Session 31, Pharmacy Pricing - US Policy and Global Perspective

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The Future Policy Framework for Pharmacy

Society of Actuaries Health Meeting
Session 031: Pharmacy Pricing –
US Policy and Global Perspective

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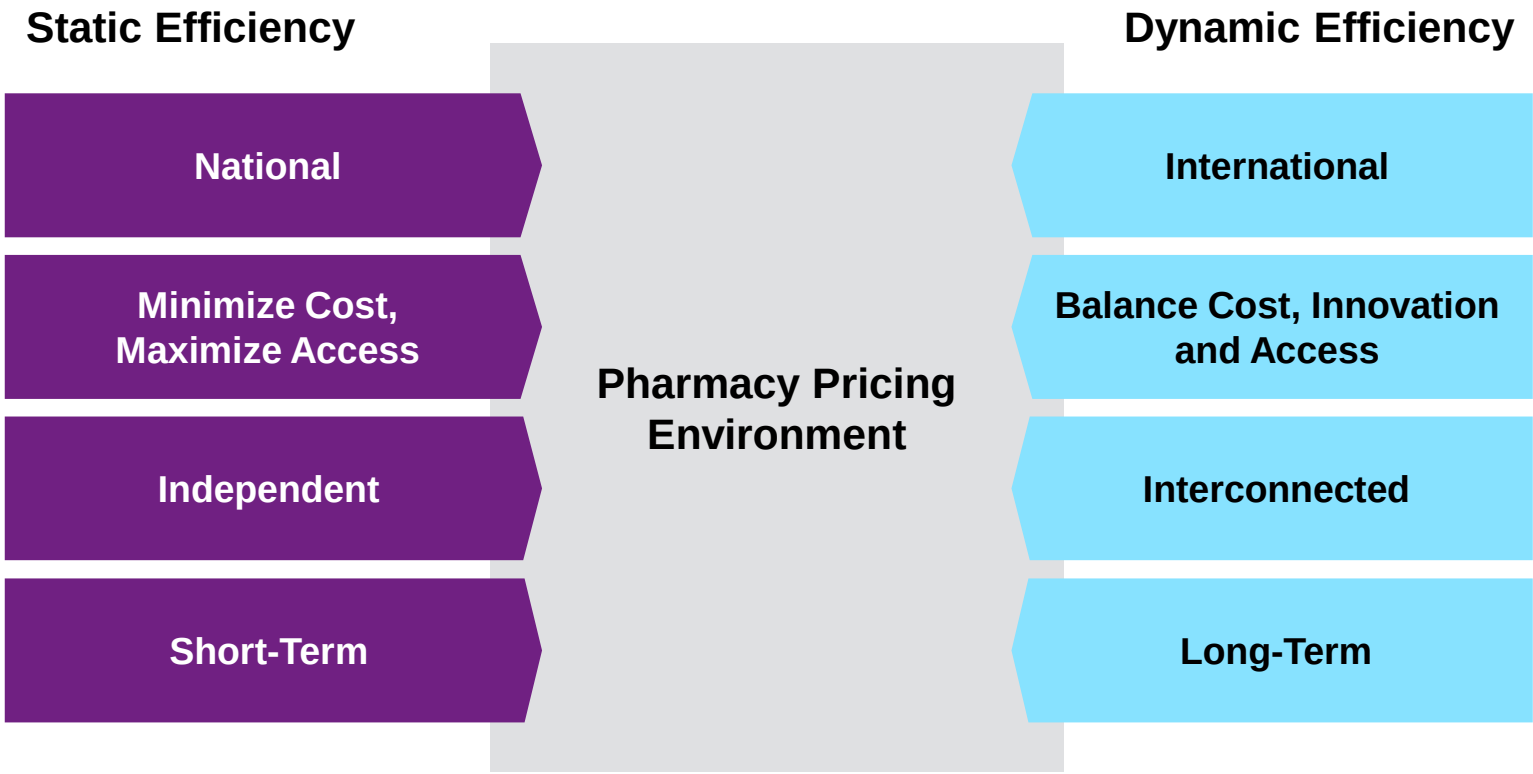
Static and Dynamic Efficiency

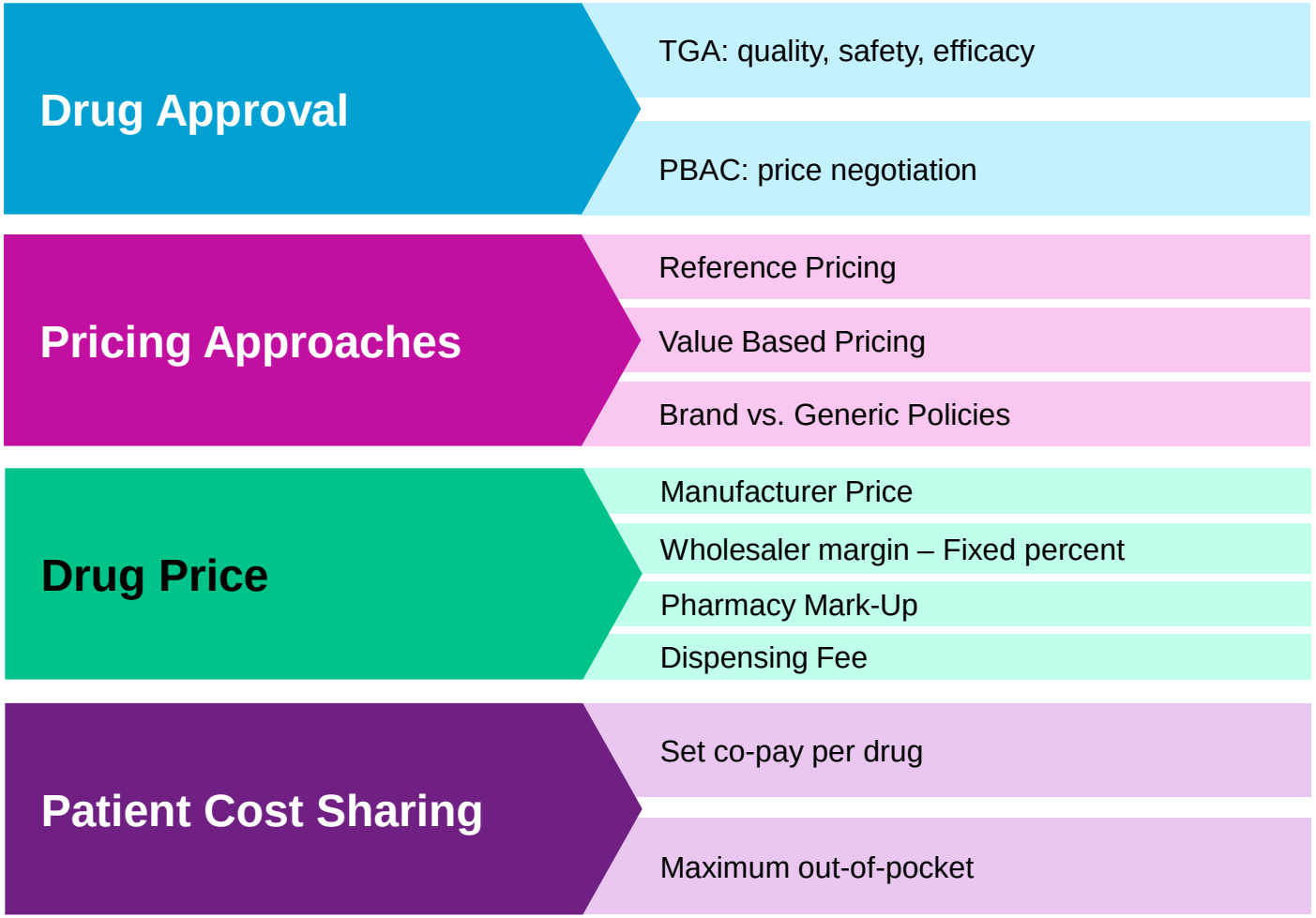


Proportion of World Drug Spend by Country

Country	% of World Drug Spend 2015
United States	36.1%
Japan	9.9%
Germany	6.0%
France	4.1%
Italy	3.6%
United Kingdom	3.1%
Canada	2.6%
Korea	2.5%
All Other OECD[1]	12.0%
All Non-OECD	20.0%[2]

1. Based on OECD31 countries: US, Japan, Germany, France, Italy, UK, Canada, Korea, Spain, Australia, Poland, Switzerland, Belgium, Netherlands, Greece, Austria, Hungary, Sweden, Portugal, Czech Republic, Ireland, Slovak Republic, Finland, Israel, Norway, Denmark, Slovenia, Latvia, Estonia, Luxembourg and Iceland.
2. All Non-OECD spending is estimated based on OECD and worldwide drug spending figures.

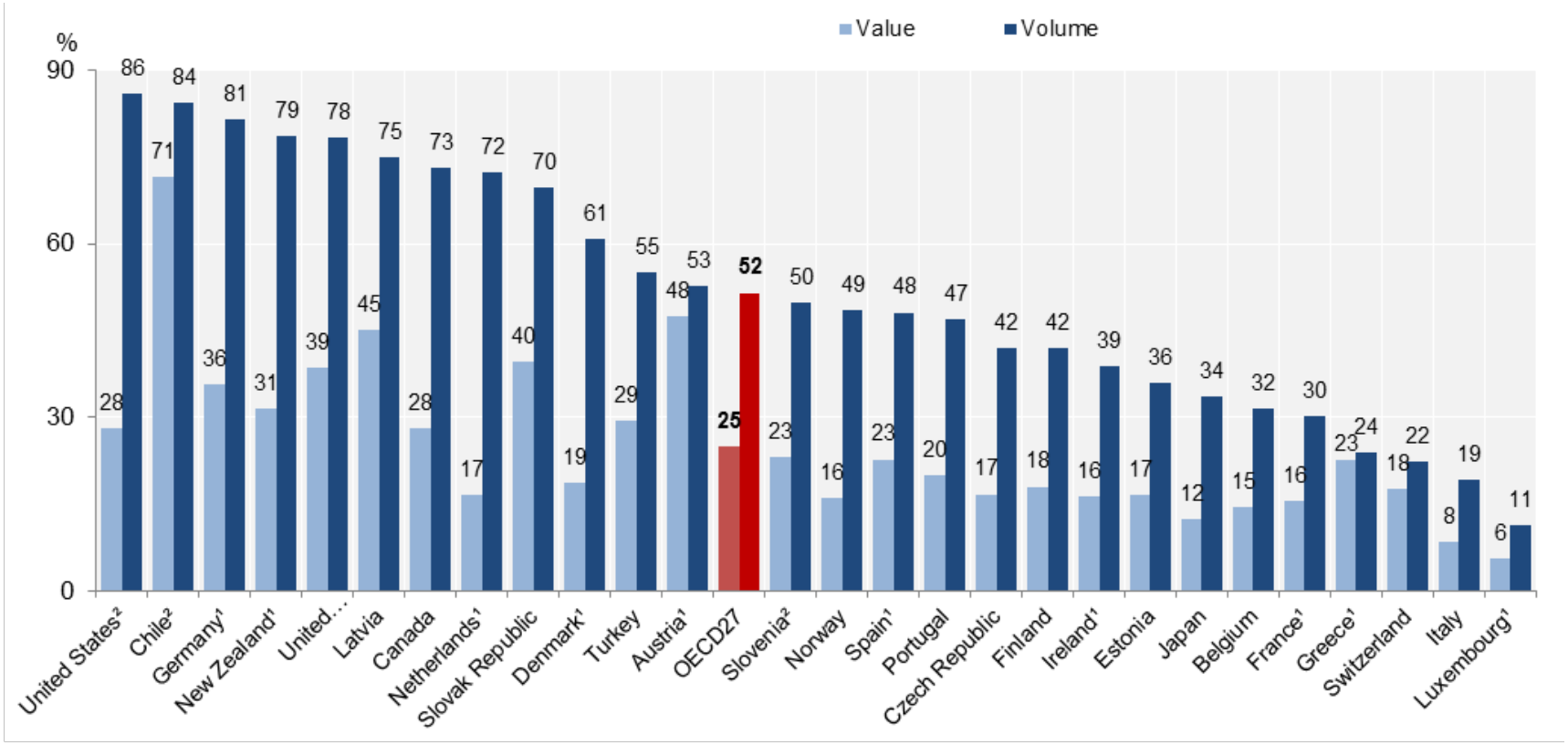
Australian Pharmacy Pricing



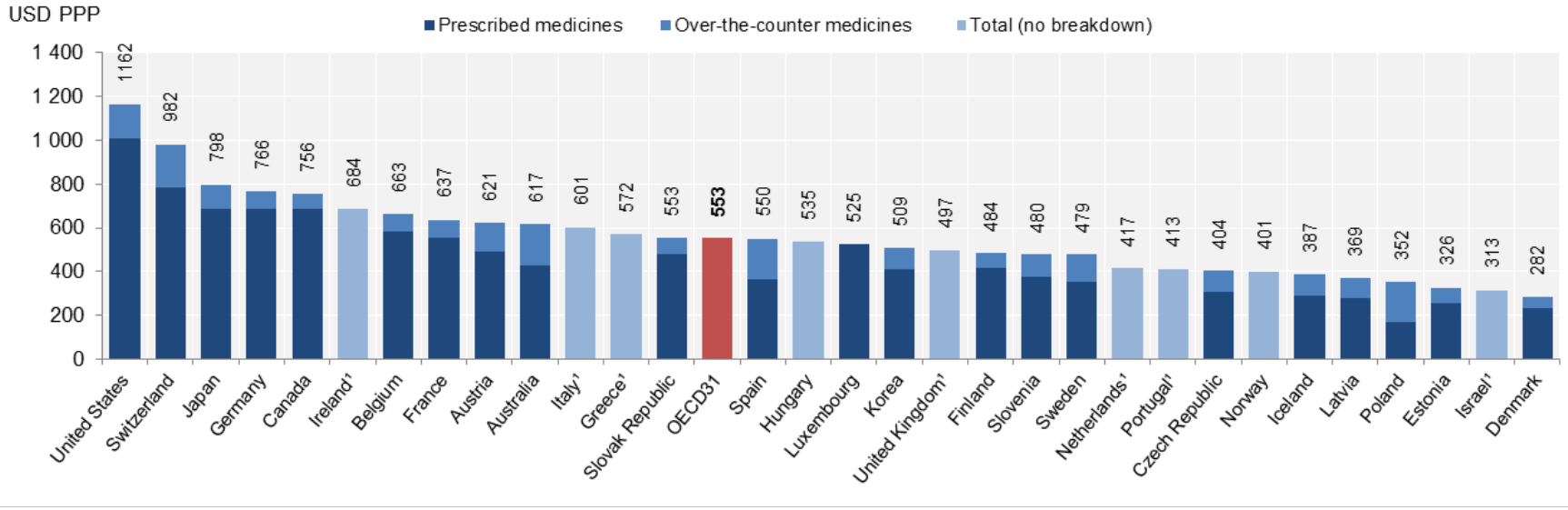
Common International Pharmacy Pricing Features

- National and State/Local Roles
- Separation of Authorization, Pricing and Reimbursement
- **National Pricing Negotiation**
- Different Brand and Generic Pricing Approaches
- **Wholesaler and Pharmacy Mark-Up Regulation**
- Different Inpatient and Outpatient Approaches
- Limited Price Transparency
- Reference Pricing and Value Pricing
- Point-of-Sale Cost Sharing

Share of Generics in the Total Pharmaceutical Market – 2015



Expenditure on Retail Pharmaceuticals per capita – 2015



US Pharmacy Policy Options

- Minimum Value-Based Assessment
- Transparency Requirements
- Public Program Price Negotiations
- Mark-Up Limits / Regulations
- Adoption of Reference Pricing for Medicare / Medicaid
- Generics Regulation Overhaul

Examples of International Drug Cost Strategies

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Discussion Outline

- Negotiation Strategies
- Utilization Strategies
- Prescribing Strategies
- Other Strategies

Discussion Outline

Negotiation Strategies

Utilization Strategies

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Other Strategies

Competitive Bidding

New Zealand

- PHARMAC encourages development of generics by running competitive bidding for the right of exclusive supply, for a limited period, once a drug's patent expires. PHARMAC also enters into risk sharing, multiproduct deals (where pharmaceutical companies lower the costs of certain drugs in their portfolio in exchange for funding for others) with drug companies and arrangements which set expenditure caps or rebates, sharing risk with the drug companies over the likely uptake of a particular medicine [1]
- These bidding and negotiating strategies create savings of more than $300 million per year, which can then be used to subsidize other drugs. To put this in context, the total community pharmaceutical budget is approximately $700 million per year [2,3]
- New Zealand is able to achieve savings because of a combination of program budgeting, tough price negotiations and different procurement mechanisms, such as competitive bidding [4]

Mexico [5]

- Until 2007, the procurement function of the Mexican Institute of Social Security (IMSS) was embedded in 60 separate entities
- The IMSS' centralization efforts, undertaken gradually since 2007, resulted in price reductions of pharmaceuticals and other medical supplies, improved stock management and creation of a centre of excellence in procurement that currently serves all public health care stakeholders
- This resulted in cumulative savings of USD 2.8 billion between 2007 and 2010

1. PHARMAC. About PHARMAC: Important events in 10 PHARMAC's history, 2008. www.pharmac.govt.nz/dhbs/AboutPHARMAC/history.
2. Pharmac. Purchasing Medicines. Wellington: PHARMAC.
3. Costing of Pharmaceuticals in New Zealand for Health Economic Studies: Backgrounder and Protocol for Costing. Burden of Disease Epidemiology, Equity and Cost-Effectiveness programme(BODE³) Technical Report: Number 6. September 2011. Department of Public Health, University of Otago, Wellington
4. Cumming J, Mays N, Daubé J. How New Zealand has contained expenditure on drugs. BMJ 2010;340:c2441.
5. OECD (2017), Tackling Wasteful Spending on Health, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266414-en

Competitive Bidding

Other International Examples of Competitive Bidding

- The Baltic Partnership Agreement sources Bacille Calmette–Guérin vaccine, botulinum and diphtheria antitoxins, direct-acting antiretrovirals for hepatitis C, pandemic vaccines, and tuberculin A [1]
- Current joint procurement/tendering process by England and Scotland of recombinant factors VIII and IX [1]
- European Commission is investigating the possibility of joint procurement for hepatitis C treatments [2,3]
- The BeNeLuxA initiative currently only collaborates to address pricing but the working agreement presents a foundation for joint procurement [4]

1. How can voluntary cross-border collaboration in public procurement improve access to health. World Health Organization 2016 . https://www.eu2017.mt/Documents/Programmes/PB21.pdf
2. Sion J. EU joint procurement for influenza vaccines success and challenges. Presentation at WHO Regional Office for Europe workshop on strategic procurement of new medicines, Copenhagen, Denmark, 22–23 September 2016. Copenhagen: WHO Regional Office for Europe; 2016
3. Medical countermeasures that could be procured in common under the Joint Procurement Agreement. Luxembourg: European Commission; 2014.
4. BENELUXA: First results of multi-country cooperation on medicine price negotiations. The European Public Health Alliance (AISBL) https://epha.org/wp-content/uploads/2017/10/EPHA-Reflection-Paper-Beneluxa-A2M.pdf

Pharmaceutical Purchasing by Hospitals

Scandinavia

- In Denmark and Norway, both countries have operated single procurement agencies for hospital pharmaceuticals (including pharmaceuticals for home therapies) and report significant annual savings, ranging from 30% to over 60% compared to list prices or average wholesale prices in a group of neighbouring countries. Notably, these are based on voluntary participation (i.e., they do not have any legal tools to influence member hospitals' decision making) [1,2]

Greece [3]

- In 2010, government undertook efforts to unify the annual tenders for pharmaceuticals and medical devices carried by public hospitals
- In the first year of operations, the centralised agency – the Health Procurement Committee (EPY) – consisting of only 26 employees, achieved 10% overall price reduction for pharmaceuticals and 20% price reduction for selected medical devices
- Additionally, payment times were significantly shortened (previously exceeding three years on average) and stock management improved, allowing for transfer of redundant stocks between hospitals

1. Derek, O., H.T. Walker and S.M. Rowlinson (2008), Procurement Systems: A Cross-industry Project Management Perspective, Routlege Press.
2. Ferrario et al. Strategic procurement and international collaboration to improve access to medicines. Bulletin of the World Health Organization 2017;95:720-722
3. Kastanioti, C. et al. (2013), "Public Procurement of Health Technologies in Greece in an Era of Economic Crisis", Health Policy, Vol. 109, No. 1, pp. 7-13, http://dx.doi.org/10.1016/j.healthpol.2012.03.015.

Pharmacy Market Price Tracking

Australia

- Australia has introduced price disclosure for manufacturers of medicines listed on their F2 formulary (350 drugs with at least one competitor) on sales revenue and incentives offered to community pharmacies to dispense their product
- This information is used to work out the true average market price at which pharmacies are reimbursed. Market price disclosures occur on 1 April and 1 October each year. The price disclosure program resulted in significant price reductions and the consequent savings are estimated to reach AUD 20 billion by 2019-20 [1,2,3]

European Union

- Many EU member states also use a similar approach to tracking pharmacy market pricing [4]

1. Quilty D. Pharmaceuticals, pharmacists and profits: the Pharmacy Guild perspective [editorial]. Aust Prescr. First published online 2014 Jul 4.
2. Clarke P. Pharmaceuticals, pharmacists and profits: a health policy perspective [editorial]. Aust Prescr. First published online 2014 Jul 4.
3. OECD (2017), Tackling Wasteful Spending on Health, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266414-en
4. Kanavos P, Gemmill M. Pharmaceutical Pricing and Reimbursement in Europe. Informa Publishing: London; August 2005.

Discussion Outline

Negotiation Strategies

Utilization Strategies

Prescribing Strategies

Other Strategies

National Formularies

Germany

- In Germany, where there is no positive list for reimbursement, there is a negative list that also excludes prescription OTC preparations and preparations seen as non-beneficial and/or not cost-efficient [1]

France

- In France, between the end of 1999 and 2011, the Transparency Commission evaluated the therapeutic value of 4,490 medicines [2]
    - Building on this initial review,. between 1999-2011, five major delisting waves were implemented as a direct result of the Transparency Commission re-evaluation of the Medical Service Rendered (SMR) for those 4,490 reimbursable pharmaceutical products
    - This resulted in 542 drugs being delisted that did not have their place in therapeutic treatment strategies
    - This included drugs that had outdated active principles, OTC drugs including expectorants, bronchodilators, homeopathic products, oligo-elements and digestive tract disorder drugs as well as peripheral vasodilators
    - These successive waves of drug delisting had an immediate impact on drug prescription rates for the pharmaceuticals concerned, resulting in a significant drop in volume

Other Developed Countries

- Many other developed countries use a national or closed ‘positive list’ formularies (e.g., Australia, Canada and Japan)

1. Pricing and Reimbursement Questions. **Conférence Bleue**
2. ANALYSIS OF THE IMPACT OF DRUG DELISTING IN FRANCE BETWEEN 2002 AND 2011, Questions d’économie de la santé n° 167 - July-August 2011.

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National Formularies

New Zealand

- The national formulary is managed by the Pharmaceutical Management Agency of New Zealand (PHARMAC) [1,2]
  - PHARMAC is legally bound to keep within an annual community drug budget (i.e., it has direct accountability for the costs/savings of its decisions)
  - Informed by independent and systematic review of the comparative cost-effectiveness of all products
  - Uses a variety of supplier contracts and coverage policies to meet annual budget targets for public expenditures
  - Negotiates rebates on list prices, uses sole-source contracts for supply of off-patent drugs, and engages in other deals with suppliers to procure drugs at the most competitive prices possible
  - PHARMAC tools are used to various extents by drug plans in the US
  - Spending on medicines in New Zealand has grown very slowly
  - Over 800 of the medicines were removed / delisted from the positive formulary listing (there was a focus on OTC and low value treatments)

1. PHARMAC. About PHARMAC: Important events in 10 PHARMAC's history, 2008. www.pharmac.govt.nz/dhbs/AboutPHARMAC/history.
2. Pharmaceutical Research and Manufacturers of America. 15 New Zealand: market access for pharmaceuticals. www.cptech.org/ip/health/phrma/nte-98/nzealand.html.

Generic Price Maximums

European Union

- An analysis of government policy for generic price setting demonstrated that national governments in all but 3 EU member states (Denmark, Germany, and the United Kingdom) impose price controls on generics (i.e., maximum allowable prices).

Denmark and Sweden [1]

- In each country, the relevant national government agency asks generic manufacturers to offer their best prices
- Usually, the least expensive generics become the only ones that pharmacists can dispense
- Additionally, If a patient requests a brand-name drug, the patient is required to pay out-of-pocket the difference in cost between the brand and generic medicine, producing additional savings
- The bidding process is repeated every 2 weeks in Denmark and every 4 weeks in Sweden
- There are safeguards to reduce the risk of supply disruptions, which is an important consideration when limiting subsidy to certain generic manufacturers

1. Pharmaceutical regulation in 15 European countries. The European Observatory on Health Systems and Policies, WHO Regional Office for Europe. ISSN 1817-6119 Vol. 18 No. 5

Generic Substitution

Sweden

- The Swedish national government, for example, introduced mandatory generic substitution in 2002, which led to a spike in generic drug use[1].

European Union

- The European Commission found that generic drugs enter the market sooner, on average, in EU member states with mandatory substitution. Generic substitution is mandatory in 11 EU countries and 14 US states [2,3,4]
- Patients in EU countries have to wait an average of about 7 months for generics to become available (2009). These delays were estimated to cost payers in EU countries €3B ($3.4B) per year [5]

France

- In France, dispensing is limited to a list of molecules established by the National Agency for Medicines and Health Product Safety. France also introduced a pay-for-performance scheme for pharmacists in 2012 with a bonus for achievement of generic drug dispensing targets [4]

Portugal

- In 2012, Portugal changed from linear to regressive remuneration [4]

Switzerland and Belgium

- In Switzerland and Belgium, pharmacists receive an additional fee for generic substitution [4]

Japan

- Japan in 2012 increased pharmacists' bonuses associated with target levels for dispensed generics [4]

1. Andersson KA, PetzoldMG, Allebeck P, Carlsten A. Influence of mandatory generic substitution on pharmaceutical sales patterns: a national study over five years. BMC Health Serv Res. 2008;8:50.
2. PanteliD, Arickx F, Cleemput I, et al. Pharmaceutical Regulation in 15 European Countries: Review. Geneva, Switzerland:Word Health Organization; 2016.
3. US Department ofHealth &Human Services. Expanding theUse of Generic Drugs.Washington, DC: Office of the Assistant Secretary for Planning and Evaluation; 2010.
4. OECD (2017), Tackling Wasteful Spending on Health, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266414-en
5. European Commission. Pharmaceutical Sector Inquiry—Final Report. Brussels, Belgium: European Commission; 2009.

“Brand Premium”

Norway

- Patients pay, what is known as the ‘stepped price’ (Trinnprismodellen). This is the price difference between the stepped price and the maximum price for full subsidy of a generic medicine when a patient refuses generic substitution [1]

Sweden

- Sweden has directed pharmacies to undertake generic substitution unless the patient decides to pay the difference between the original preparation and the cheapest available alternative [1]

Australia

- The Australian Government, through the Pharmaceutical Benefit Scheme (PBS), subsidizes up to the price of the lowest priced brand. This means that consumers may have to pay extra for more expensive brands (essentially a “brand premium”) [2]

New Zealand

- The New Zealand government sets the basic prescription fee for patients. There may be extra charges on some medicines that are not fully subsidized where the manufacturer does not meet the fully subsidized price [3]

1. PPRI Pharma Profile Norway. World Health Organisation. http://whocc.goeg.at/Publications/CountryReports
2. Are pharmaceuticals inexpensive in Norway? A comparison of prices of prescription pharmaceuticals between Norway and nine west European countries. SNF project no. 2713. THE INSTITUTE FOR RESEARCH IN ECONOMICS AND BUSINESS ADMINISTRATION BERGEN, MAY 2008
3. PBS. https://www.pbs.gov.au/browse/brand-premium
4. PHARMAC. https://www.pharmac.govt.nz/medicines/medicines-information/costs-of-medicines/

Summary of Generic Strategies

The below table shows a range of international countries in which pharmacist-driven generic substitution is allowed and where a brand price premium (or equivalent concept) applies [1,2]

Country	Pharmacist Driven Generic Substitution	Brand price premium i.e. % Co-Payment above fully subsidised medicine price
Belgium	No	Yes
Denmark	Yes (mandatory)	Yes
Finland	Yes (mandatory)	Yes
France	Yes	Yes
Greece	Yes	Yes
Hungary	Yes	Yes
Italy	Yes (mandatory)	Yes
Norway	Yes	Yes
Sweden	Yes (mandatory)	Yes
Switzerland	Yes	Yes
Spain	Yes (mandatory)	Yes
Australia	Yes	Yes
New Zealand	Yes	Yes
Canada	Yes	Yes
USA	Yes	Yes
U.K.	No	No

1. Are pharmaceuticals inexpensive in Norway? A comparison of prices of prescription pharmaceuticals between Norway and nine west European countries. SNF project no. 2713. THE INSTITUTE FOR RESEARCH IN ECONOMICS AND BUSINESS ADMINISTRATION BERGEN, MAY 2008
2. OECD (2015), “Share of generic market”, in Health at a Glance 2015: OECD Indicators

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Negotiation Strategies

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Generic Prescribing Strategies

Japan

- Japan introduced bonuses linked to the share of generics in prescribed medicines [1]

Germany

- Germany uses similar generic-prescribing target levels and introduced financial penalties for physicians who do not reach them [2]

France and Hungary

- In recent years, France (in 2009) and Hungary (in 2010) introduced incentives for GPs to prescribe generics through a pay-for-performance (P4P) scheme [2]
- France sets rates of reimbursements for drugs based on the drug's effectiveness for a given indication and condition severity. A point system exists for prescribers who meet objectives, such as monitoring diabetes. Doctors who are outliers in prescribing practices can incur financial sanctions. The pay-for-performance scheme in ambulatory care rewards appropriate prescribing of benzodiazepines. Quality and safety indicators are linked to financial rewards for quality improvement [3]

1. Belloni, A., D. Morgan and V. Paris (2016), "Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges", OECD Health
2. Godman, B. et al. (2012), "Payers Endorse Generics to Enhance Prescribing Efficiency: Impact and Future Implication, A Case History Approach", Generics and Biosimilars Initiative Journal, Vol. 1, No. 2, pp. 69-83.
3. Expert Review of Pharmacoeconomics & Outcomes Research Volume 5, 2005 - Issue 1. Provider incentives and prescribing behavior in Europe. Pages 81-93 | Published online: 09 Jan 2014

e-Prescribing

Estonia

E-prescription in Estonia embarked on a comprehensive e-health strategy, with e-prescription as one element to improve efficiency [1]

- E-prescription was launched in 2010 and is integrated in a platform that also incorporates electronic health records (EHRs), a digital image archive, a patient portal, an e-laboratory and e-emergency care solutions
- All e-prescriptions issued by physicians are sent to a national database that can be accessed by pharmacies, physicians and the health insurance fund
- Patients can pick up their medication at any pharmacy by identifying themselves with their ID card. Repeat prescriptions can be issued by physicians after an email or a phone call, no longer requiring physical visits to the doctor
- Digitalisation reduced the administrative workload of pharmacists; the health insurance fund gained better information about the pharmaceutical market and can now monitor prescription habits more effectively
- It also improved efficiency for the Estonian health insurance fund: staff costs related to administering incorrect prescriptions reduced by more than 90% between 2009 and 2015
- The database can provide an overview of all prescriptions issued for a patient and help signal possible interactions between different pharmaceuticals
- By May 2011, 84% of all prescriptions were issued digitally and over 95% of pharmacies were ready to process e-prescriptions. Over 90% of patients are satisfied with these services

1. Estonian Health Insurance Fund (2016), www.haigekassa.ee/en/people/digital-prescription.

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Patents and Off-label Use and Comparisons

Off-Label Use in France

- In 2012 France amended the law allowing its authorities to recommend off-label use for solely economic reasons where licensed alternatives existed

Off-Label Use in Italy

- In 2014 Italy similarly allowed the authorities to make recommendations on cost grounds as to the safety and efficacy of a given medicine for off-label use

Off-Label Comparators in the United Kingdom

- In the UK, the National Institute for Health and Care Excellence (NICE) appraised the cost-effectiveness of Avastin® (bevacizumab) against Lucentis® (ranibizumab) in the treatment of wet age-related macular degeneration although the former has only been licensed for oncology indications; NICE has indicated that it plans to continue off-label comparators in the future despite on-going criticism of such practices

Off-Label Comparators in Austria, France, Germany and Norway

- Similar comparisons have been carried out by authorities in Austria, France, Germany and Norway

New Pricing Models

Europe

Looking to international examples for controlling healthcare and medicine spending, there is a uniform focus across European governments that the challenge needs addressing. While policy approaches differ and there are a number of mechanisms available to payers, they are all generally intended to balance desirable access to medicines within a sustainable budget:

Price negotiation collaboration

- Netherlands and Belgium announced pilot collaborative price negotiations for orphan drugs
- Greek and Portuguese health ministers call for increasing payer collaborations\
- In May 2015, the G-BA in Germany gave a ruling of 'non-quantifiable' benefit for Glybera. The delays experienced in the uptake and use of Glybera have been widely seen as a rejection of the upfront payment model and a sign from the payer that the healthcare system struggled with the budget impact despite the small patient population [1]

Budget capping and rebate schemes

- Portugal and Italy reviewing payback mechanisms for budget overspend
- French Hepatitis C spending cap

Post launch Real World Evidence scrutiny

- France Novel Oral Anti Coagulant (NOAC) re-assessment based in part on own real world evidence
- Italy and France reviewing Avastin reimbursement for use in age-related macular degeneration (AMD)

Increasing emphasis on value based pricing

- French Ministry of Health reviewing current drug reimbursement systems
- Italy's healthcare system has fully embraced outcomes-based contracts, however this has only led to aggregate savings of 3.3% of their total drug spending from 2006-2012.[2] Analysis of the application of the cost-containment strategies approved in Italy shows several issues resulting in small actual refunds through the application of these schemes with the largest portion coming from discounts that are not based on the assessment of an outcome ("cost sharing")

Source: IIMS Quintiles, 2016

[1] Kusel, Spoors; Recent trends in the pricing of high-cost pharmaceuticals. British Journal of Healthcare Management 2016 Vol 22 No 5

[2] Livio Garattini, A. Curto, K. van de Vooren. Do the Current Performance-Based Schemes in Italy Really Work? "Success Fee": A Novel Measure for Cost-Containment of Drug Expenditure. Value in Health Volume 18, Issue 1, January 2015, Pages 131-136

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Horizon Scanning

BeNeLuxA

The Belgian Health Care Knowledge Centre (KCE) Report reviewed the BeNeLuxA collaborative for exemplar processes and identified the following [1]:

- During the development phase identify early:
  - Products that have received an orphan designation, including details of the condition and high-level information about the development stage
  - Products with confirmed eligibility for the PRIority MEdicines scheme (PRIME)
- Horizon scanning was identified as an area for collaboration between regulators and health technology assessment (HTA) bodies including:
  - The European Medicine Administration (EMA)
  - The Synergy group from the HTA Network
  - Opportunity to link up activities on a European level, capitalizing from synergies in data needs whilst recognizing differences in objectives (due to different mandates)
- Incorporate additional information that can be used as source data:
  - During the regulatory review of the marketing authorization application:
    - Monthly listings of “Medicines under evaluation”
    - Progress updates through milestones in published agendas/minutes. Examples of information available from include accelerated assessment agreed and evaluation milestones achieved

1. Horizon scanning for pharmaceuticals: proposal for the BeNeLuxA collaboration; 30 May 2017. KCE Report 283: Belgian Health Care Knowledge Centre

Thank you!

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