celesio

Celesio Policy Position

Pharmacist-Led Generic Substitution – Benefits for Healthcare Systems

Supporting Material

Overview of national generic substitution policies in Europe [1]

Country [2]	Allowed	Mandatory / Incentivised [3]	INN prescribing	Patient may refuse
Austria	No	n/a	No	n/a
Belgium	No [4]	n/a	Allowed	n/a
Bulgaria	Yes		Allowed	Yes
Croatia	No	n/a	Allowed	n/a
Czech Rep.	Yes		Allowed	Yes
Denmark	Yes	Mandatory	Allowed	Yes
Estonia	Yes	No	Mandatory	Must pay difference
Finland	Yes	Mandatory	Allowed	Yes
France	Yes	Incentivised	Mandatory	Must pay difference
Germany	No [5]		Allowed	Must pay difference
Greece	Yes	Mandatory	Mandatory	Yes
Hungary	Yes		Allowed	No
Ireland	Yes	Mandatory	Allowed	Must pay difference
Italy	Yes	No [6]	Mandatory	Must pay difference
Luxembourg [7]	Yes	Incentivised	Allowed	Must pay difference
Netherlands	Yes	Mandatory	Mandatory	Must pay difference
Norway	Yes	Incentivised	Allowed	Must pay difference
Poland	Yes		Allowed	Yes
Portugal	Yes	Mandatory	Mandatory	Yes
Romania	Yes		Allowed	Yes
Slovakia	Yes		Mandatory	Yes
Slovenia	Yes	No	Allowed	Must pay difference
Spain	Yes	Mandatory	Mandatory	Yes
Sweden	Yes	Mandatory	No	Must pay difference
Switzerland	Yes	Incentivised	Allowed	Yes
UK	No	n/a	Allowed	n/a

[1] Medicines for Europe – Market Review, European Generic Medicines Markets, Policy Overview (2016); Busse *et al*., Arzneimittel-versorgung in der GKV und 15 anderen europäischen Gesundheitssystemen (2015); European Commission, OECD – Health at a Glance: Europe 2016; Panteli *et al.*, Pharmaceutical regulation in 15 European countries – European Observatory on Health Systems and Policies (2016); European Observatory on Health Systems and Policies – Health Systems in Transition (2012-2016)

[2] Highlighted = countries in which Celesio has operations

[3] In some countries pharmacists may decline to substitute if in their judgement it is necessary to stick to originator medicine.

[4] Except for antibiotics and antimycotics, in which case it is mandatory.

[5] Most frequently used prescription medicines are subject to tender agreements between sick funds and manufacturers. Tender contracts of public sick funds dominate substitution. In case of single-slot tenders no substitution is allowed. In cases of multiple tenders, substitution is possible but just between the different contract winners. This cannot be considered as genuine substitution.

[6] The pharmacist must inform the patient of generic alternatives. The GP may indicate 'no substitution' on the prescription, but must include a justification. There are also a few cases (for specific pathologic situations, e.g. Ciclosporina for transplant) where the regulator obliges pharmacists to stick to the GP's prescription.

[7] Luxembourg Ministry of Health website

Policies towards uptake of generics and biosimilars

- **EU:** The European Parliament's Public Health Committee: 'Calls on the Commission and Member States to set up a framework to promote, guarantee and reinforce the competitiveness and use of generic and biosimilar medicines…' [8]
- **France: '**France's national union of health insurance offices (UNCAM) and the two pharmacists' unions have agreed to renew the scheme remunerating pharmacists for achieving public health objectives (ROSP) and have fixed a generics substitution objective of 86% for 2017, according to texts seen by APM. According to the Federation of French Pharmacists Unions (FSPF) and the Federation of community pharmacists' union (USPO), the ROSP budget is the same as for 2016, namely 140 million euros (an average of 6,000 euros per pharmacy).' [9]
- **Ireland – generic substitution:** 'If no clinical exemption is indicated, the pharmacist must offer the patient the least expensive medicine that they have in stock within a list of interchangeable medicines as determined by the HPRA (in some cases, this may indeed be the branded product). If a clinical exemption is indicated, the pharmacist must dispense that brand.' [10]
- **Ireland - biosimilars:** From newspaper report, February 2017:
  'Minister for Health Simon Harris will publish a consultation paper on the use of biosimilar drugs in the next few weeks as the Government looks for ways to save money in the health budget… The Minister said the bill for high-tech medicines had jumped from €170 million in 2005 to €590 million last year, and was up almost 10 per cent last year alone… The only biosimilar drug introduced to the Irish market since the signing of the Framework Agreement on Supply and Pricing of Medicines last August, the rheumatoid arthritis drug Benepali, sold just three packets by the end of 2016. The agreement, which is targeting savings of €785 million over four years, mandates a 30 per cent cut in the price of off-patent biologics once a competing biosimilar enters the Irish market. However, Benepali's off-patent branded competitor, Enbrel, still sold close to 10,000 packets in the same period, despite being 10 per cent more expensive.' [11]
- **Norway:** 'Generic substitution has been allowed in Norway since 2001. Pharmacies are not allowed to substitute therapeutically (i.e. dispense a medicine with equal therapeutic benefits), but they are allowed to substitute with parallel imported medicines. The NoMA evaluates new medicines on the Norwegian market in terms of their substitutability and publishes a "substitution list", which is updated monthly.' As well as parallel imports, substitution includes medicines products with the same active ingredient.[12]
- **Sweden:** The financial benefit of generic substitution goes to the public payer. However, the regulator contracts with a generic manufacturer – the pharmacy must use this product, even if they find a cheaper one.[13]

[8] Report of European Parliament Public Health Committee on EU options for improving access to medicines, paragraph 24, adopted 31 January 2017
[9] APM Health Europe News, 24 February 2017
[10] IPU Guide to Generic Substitution & Reference Pricing (2015)
[11] Minister for Health to publish consultation paper on biosimilar drugs', Irish Times (8 February 2017) http://www.irishtimes.com/business/health-pharma/minister-for-health-to-publish-consultation-paper-on-biosimilar-drugs-1.2967894
[12] European Observatory on Health Systems and Policies – Health Systems in Transition (2013); Celesio internal research
[13] Celesio internal research

Examples of positive impact of generic substitution policies

- **Europe:**
  - 'Several countries took steps to tighten their generics policies in response to the economic crisis. For example, Belgium and Spain encouraged the cost-efficient use of medicines (and thus generics) and generic substitution, respectively. Greece and Portugal introduced INN prescribing. According to the OECD, such policies have in all likelihood facilitated the increasing market share of generics in many countries over the past ten years' [14]
  - 'We found strong empirical evidence that generic substitution and regressive pharmacy mark-ups have a negative effect on originator drug prices. Generic substitution enhances price competition, as more expensive products are substituted by cheaper alternatives at the pharmacy. This gives producers an incentive to reduce prices in order to have their products reimbursed by health insurance.' [15]
- **Estonia:** 'Generic prescription has been strongly promoted in public campaigns organized by the EHIF in 2010 and 2011. It has successfully reduced costs on reimbursed prescription pharmaceuticals for the EHIF and the patients, as well as increasing the proportion of generic prescription to 70% by the end of 2011.' [16]
- **Finland:**
  - 'The price competition induced by reference pricing and extended generic substitution generated total savings of EUR 110 million (figure A). EUR 76 million were savings in Health Insurance Scheme reimbursement payments and EUR 34 million were savings for patients. The overall savings for patients were calculated by subtracting EUR 12 million, paid by patients refusing substitution to cover the costs in excess of the reference price, from EUR 46 million saved by patients by price competition.'
  - 'Ninety per cent of the savings made during the first year under the reference price system were attributable to generic substitution being extended to cover drugs holding analogous process patents. Three quarters of these savings arose from four medicinal products: atorvastatin, quetiapine, losartan and olanzapine.' [17]
  - Portugal: Savings from increased generic substitution in Portugal in 2004 for nine medicines amounted to €110 million, representing 45% of the costs of the originator products. [18]
- **Sweden:**
  - 'Pharmaceutical prices in Sweden have decreased by about 15 percent since generic substitution was introduced, (from October 2002 to December 2005). This drop in prices is due entirely to the decrease in prices for off-patent drugs. Market prices for generic drugs have fallen by approximately 40 percent...'
  - 'The effects of generic substitution is... not limited to the generics market, it also affects the competitive situation in an entire therapeutic area.' [19]

[14] Panteli *et al.*, Pharmaceutical regulation in 15 European countries, European Observatory on Health Systems and Policies (2016);
[15] von der Schulenburg *et al. 'The effects of drug market regulation on pharmaceutical prices in Europe: overview and evidence from the market of ACE inhibitors'*, Health Economics Review (2011)
http://www.healtheconomicsreview.com/content/1/1/18
[16] European Observatory on Health Systems and Policies – Health Systems in Transition (2012)
[17] Finnish Statistics on Medicines 2009, Finnish Medicines Agency and the Social Insurance Institution (2010)
http://www.kela.fi/documents/12099/12170/slt_2009_kansikuvalla.pdf/3ce37f43-d82c-465a-8dad-a84d280cbb33?version=1.0
[18] Steven Simoens: The Portuguese generic medicines market: a policy analysis (2009)
http://apps.who.int/medicinedocs/en/d/Js16217e/ (See Table 1)
[19] Andreas Engstrom *et al.*, Sharp drop in prices after the introduction of generic substitution, Läkemedelsförmånsnämnden (2006)
http://www.asksource.info/resources/sharp-drop-prices-after-introduction-generic-substitution