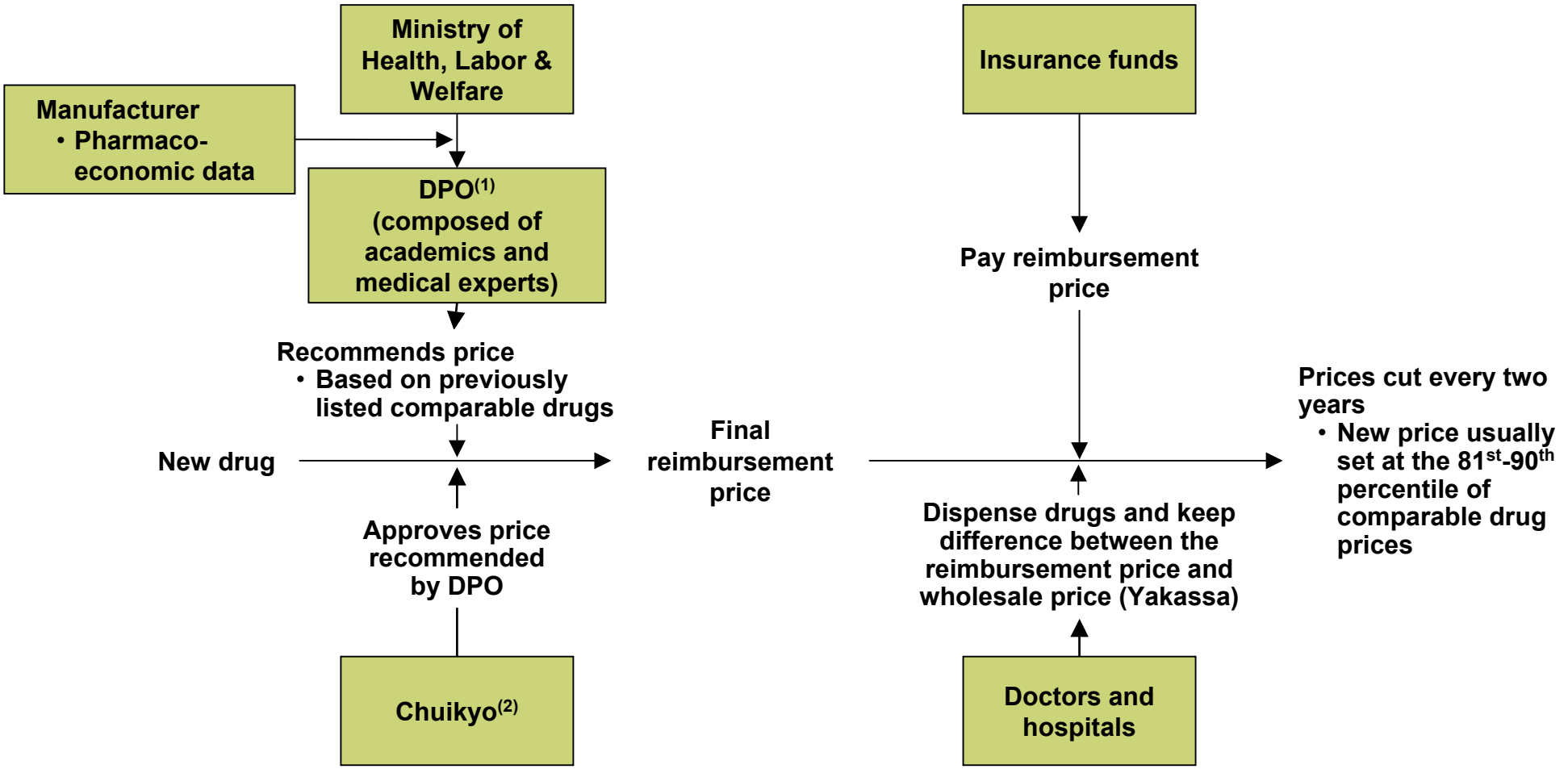
(1) The reference price is the reimbursement price
(2) Drug prices cut every two years; prices cut by an average of 4.4% in 1997, 9.7% in 1998; 7% in 2000, 6.3% in 2002
Sources: "Japan – Pricing and Reimbursement of Pharrmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "Pricing of Prescription Drugs,"U.S. International Trade Commission, 2000; "World Pharmaceutical Markets – Japan," Epsicom Business Intelligence, March 2003 ; "Pharmaceutical Administration and Regulations in Japan," JPMA 2003

JAPANESE PHARMACEUTICAL CONTROLS

Drug type	Regulating body	Market intervention
Patented drugs	Ministry of Health, Labor and Welfare (MHW) through the Drug Pricing Organization (DPO) and Central Social Insurance Medical Council (Chuikyo)	• Price recommendation by DPO to Chuikyo based on - comparison with previously listed comparable drugs - comparison done internationally, changes made if price is higher by more than 50% or lower by more than 25% compared to reference country prices in the U.S., U.K., Germany and France - premiums can be added based on innovation, usefulness and market size; however premiums are rarely added - manufacturers present pharmacoeconomic data • Chuikyo approves price recommendation made by DPO • Prices cut every two years; new price usually set at the 81st-90th percentile of comparable drug prices
Generics	MHW	• Listed annually • First generic priced at 80% of original drug's reimbursement price • Subsequent alternatives priced at the same level as the cheapest alternative, or at 90% of this price, should the number of generics exceed 20

Sources: "Japan – Pricing and Reimbursement of Pharrmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "Pricing of Prescription Drugs,"U.S. International Trade Commission, 2000; "World Pharmaceutical Markets – Japan," Epsicom Business Intelligence, March 2003 ; "Pharmaceutical Administration and Regulations in Japan," JPMA 2003

JAPAN GOVERNS PRICES THROUGH REFERENCING AND BIENNIAL PRICE REDUCTIONS



(1) Drug Pricing Organization
(2) Central Social Insurance Medical Council

Source: "Japan – Pricing and Reimbursement of Pharmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "Pricing of Prescription Drugs," U.S. International Trade Commission, 2000; "World Pharmaceutical Markets – Japan, "Epsicom Business Intelligence, March 2003; "Pharmaceutical Administration and Regulations in Japan," JPMA 2003

TIMELINE OF PHARMACEUTICAL CONTROLS IN JAPAN (I)

1922 • Health Insurance Law provided insurance coverage for major occupational groups

1950 • Bulk-line method instituted for reimbursement
- reimbursement price set at 80-90 percentile of market prices (based on prices of comparable drugs)
- encouraged pharmaceutical market expansion

1958 • Law extended to provide universal health insurance coverage based on residence rather than employment

1992 • Chuikyo(1) starts accepting economic data from manufacturers in support of a preferred price
• R-zone at 15%

1994 • Generics priced at 90% of lowest tariff rate of branded version

1997 • Pharmaceutical prices reduced by an average of 4.4%

(1) Central Social Insurance Medical Council

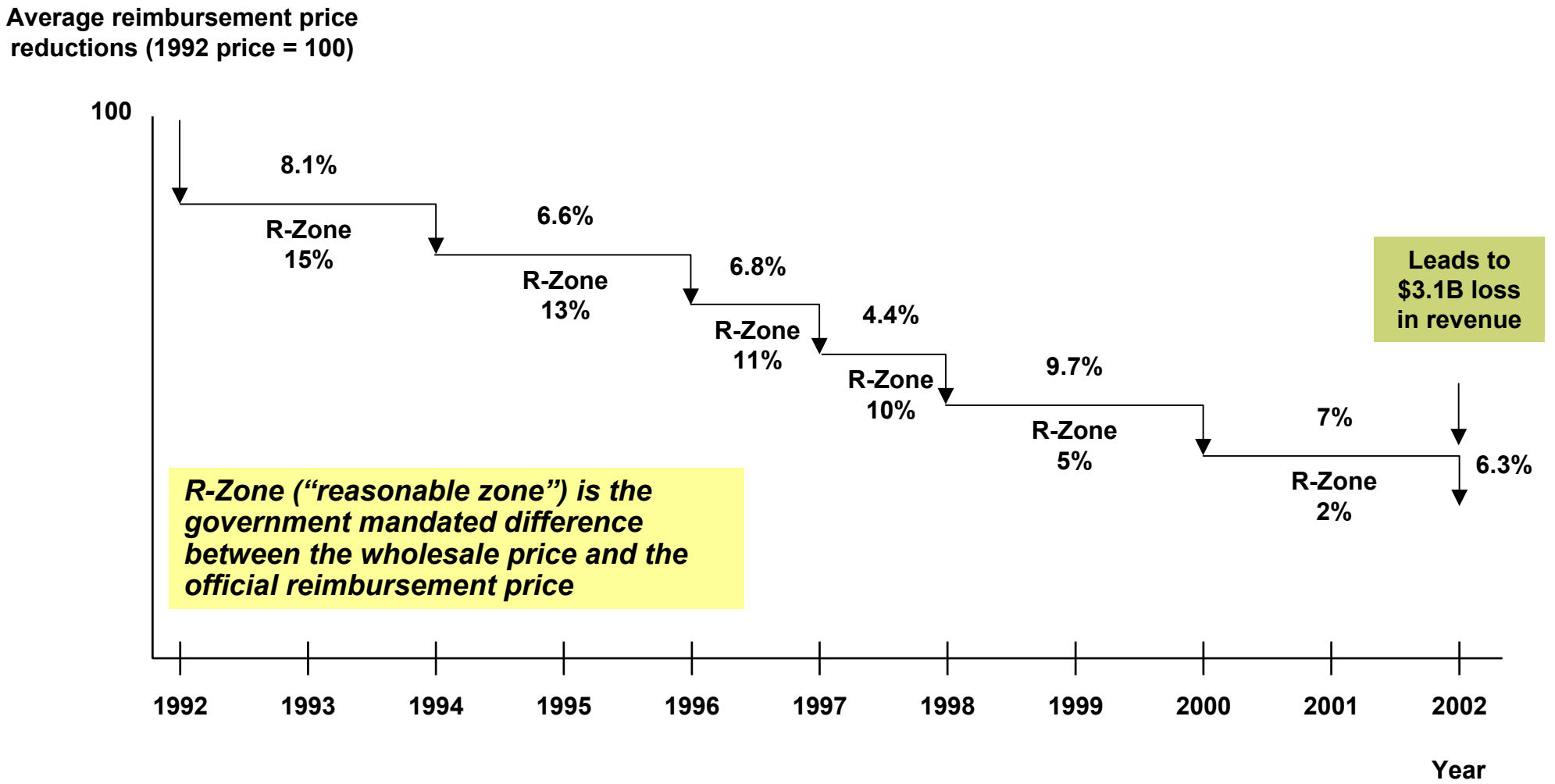
Sources: "Japan – Pricing and Reimbursement of Pharrmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "Pricing of Prescription Drugs,"U.S. International Trade Commission, 2000; "World Pharmaceutical Markets – Japan," Epsicom Business Intelligence, March 2003 ; "Pharmaceutical Administration and Regulations in Japan," JPMA 2003

TIMELINE OF PHARMACEUTICAL CONTROLS IN JAPAN (II)

1998	• **Prices of nearly 1600 prescription drugs reduced by 10%** • **R-zone reduced to 2-5% in a gradual manner**
2000	• **A maximum 2% R-zone is introduced, brings reimbursed drug prices down to average market price** • **Of 14,000 drugs, 8,935 drugs had their prices cut; prices cut by an average of 7%; only 61 drugs received price increases**
2002	• **Price cuts of 6.3% leading to a U.S. $3.1 billion loss in revenue to the domestic pharmaceutical industry**
2002	• **Drug approval system changed from manufacturing approval to marketing approval**

Sources: "Japan – Pricing and Reimbursement of Pharrmaceuticals," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm; "Pricing of Prescription Drugs,"U.S. International Trade Commission, 2000; "World Pharmaceutical Markets – Japan," Epsicom Business Intelligence, March 2003 ; "Pharmaceutical Administration and Regulations in Japan," JPMA 2003

JAPAN HAS MANDATED PRICE REDUCTIONS THROUGH 1990s



Source: "Pharmaceutical Administration and Regulations in Japan", JPMA 2003; "World Pharmaceutical Markets – Japan", Epsicom Business Intelligence, March 2003; OECD Health Data 2003

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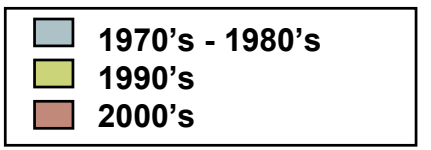
Demand	• Co-payments/co-insurance • Generic substitution incentives(2)		• Prescribing guidelines • Positive/negative lists • Formularies • Parallel import dispensing targets/incentives		• Physician Rx budgets • Physician healthcare budgets

(1) The reference price is the national list price; actual reimbursed prices set at provincial level; reimbursed prices typically lower than list prices
(2) All provinces except Quebec mandate generic substitution
(3) Some provincial formularies use price freezes to control generic drug prices

Sources: Annual Report 2002 of the Patented Medicine Prices Review Board, Canada; "Canada – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm



CANADIAN PHARMACEUTICAL CONTROLS (I)

Drug type	Regulating body	Market intervention
Patented Drugs	Patented Medicine Prices Review Board (PMPRB)	• Regulates "factory-gate" price of each patented product including each strength of each dosage form • Patentees required to report information on prices and sales of new patented medicines within 60 days of date of first sale and to continue to file detailed information on prices and sales every six months while drug remains patented • PMPRB guidelines on price as follows - prices for most new patented drugs limited such that cost of therapy for new drug does not exceed cost of therapy for existing drugs in same therapeutic class in Canada - prices of breakthrough patented drugs and those which bring a substantial improvement are generally limited to the median of the prices charged for the same drug in other industrialized countries – France, Germany, Italy, Sweden, Switzerland, U.K. and U.S. - price increases for existing patented medicines limited to changes in CPI - price of patented drug in Canada cannot exceed the highest price for same drug in the countries listed above • PMPRB conducts investigation and takes remedial measures if price of a patented drug exceeds guidelines • The Patented Medicine Price Index (PMPI) has mostly declined since 1993

Sources: Annual Report 2002 of the Patented Medicine Prices Review Board, Canada; "Canada – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

CANADIAN PHARMACEUTICAL CONTROLS (II)

Drug type	Regulating body	Market intervention
Patented Drugs	**Provincial regulations**	• **In addition to price regulation by PMPRB, provinces have their own regulations** • **Except British Columbia, the lowest drug price in one province applies to all others** • **British Columbia uses reference pricing, i.e. fixed reimbursement levels for drugs in a reference category** • **Most provinces have co-payment plans: 20-35% of the price of the drugs, or flat payments per prescription** • **Most provinces make extensive use of formularies, mostly in the form of positive lists of drugs that can be reimbursed** • **In some provinces, maximum reimbursement set to the level of the lowest priced alternative** • **Some provincial programs do not cover everybody; there are eligibility requirements to be covered under most provincial programs; for example, Ontario covers people including:** - **people aged 65 and older** - **residents of long term care facilities** - **residents of Homes for Special Care** - **people receiving professional services under the home care program**

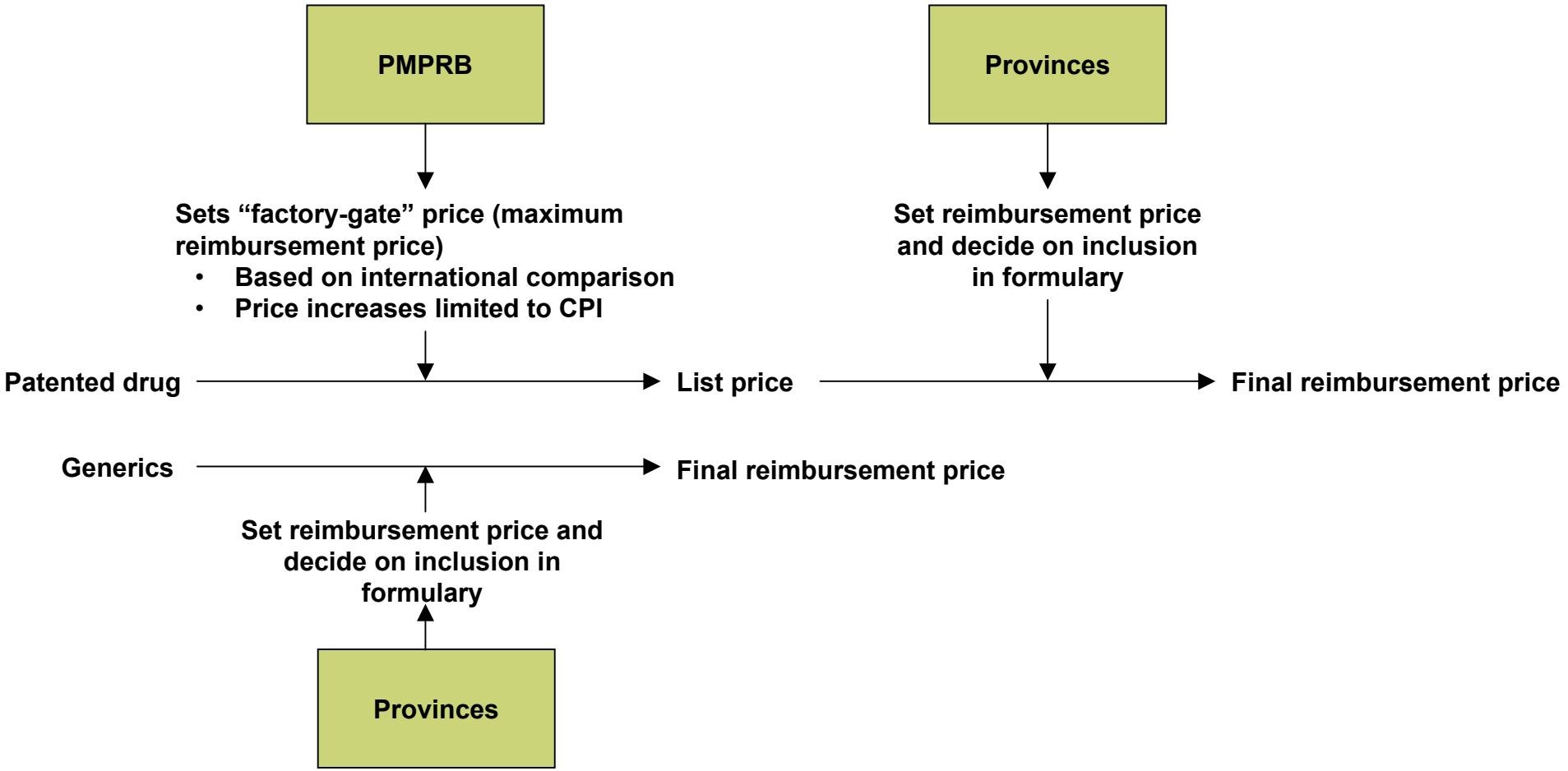
Sources: Annual Report 2002 of the Patented Medicine Prices Review Board, Canada; "Canada – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

CANADIAN PHARMACEUTICAL CONTROLS (III)

Drug type	Regulating body	Market intervention
Generics	Provincial regulations	• Generics prices established in provincial formulary pricing policies • Most provinces buy drugs at best available price; lowest bid from manufacturers is made the claim rate • All provinces, except Quebec have laws mandating generic substitution • In Ontario, first generic has to be 30% cheaper, and subsequent entrants must be priced a further 10% lower • Some provinces also employ price freezes to control generic drug prices • Provincial formularies and prescribing guidelines favor generics • Most provinces specify that they will only pay the lowest available price in Canada; leads to a de facto single market price for generics (an exception is Saskatchewan)

Sources: Annual Report 2002 of the Patented Medicine Prices Review Board, Canada; "Canada – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

IN CANADA, LIST PRICE SET FEDERALLY WHILE PROVINCES SET REIMBURSEMENT PRICES AND CREATE FORMULARIES



Note: PMPRB – Patented Medicine Prices Review Board; CPI – Consumer Price Index

Sources: Annual Report 2002 of the Patented Medicine Prices Review Board, Canada; "Canada – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

TIMELINE OF PHARMACEUTICAL CONTROLS IN CANADA

1987
- **The Patented Medicines Prices Review Board set up by Parliament to regulate prices of patented medicines**

1993
- **Ontario Drug Benefit List: 134 drugs dropped from reimbursable list**
- **Some provincial formularies also employ price freezes to control generic drug prices**

1994
- **PMPRB mandates that the price of patented drugs cannot be greater than the price in other developed countries; any price increase may not be greater than 1.5 times the percentage increase in the CPI**
- **In Ontario, first generic has to be 25% cheaper, and subsequent entrants must be priced a further 10% lower, has led to much lower prices**

1995
- **88% of Canadians have some form of coverage for Rx, 62% covered under private plans, 19% under provincial plans, 7% under both**
- **Monitoring of patent product prices for the whole length of the term (17 if patented before 1987, 20 after) even if the drug is taken off patent by the manufacturer**

1997
- **45% of pharmaceutical market reimbursed by provincial plans, up from 28% in previous year**

Sources: Annual Report 2002 of the Patented Medicine Prices Review Board, Canada; "Canada – Pharmaceutical Pricing and Reimbursement," LSE study, http://pharmacos.eudra.org/F3/g10/p6.htm

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U.S. PRIVATE PAYERS USE BROAD ARRAYS OF TOOLS TO MANAGE DRUG COSTS

Target	Drug cost management levers	Description
Manu-facturers	• Concentration of buying power (e.g., PBMs)	• Pool drug purchasing volume to increase negotiating leverage
Physicians	• Formularies • Prior authorization • Physician incentives/capitation • Generic substitution • Counter-detailing • Disease management • Step therapy	• List of preferred drugs • Pre-approval for specific high cost branded drugs • Allowable monthly budget per patient • Physician notified of generic alternative • Plan-sponsored info on value/cost • Protocol and treatment guidelines • Initial therapy with least expensive option
Enrollee	• Co-insurance • Tiered co-pays • Mail-order substitution • Script limits • Covered lowest-cost drug	• Patient cost sharing • Co-pay increases with drug cost to payer • Encourage use of mail-order to lower cost • Monthly limit on total scripts per patient • Only lowest-cost drug covered; all other drugs available only at patient expense

THE U.S. PHARMACEUTICAL MARKET (I)

Drug type	Regulating body	Market description
All Rx	Private sector purchasers – e.g., health insurance companies or PBMs (pharmacy-benefits managers)	• Drug prices established through negotiations between pharmaceutical companies and private sector purchasers • Same Rx sold at different prices to different purchasers, generally based on volume • Purchasers use volume-control techniques such as formularies and tiered co-payments to influence physician prescribing and enrollee purchasing practices • Some HMOs use techniques such as requiring prior authorization or step-therapy to limit use of selected pharmaceuticals – although these measures have become less popular over time • HMOs increasingly making use of pharmacoeconomic criteria
All Rx	Medicaid (state-administered; funded by state and federal government)	• Formularies, co-pays • Direct negotiations with manufacturers for discounts and volume rebates • Legislated minimal discount of 15% • Best-price requirement (relative to private sales, not TriCare sales)

THE U.S. PHARMACEUTICAL MARKET (II)

Drug type	Regulating body	Market description
All Rx purchased through federal agencies, e.g., TriCare	Federal government	• Federal laws require manufacturers to offer federal departments discounts on Rx • Tricare agencies are guaranteed 'best-price' • Under federal law, manufacturer must sell brand-name drugs to federal purchasers at the Federal Ceiling Price (FCP) of at least 24% lower than NFAMP (Non-Federal Average Manufacturer Price)
Provider-administered drugs	Medicare	• 20% co-pay for provider administered drugs
All other Rx	Medicare	• Prescription coverage will be administered through private health plans competing for consumer business and will use techniques such as formularies and co-pays • Government explicitly forbidden from interfering in price negotiations (Rx benefit begins in 2006)

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SURVEY OF GOVERNMENT INTERVENTIONS IN REST OF OECD

The intent of the following slides is to

- **Briefly review the broad policies deployed in the remaining OECD countries**
- **Identify whether there are similar patterns of government intervention found in the countries studied in detail**

Further, the summary profiles are based on a brief review of publicly available studies summarizing policies in each country

Therefore, these summaries are not exhaustive and some elements of each country's policies may not be fully described.

GOVERNMENT INTERVENTIONS CONTINUE TO PROLIFERATE (I)

			Australia	Austria	Belgium	Czech Republic	Denmark	Finland	Greece
SUPPLY	Price	•Cost plus pricing							
		•Pharmacoeconomic criteria							
		•Molecule/class reference pricing							
		•Cross-country reference pricing							
		•Mandatory rebates							
		•Price cuts/price freezes							
	Volume	•Marketing spend limits							
		•Product volume caps							
	Spending	•Profit controls							
		•Revenue controls							
DEMAND	Price	•Co-payments/co-insurance							
		•Generic substitution incentives							
	Volume	•Prescribing guidelines							
		•Positive/negative lists							
		•Formularies							
		•Parallel import dispensing targets/ incentives							
	Spending	•Physician Rx budgets							
		• Physician healthcare budgets							

Note: Interventions noted above may not be exhaustive

GOVERNMENT INTERVENTIONS CONTINUE TO PROLIFERATE (II)

			Hungary	Iceland	Ireland	Italy	Korea	Luxembourg	Mexico
SUPPLY	Price	• Cost plus pricing							
		• Pharmacoeconomic criteria				■			■
		• Molecule/class reference pricing		■		■		■	
		• Cross-country reference pricing			■	■		■	■
		• Mandatory rebates							
		• Price cuts/price freezes			■		■		
	Volume	• Marketing spend limits							
		• Product volume caps							
	Spending	• Profit controls							
		• Revenue controls							
DEMAND	Price	• Co-payments/co-insurance	■	■	■	■	■	■	■
		• Generic substitution incentives	■						
	Volume	• Prescribing guidelines		■		■		■	
		• Positive/negative lists	■	■	■	■	■	■	■
		• Formularies		■				■	
		• Parallel import dispensing targets/ incentives							
	Spending	• Physician Rx budgets			■				
		• Physician healthcare budgets							

Note: Interventions noted above may not be exhaustive

GOVERNMENT INTERVENTIONS CONTINUE TO PROLIFERATE (III)

			Netherlands	New Zealand	Norway	Portugal	Slovakia	Sweden	Switzerland	Turkey
SUPPLY	Price	•Cost plus pricing								■
		•Pharmacoeconomic criteria		■		■		■	■	
		•Molecule/class reference pricing	■	■		■			■	
		•Cross-country reference pricing	■		■	■		■	■	
		•Mandatory rebates								
		•Price cuts/price freezes								
	Volume	•Marketing spend limits								
		•Product volume caps								
	Spending	•Profit controls								
		•Revenue controls								
DEMAND	Price	•Co-payments/co-insurance		■	■	■	■	■	■	■
		•Generic substitution incentives	■	■	■	■			■	
	Volume	•Prescribing guidelines		■		■	■			
		•Positive/negative lists	■	■	■	■	■	■	■	■
		•Formularies		■	■	■	■	■		
		•Parallel import dispensing targets/ incentives	■							
	Spending	•Physician Rx budgets					■			
		•Physician healthcare budgets								

Note: Interventions noted above may not be exhaustive

INTERVENTIONS IN AUSTRALIA

Uses positive/negative list, patient co-payments, prescribing guidelines, generic substitution incentives, pharmacoeconomic criteria, and molecule/class reference pricing

The PBS (Pharmaceutical Benefits Scheme) is responsible for subsidizing pharmaceuticals based on the Pharmaceutical Benefits Pricing Authority price recommendations to the Minister for Health

Supports a Pharmaceutical Investment Program(PIP), participating companies receive partial compensation for the effects of price and volume constraints under the PBS in exchange for performing additional "Production Value Added and Research and Development activities," compensation comes from increases in the prices of PBS products selected by the participating companies

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Australia, 2002 Pharmaceutical Benefits Pricing Authority Annual Report, 2003

INTERVENTIONS IN AUSTRIA

Uses positive list, patient co-payments, prescribing guidelines, physician Rx budget (only if persistently above peers), cost plus pricing and pharmacoeconomic criteria

Practitioner guidelines defined by the ASVG (General Social Security Act) and reimbursement status set by *Krankenkassen*

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Austria, 2001, and LSE Country Profile, 1999

INTERVENTIONS IN BELGIUM

Uses positive/negative list, patient co-payments, and pharmacoeconomic criteria

Have used reimbursement freezes and cuts

New products must first be registered with the Ministry of Public Health

The Ministry of Economic Affair's Pricing Committee for Pharmaceutical Specialties sets the maximum prices

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Belgium, 2000

INTERVENTIONS IN THE CZECH REPUBLIC

Uses positive list, patient co-payments, formularies, cost plus pricing, and reference pricing calculated on the basis of the amount of substance contained in each product

Physician Rx budgets imposed by health insurance funds

The Ministry of Health along with the Ministry of Finance and the GHIF (General Health Insurance Fund) license pharmaceuticals and allocate them into reimbursement categories

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Czech Republic, 2000

INTERVENTIONS IN DENMARK

Uses positive/negative list, patient co-payments, pharmacy profit controls, formularies, generic substitution incentives, and pharmacoeconomic criteria

Prescribing guidelines influenced at a county not national level

Have used price freezes and price cuts

Practice guidelines established by the Danish College of General Practice, and the Danish Medicines Agency approves pharmaceuticals and determines their reimbursement status

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Denmark, 2001

INTERVENTIONS IN FINLAND

Uses cost plus pricing, formularies, pharmacy profit controls, prescribing guidelines, positive list, and patient co-payments

The National Agency of Medicines admits new products to the market

Pharmaceuticals Pricing Board deals with the pricing of reimbursed drugs

Non-reimbursement drugs can be freely priced

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Finland, 2001

INTERVENTIONS IN GREECE

Uses cost plus pricing, molecule/class and cross country referencing, positive list, and patient co-payments

The reference price of imported drugs is based on the lowest of either the ex-factory price of the drug in Europe or the ex- factory price from the country of origin

A pharmaceutical will not be approved unless it is marketed in at least 1 European country, and will not be reimbursable unless it is marketed in at least 3 of the following 6 countries- France, Germany, Sweden, Switzerland, USA, and U.K.

The Minister of Development is responsible for pharmaceutical pricing through a 9 member pricing committee

Source: LSE Country Profile, 2000

INTERVENTIONS IN HUNGARY

Uses national Rx subsidy budget, patient co-payments, generic substitution incentives, and positive/negative list

The OGYI (National Institute of Pharmacy) administers drug registration

National Health Insurance Fund determines subsidies, prices, and marketing practices,

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Hungary, 1999 CEECICnet "Pharmaceutical and Medical Products" 2002

INTERVENTIONS IN ICELAND

Uses positive/negative list, patient co-payments, molecule/class reference pricing, formularies, and prescribing guidelines

Registration and deregistration of pharmaceuticals regulated by the IMCA (Icelandic Medicines Control Agency)

The wholesale and retail prices of pharmaceuticals are determined by the Pharmaceuticals Pricing Committee reimbursement decisions are made by an expert committee consisting of doctors, pharmacists, and Ministry members

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Iceland, 2003

INTERVENTIONS IN IRELAND

Uses positive/negative list, patient co-payments, cross country reference pricing, and physician Rx budgets

Use price freezes, but during this will allow a few products to modulate pricing with the commitment that the average annual price will be equal to the freeze price

Maximum wholesale prices for new products set based on the wholesale prices in 5 reference countries-Denmark, France, Germany, Netherlands, and the U.K.. Price may be no more than the lesser of either the U.K. wholesale price or the average wholesale prices in the reference countries

Source: LSE Country Profile, 2000

INTERVENTIONS IN ITALY

Uses positive/negative list, patient co-payments, prescription guidelines, pharmacoeconomic criteria, molecule/class, cross country, and cheapest generic drug reference pricing

Reimbursement up to the price of the cheapest generic drug in each category within individual regions (puts pressure on all off-patent and generic products)

Pricing for old products based on Average European Price (AEP)

Prices for new and innovative drugs set through negotiation

Pricing and reimbursement regulated by CUF (Commissione Unica sul Farmaco, Drug Committee)

Source: ABN-AMRO Country Profile, 16 October 2003 and Credit Suisse First Boston research "Pharmaceutical Distribution in Europe," Jan. 2004

INTERVENTIONS IN KOREA

Uses positive/negative list, patient co-payments

Korean Ministry of Health and Welfare sets reimbursement levels for drugs on the positive list and shows favoritism toward domestic drugs

The Korean Pharmaceutical Manufacturers Association (KPMA), the Korean Pharmaceutical Traders Association (KPTA) and the Korean Pharmacists Association (KPA) set prices for drugs not included on the positive list

Have used price cuts, specifically in March 2001

Source: Pacific Bridge Medical " 2000 Regulatory Update: South Korea's Pharmaceutical market" Jo, Jaigoog and Kwang Choi "Health Policy in Korea," 2002

INTERVENTIONS IN LUXEMBOURG

Uses positive/negative list, patient co-payments, prescription guidelines, formulary, molecule/class and cross country reference pricing

Pricing based on those used in the country of origin, which is normally Belgium, France, or Germany

New drugs authorized by the Minister of Health as the Union of Sickness Funds determines reimbursement percentages

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Luxembourg, 1999

INTERVENTIONS IN MEXICO

Uses positive/negative list, pharmacoeconomic criteria, cross country reference pricing, and patient co-payment

The Mexican government is the largest domestic purchaser of pharmaceuticals; it buys primarily copy and generic drugs and sets the prices

Patented products are mainly sold in the private sector, but the government must approve all final prices

To justify the suggested price for a patented product manufacturers must provide comparisons of the price of the product in other countries

Source: U.S. International Trade Commission paper "Pricing of Prescription Drugs" 2000
Pharma Prognosis International 1999-Mexico, IMS Health

INTERVENTIONS IN THE NETHERLANDS

Uses positive/negative list, generic substitution incentives, parallel import dispensing incentives, and maximum reimbursement system based on molecule/class and cross-country reference pricing

Reimbursement system entices wholesalers to offer volume discounts to pharmacies and the government now mandates that the pharmacies partially pass this savings along to insurers

Maximum reimbursement system sets maximum price reimbursed for all drugs categorized as equivalent, if a pharmacist dispenses a drug with a lower price they are able to keep 1/3 of the price difference

Prices referenced twice a year against the prices in the U.K., Belgium, France, and Germany

Source: ABN-AMRO Country Profile, 16 October 2003 and Credit Suisse First Boston research "Pharmaceutical Distribution in Europe," Jan. 2004

INTERVENTIONS IN NEW ZEALAND

Uses positive/negative list, patient co-payments, prescribing guidelines, formularies, generic substitution incentives, pharmacoeconomic criteria, and molecule/class reference pricing

Medsafe (New Zealand Medicines and Medical Devices Safety Authority) ensures that medicines are safe and effective, while PHARMAC (Pharmaceutical Management Agency) decides on the subsidy levels of approved drugs

Source: European Observatory on Health Care Systems document, HiT Country Profiles- New Zealand, 2002

INTERVENTIONS IN NORWAY

Uses a positive list, patient co-payments, generic substitution incentives, cross country referencing and formularies

Pricing set to equal the average of the three lowest package prices found in nine European countries (Sweden, Finland, Denmark, Germany, U.K., Netherlands, Austria, Belgium, and Ireland)

The Norwegian Ministry of Health and Social Affairs is responsible for supervising pharmaceuticals, the Medicines Control Authority sets prices, and the Board of Health supervises the drugs from the manufacturers to the end users

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Norway, 2000
Credit Suisse First Boston research "Pharmaceutical Distribution in Europe," Jan. 2004

INTERVENTIONS IN PORTUGAL

Uses positive/negative list, molecule/class and cross country reference pricing, pharmacoeconomic criteria, patient co-payments, formularies, generic substitution incentives and prescribing guidelines

Prices based on the lowest of France, Italy, and Spain and frequently involve negotiation with the authorities

INFARMED (National Institute of Pharmaceuticals and Medicines) approves drugs to be reimbursed and sets co-payment levels

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Portugal, 2004

INTERVENTIONS IN SLOVAKIA

Uses positive/negative list, patient co-payments, prescribing guidelines, physician Rx budgets mandated by insurers, and formularies

Patient co-payment based on a fixed ratio of consumer to insurance company payment

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Slovakia, 2000, The Slovakia Spectator "Prices Worry Druggists" March 1, 2004

INTERVENTIONS IN SWEDEN

Uses positive/negative list, patient co-payments, formularies, pharmacoeconomic criteria, and cross country reference pricing

Reimbursement price based on comparison among Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Norway, Switzerland, and the U.K.

The Drug Affair Division within the RVF (National Insurance Board) is responsible for setting reimbursement prices

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Sweden, 2001

INTERVENTIONS IN SWITZERLAND

Uses positive/negative list, patient co-payments, pharmacoeconomic criteria, molecule/class and cross country reference pricing, and generic incentives

Prices for new drugs set equal to the average of equivalent products in Denmark, Germany and the Netherlands

As of January 2002, pharmaceutical pricing in Switzerland has been regulated by Swissmedic, taking over from the Intercantonal Office for the Control of Medicines (IKS)

The system of reimbursement is regulated by the Bundesamt fur Sozialversicherung - BSV (Federal Authority of Social Insurance)

Prices for new drugs set equal to the average of equivalent products in Denmark, Germany and the Netherlands

Source: ESPICOM BUSINESS INTELLIGENCE Pharmaceuticals "World Pharmaceutical Markets – Switzerland" June 2003
Swissmedic (Swiss Agency for Therapeutic Products) website, 2004

INTERVENTIONS IN TURKEY

Uses cost plus pricing by the government

Each social insurance organization has negative lists and co-payments

Government has an unofficial list of essential drugs but it has no practical applications, all social insurance organizations have their own negative lists for prescriptions

Pharmaceutical industry regulated by the government with the Ministry of Health setting prices

Source: European Observatory on Health Care Systems document, HiT Country Profiles- Turkey, 2002

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DEFINITIONS OF INTERVENTIONS USED TO CONTAIN COSTS
Supply

	Policy Instrument	Description
Price	• Cost plus pricing	• Controls that set price at a certain margin above cost, irrespective of how cost is calculated (marginal cost, average cost)
	• Pharmacoeconomic criteria	• Pricing based on therapeutic benefit, innovativeness, and/or overall economic benefit (cost-effectiveness)
	• Molecule/class reference pricing	• Pricing/reimbursement based on the costs of drugs with same active ingredient or similar therapeutic benefit
	• Cross-country reference pricing	• Pricing based on prices of same/similar drugs in other countries
	• Mandatory rebates	• Government-mandated discounts or rebates on drugs sold to the national health service or bought by national health insurance; sometimes take the form of a 'voluntary' contribution to the government
	• Price cut mandates/price freezes	• Government mandated price cuts on select or all drugs • Government mandated price freezes for a fixed period of time
Volume	• Marketing spend limits	• Limits imposed on a firm's spending on sales and marketing
	• Product volume caps	• Limits imposed on the volume of drugs sold that will be reimbursed
Spending	• Profit controls	• Explicit caps on profits of overall company (does not apply to profit on any given drug)
	• Revenue controls	• Explicit caps on a firm's overall revenues from its product portfolio

DEFINITIONS OF INTERVENTIONS USED TO CONTAIN COSTS
Demand

	Policy Instrument	Description
Price	• Co-payments/co-insurance	• Co-payments/insurance contributions by the patient
	• Generic substitution incentives	• Active incentives for generic substitution (GS); GS is not included as an intervention if a country only allows, but does not actively encourage, GS
Volume	• Prescribing guidelines	• Mandatory or advisory prescribing guidelines given to doctors
	• Positive/negative lists	• Positive list contains reimbursable drugs, while the negative list contains drugs that will not be reimbursed; these lists are usually the same throughout a country
	• Formularies	• A list of drugs that would be reimbursed in full or partially; formularies can be a subset of the positive list (can be used to influence prescribing among approved drugs)
	• Parallel import dispensing targets/ incentives	• Incentives to the patient, doctors or the pharmacies to increase the consumption of parallel imports. Is not included as a category, if the government only allows PI but does not do anything to actively promote it
Spending	• Physician Rx budgets	• Caps on doctors' Rx budgets; physicians can be penalized if exceed cap (but in practice rarely enforced)
	• Physician healthcare budgets	• Caps on doctors' total healthcare budgets

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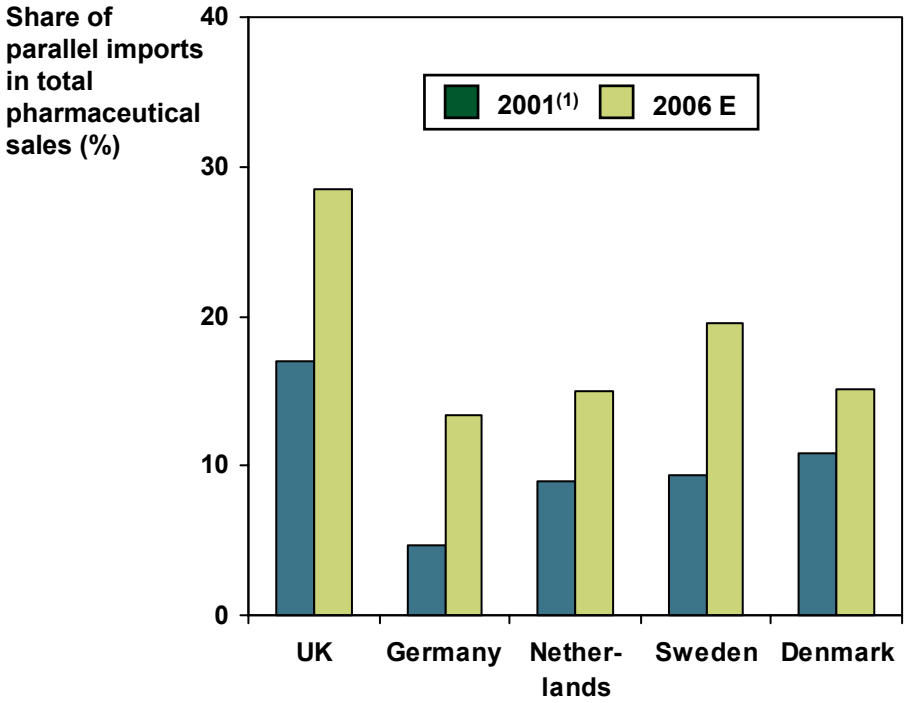
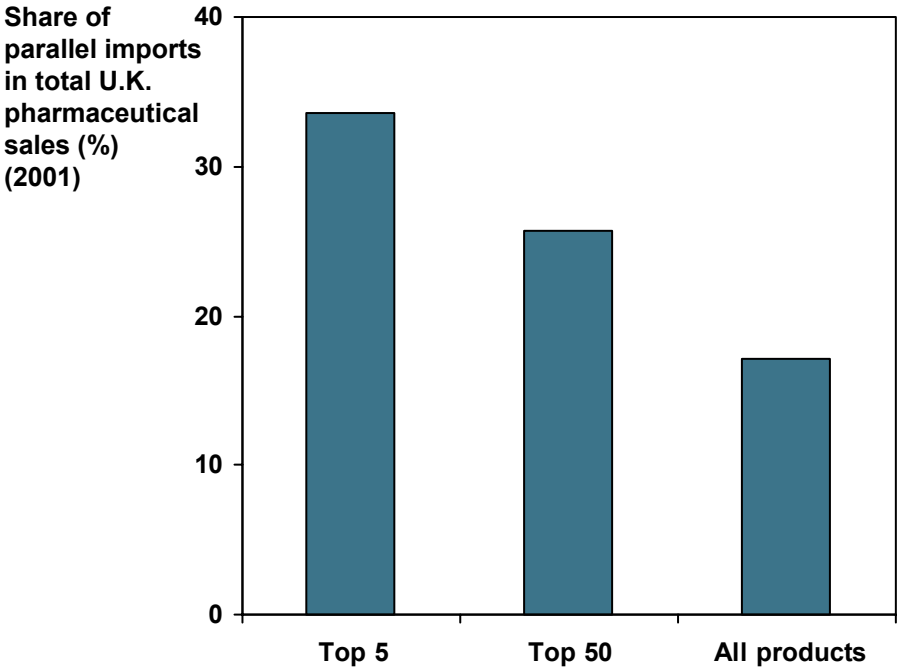
IMPACT OF MARKET INTERVENTIONS TRANSMITTED ACROSS COUNTRIES

European Parallel Trade

Parallel trade expected to increase



Blockbusters disproportionably affected by parallel trade



Sources: 2001 - EFPIA Member Associations (2000 data for Denmark and Netherlands); 2006 - The Global Parallel Trade Outlook, Reuter's Business Insight
IMS Health BPI December 2001

CROSS COUNTRY REFERENCE PRICING CAUSES GOVERNMENT INTERVENTIONS TO PROPAGATE ACROSS COUNTRIES

Reference country	Country setting prices									
	Ireland	Italy(1)	Luxembourg	Netherlands	Norway	Portugal	Sweden	Switzerland	Canada	Japan
Austria					X		X			
Belgium			X	X	X		X			
Denmark	X				X		X	X		
Finland					X		X			
France	X		X	X		X	X		X	X
Germany	X		X	X	X		X	X	X	X
Ireland					X					
Italy						X			X	
Netherlands	X				X		X	X		
Norway							X			
Spain						X				
Sweden					X				X	
Switzerland							X		X	
U.K.	X			X	X		X		X	X
U.S.										
Country of origin			X			X			X	X

Parallel imports provide another means to use prices set by governments in other countries

Note: Many countries use price comparisons as part of a direct price setting discussion, the above chart only summarizes explicit price comparison rules
(1) Pricing for off patent products based on Average European Price (AEP), prices for new and innovative drugs set through negotiation
Source: LSE paper "Overview of Pharmaceutical Pricing and Reimbursement Regulation in Europe" 2001, and sources listed on country specific pages