

# Disinvestment and Value-Based Purchasing Strategies for Pharmaceuticals: An International Review

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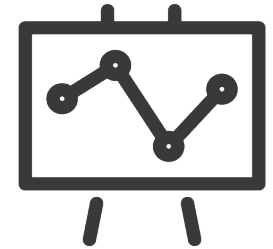


## Pharmaceutical expenditure ↑ across many OECD countries

- US\$190 per capita in 1990 → US\$497 per capita in 2012
- 9.6 % per annum (unadjusted for inflation).

### Key drivers:

- ↑ Utilisation: ageing, ↑ chronic diseases, conversion from acute → chronic diseases, relaxation of disease and pre-disease definitions, ↑ screening, lifestyle/behavioural changes and ↑ patient expectations.
- ↑ Cost of new drugs



→ Concerns regarding sustainability

To stabilise expenditure growth, and create headroom for increasing utilisation and to fund new high-cost therapies, there is an active push to disinvest\* from low value drugs.

\* 'partial or complete withdrawal of health resources from any existing health care practices, procedures, technologies or drugs that are deemed to deliver little or no health gain for their cost, and thus are not efficient health resource allocations' with an explicit view towards reallocation to higher value applications

# Aim

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To review how reimbursement policy decision makers have sought to partially or completely disinvest from drugs in a range of OECD countries where they are publicly funded or subsidised.

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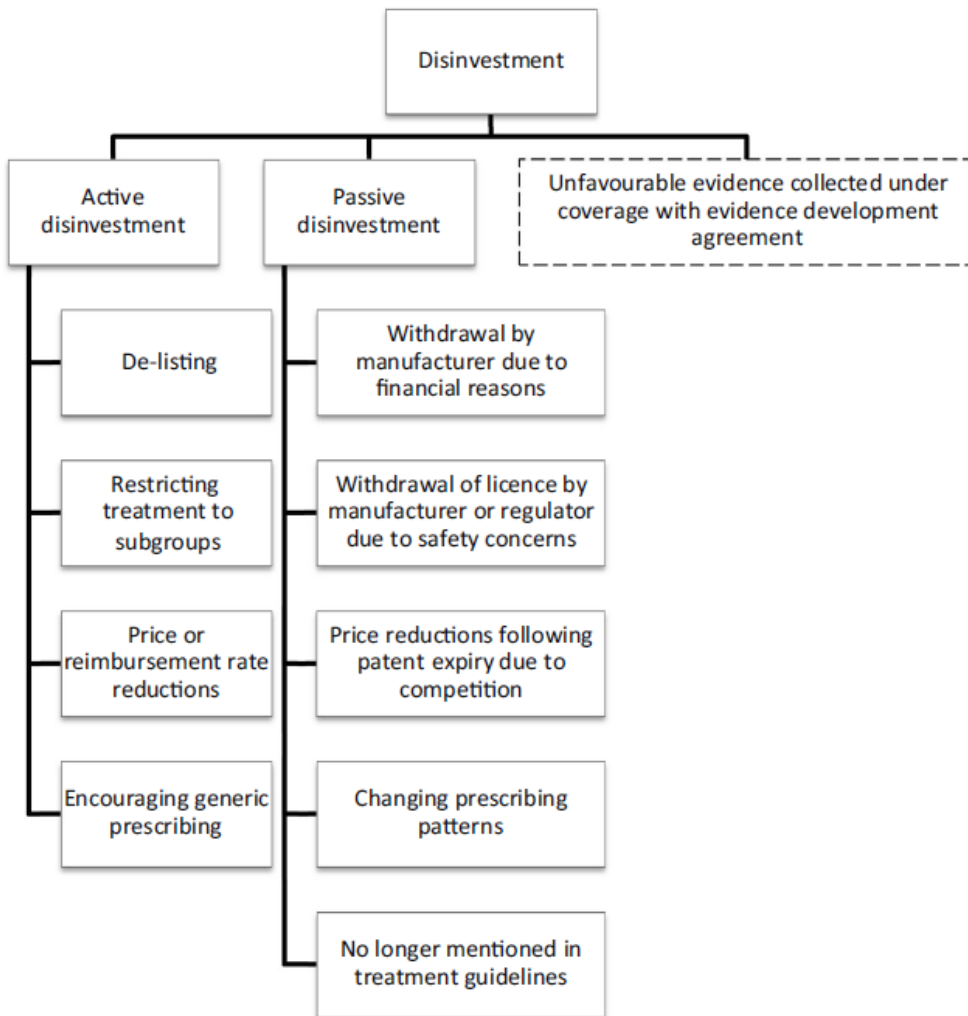
Reviewed disinvestment in France, the UK, Canada, Australia and New Zealand.

- Chosen on the basis of known documented activity in disinvestment.

Conducted a literature search combined with key papers in this field known by the co-authors and the expert knowledge of the co-authors regarding the policy situation in their country (including grey literature).



# Disinvestment in drugs typology



## PASSIVE

Not reliant on direct intervention by reimbursement policy makers.

- Not sufficiently reliable or too slow (e.g. due to not considering new evidence quickly or market failure)

## ACTIVE

Reviews of drugs currently receiving public funding to identify those candidates appropriate for disinvestment.

## COVERAGE WITH EVIDENCE DEVELOPMENT

In the future...

# Identification of Potential Candidates for Disinvestment

In theory (based on Elshaug 2009)

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1. **New evidence** of safety, efficacy or cost effectiveness becomes available.
2. **Geographic and/or provider variations** in prescribing patterns.
3. **Temporal variations** in volume or higher than expected utilisation/above specified restriction limits (i.e. 'leakage').
4. **Technology development** such that a drug is significantly different from that originally assessed or funded (e.g. dosage, administration, or leakage).
5. **Public interest or controversy.**
6. **Consultation** or nomination by clinical, nursing, allied health and technical staff, healthcare administrators and funders.
7. Assessment of **new drugs** and disinvestment in the comparator drugs.
8. **Legacy items.**
9. Evidence becomes available indicating that **drug utilisation** does not reflect what is considered best practice based on treatment guidelines.
10. **Precedent** (i.e. another jurisdiction).

# Identification of Potential Candidates for Disinvestment

In practice

**Table 2** Criteria used to identify potential candidates for assessment and disinvestment when conducting active disinvestment reviews

Country, agency	Identification of potential candidates for disinvestment	Criteria for assessing candidates for disinvestment
Australia, Pharmaceutical Benefits Advisory Committee (PBAC)	Ad hoc. Drugs considered where there are concerns regarding the quality of use, cost effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences [28]	Drugs considered not sufficiently safe, sufficiently effective, or sufficiently cost effective following multiple technology assessment
Canada, Atlantic Common Drug Review	Ad hoc. Drugs considered where there have been changes in scientific evidence, regulatory status, cost effectiveness, or budget impact related to changes in the drug cost or the cost of its comparators	Drugs considered not sufficiently safe, sufficiently effective or sufficiently cost effective following multiple technology assessment
France, Transparency Commission	All listed drugs	SMR rating: (1) effectiveness and safety; (2) availability of alternatives; (3) disease severity; (4) impact on health of individual; and (5) impact on public health [27]. Excludes cost effectiveness
New Zealand, Pharmaceutical Management Agency (PHARMAC)	Drugs facing price competition where there are alternatives that can deliver the same or similar health outcomes	Those not delivering value for money
UK, National Institute for Health and Care Excellence (NICE)	Any included in NICE cancer service guidance, clinical guidelines, interventional procedures and technology appraisals guidance since 2007 [61, 62]. Cochrane reviews that conclude that interventions should not be used or could not be recommended [23, 63, 64]	Drugs considered not sufficiently safe, sufficiently effective or sufficiently cost effective following multiple technology assessment

*SMR Service Médical Rendu*

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New Zealand, Pharmaceutical Management Agency (PHARMAC)	Drugs facing price competition where there are alternatives that can deliver the outcomes	Those not delivering value for money
UK, National Institute for Health and Care Excellence (NICE)	Any included in NICE cancer guidelines, interventional procedure appraisals guidance since 2007, or clinical reviews that conclude that intervention used or could not be recommended	

SMR Service Médical Rendu

## Comprehensive review 2000-2004

High rates of return in terms of appropriate use and value for money BUT resource intensive, political, and requires ongoing rolling amalgamation of new evidence

Now:

- Conducts a systematic re-assessment 5 years after first listed
- Re-assessments of a single drug or therapeutic class



# Identification of Potential Candidates for Disinvestment

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Country, agency	Identification of potential candidates	Additional information
Australia, Pharmaceutical Benefits Advisory Committee (PBAC)	Ad hoc. Drugs considered where regarding the quality of use, cost effectiveness, higher than predicted international differences [28]	Piloted a process involving consultation and nomination to identify candidates in 2006. BUT many suggestions were based on “social judgments” rather than evidence of poor clinical or cost effectiveness. Abandoned.
Canada, Atlantic Common Drug Review	Ad hoc. Drugs considered where changes in scientific evidence, effectiveness, or budget impact the drug cost or the cost of its	Now relies on identifying candidates through its existing processes.
France, Transparency Commission	All listed drugs	Maintains a ‘do not do’ database (since 2007). BUT largely relates to inappropriate use of technologies (e.g. contraindications) and ‘experimental’ use of technologies outside their indications and evidence base.
New Zealand, Pharmaceutical Management Agency (PHARMAC)	Drugs facing price competition with alternatives that can deliver the outcomes	Working with the UK Cochrane Centre to develop summaries regarding technologies that should not be used or could not be recommended.
UK, National Institute for Health and Care Excellence (NICE)	Any included in NICE cancer service guidance, clinical guidelines, interventional procedures and technology appraisals guidance since 2007 [61, 62]. Cochrane reviews that conclude that interventions should not be used or could not be recommended [23, 63, 64]	Drugs considered not sufficiently safe, sufficiently effective or sufficiently cost effective following multiple technology assessment

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Has also conducted therapeutic reviews.

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# Types of active disinvestment

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De-listing



Restricting treatment



Price or Reimbursement Rate Reductions



Encouraging Generic Prescribing

# Types of disinvestment

## De-listing

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### Complete removal of subsidy/funding

- UK: NICE concluded that there were few obvious candidates for complete disinvestment (i.e. de-listing)
- Australia: Reviews have resulted in only one drug being de-listed (a bDMARD).
- France: initially de-listed around half (840 of 1675 drugs), but re-evaluated following public pressure and only two-thirds of the de-listing decisions were maintained (525 of 763 drugs re-evaluated).
- New Zealand: rarely de-lists drugs, but often delists pack options, brands and formulations.



### Rarely used



# Types of disinvestment

## De-listing

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### Why?

- ↓ a patient's ability to pay, which restricts clinical autonomy and ↓ patient and prescriber choice
  - Perverse incentives (e.g. payments for administration).
  - Sunk costs of training and any physical capital investments
  - Resistance to changing prescribing behaviours
  - ↓ prices once listed → cost-effectiveness ↑
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- France: Patients do not understand why drugs not worthy of reimbursement were still suitable to be sold OTC.



# Types of disinvestment

## Restricting treatment

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Identifying subgroups where most clinically and cost-effective and applying restrictions, or tightening existing restrictions, on who may receive treatment.

- Who is initiated on treatment:
  - UK: In 2008 NICE recommended the cessation of antibiotic prophylaxis against infective endocarditis for patients undergoing certain procedures.
  - France: From 1 November 2014, clinicians must obtain prior authorisation for each treatment initiation of rosuvastatin or ezetimibe (non-generics).
- ‘Conditional treatment continuation rules’ :
  - France: a review of Alzheimer’s disease drugs recommended: (1) limitation to 1 year; and (2) after 6 months, continuation if the patient responds to the treatment and there are no adverse effects



## Commonly used

# Types of disinvestment

## Reimbursement Rate or Price Reductions

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### ↓ reimbursement rate

- France: following the 2000-04 review
- ↑ costs borne by patients.

### Monopsony power to ↓ prices

- Australia: price ↓ sought from manufacturers as a result of reviews of treatments for Alzheimer's disease and bDMARDs.

### ↓ prices of off-patent drugs:

- Australia and France: mandatory price discounts
- Australia: reference pricing and 'price disclosure'
- Canada: reference pricing and price–volume agreements
  - price negotiation falls to each individual province.
- New Zealand: reference pricing, price–volume agreements, package agreements/bundling and tendering sole supply



### Commonly used, but not in the UK

- Limited remit of NICE to force price ↓ and reluctance by manufacturers to offer price ↓ due to referencing

# Types of disinvestment

## Encouraging Generic Prescribing

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In the UK, prices of high-volume generics can be as low as 3–12 % of prices pre-patent.

Can result in ↑↑ savings without compromising care.

### Commonly used



**Table 3** Tools to encourage prescribing of generics versus originators

Country	Mandatory writing of prescriptions using INN	Mandatory dispensing of generics	Allowing pharmacists to substitute between originator and generic drugs	Dispensing incentives for pharmacists	Education or awareness campaigns	Prescribing targets/fund holding
Australia	✗	✗	✓	✓	✓	✗
Canada	Varies by province	Varies by province	Varies by province	✗	✓	✗
France	✓	✓	✓	✓	✓	✓
New Zealand	✗	✓	✗	✗	✓	✗
UK	✗	✗	✗	✗	✓	✓

*INN* international non-proprietary name

# Coverage with Evidence Development

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- Reimbursement linked to prospective data collection
- Used when there is uncertainty regarding clinical effectiveness, safety or cost-effectiveness
- Risk that new evidence points to the need to reverse decision
- Need to pre-identify avenues for disinvestment prior to approval (e.g. price discounts, restrictions) or pre-agree rebates

# Lessons Learnt

- ↑ focus towards ‘active disinvestment’
- De-listing difficult
  - Identifying suitable candidates, unpopular among various stakeholders, potentially inappropriate, and risks engendering substitution effects (some may be unexpected/harmful/costly)
- Other types of disinvestment strategies are more likely to be successful
  - Although the threat of delisting a drug makes manufacturers more amenable
- Disinvestment may prove to be temporary and may also depend on the availability of other treatments.
- Stakeholder Management
  - Communicate with stakeholders upfront and throughout process regarding what research is required, what level of evidence is required to continue funding, what are the ramifications of not supplying the evidence, and what are the alternative uses of funds

# Conclusions

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Any disinvestment strategy for drugs requires:

- a mix of active and passive methods to identify candidates,
- agreed criteria for prioritising/selecting candidates, and
- a mix of mandatory, incentivised and encouragement methods.

# Thank you

For further information:

Parkinson, B., Sermet, C., Clement, F., Crausaz, S., Godman, B., Garner, S., Choudhury, M., Pearson, SA., Viney, R., Lopert, R., Elshaug, AG. (2015) Value-Based Purchasing and Disinvestment Strategies for Pharmaceuticals: An International Review, *Pharmacoeconomics*, 33(9):905-24.