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Celesio Policy Position

Pharmacist-Led Generic Substitution – Benefits for Healthcare Systems

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Background

The Celesio Group owns over 2,150 community pharmacies across six European countries. Our pharmacists have at least five years of professional medical training and dispense medicines to millions of patients every day. Additionally, we supply more than 50,000 pharmacies and hospitals with up to 130,000 medicines per day as a medicines wholesaler. Celesio believes that pharmacists are ideally placed to make significant cost savings and outcomes improvements to support public healthcare budgets. One area where immediate savings are possible is where they are empowered to conduct generic substitution. This paper explains the concept of generic substitution by pharmacists and how it contributes to the long-term sustainability of Europe's healthcare systems.

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What is pharmacist-led generic substitution?

Pharmacist-led generic substitution is the replacement of a prescription reference (originator) medicine with an equivalent generic medicine by a pharmacist. If a physician's prescription refers to the reference branded product, the pharmacist can, using their professional judgement, make a decision to switch where clinically appropriate to a less expensive but equally safe and effective generic, i.e. a non-reference product with the same medical effect.

What are the advantages of using generics?

- **Safety/efficacy:** Generic drugs are just as safe and efficacious as reference products; this is not always understood by patients, who sometimes favour the reference product purely due to its familiarity. Just like reference products, generics must meet rigorous standards to be approved for use by EU or national regulators. This includes having the same active

ingredient(s) / molecule(s), strength, pharmaceutical form, bioequivalence, batch requirements and Good Manufacturing Practices as the reference product. [1]

- **Cost savings:** Generic drugs are less expensive than their reference products, and their use drives down a medicine's price once generic medicines enter a market, i.e. after expiry of exclusivity rights (the patent). The contribution of generic medicines towards cost savings is enormous: a recent IMS study[2] estimated that in the EU, generic medicines:
  - Drive down the price of off-patent medicines by an average of 61%
  - Accounted for 92% of prescription volume in 2014 and only 47% of the cost
  - Saved payers €100 billion in the same year.

What is the role of the pharmacist?

The pharmacist can play the following role in the substitution of the generic medicine:

- Reassure the patient about the efficacy and safety of the substitute medicine
- Educate the patient about any differences in administration
- Monitor adherence and report any adverse effects
- Recommend an alternative generic substitute if compliance issues develop.

How do generic substitution policies influence generic uptake?

Surprisingly, with such evidence around cost savings, European countries have different policies towards generic substitution. In most EU Member States, it is allowed unless the doctor has expressly prohibited it; in some cases it is encouraged or mandatory; in a few countries it is not legally permitted. There are several key policies that should be considered to enable generic substitution by pharmacists:

- One key enabling policy is the introduction of prescribing using the substitutable international non-proprietary name (INN). An **INN** is an official generic name given to a pharmaceutical, drug or active ingredient. Every medicine has a unique INN. With greater penetration of electronic prescribing it is now possible for medical practitioners' prescribing systems to default to INN, rather than the reference product, allowing pharmacists to choose a lower-priced product. A recent study[3] concluded that countries that have both 'mandatory or strongly encouraged INN prescribing (UK) and/or mandatory generic substitution (Germany, Denmark, Finland, Sweden) show the highest degree of generic penetration... and also seem to have the lowest time delay to generic entry'.
- Remuneration systems where the pharmacist's or doctors income is related to medicine costs will act as a disincentive and will therefore need closer consideration.
- Pharmacist-led generic substitution should be viewed as part of the patient management process whereby pharmacists are a key contributor to better outcomes for patients and healthcare systems.
- In principle pharmacists will always respect a patient's wishes should they prefer to stick with the reference product, so provisions can be made to allow exceptional originator dispensing at the expense of the patient, or at the explicit request of the prescriber for some medicines.

Country-specific studies have shown the positive impact that generic substitution policies have had in saving public money in Estonia, Finland, Portugal and Sweden (see Supporting Material).

Our key messages

Generic medicines are just as safe and efficacious as their reference products and offer enormous cost-saving opportunities for the public payer.

Pharmacists can aid this process if they are empowered to substitute generics for the reference product.

Other public policies to encourage generic substitution should include prescribing focused on INN, remuneration structures and patient options if they choose the reference product.

Biosimilar medicines also offer huge potential: policymakers should allow pharmacists to substitute them when they consider it safe to do so.

[1] EGA Factsheet: Assured Quality, Safety and Efficacy of Generic Medicines
[2] IMS: The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective (2015)
[3] Kanavos : Measuring performance in off-patent drug markets: A methodological framework and empirical evidence from twelve EU Member States – Health Policy 118, 229-241 (2014)

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Biosimilars

A similar but not identical situation is emerging in the field of expensive biomedicines. These are complex chemical combinations rather than single molecules and are used to treat diseases such as rheumatoid arthritis, and some cancers. They include for example: recombinant proteins, monoclonal antibodies, medicinal products derived from human blood / plasma, and immunological medicinal products.

Biosimilar is the term used for the generally less expensive generic equivalents of these biomedicines. We strongly urge policymakers to ensure that where clinical equivalence is safely determined, pharmacists are enabled to make safe substitution decisions as they are at least as qualified as general practitioners with respect to biosimilars.

What we are calling for

With Europe's healthcare systems under growing strain, generic medicines already offer a significant opportunity to reduce medicine-related spending. However, there remains considerable scope for further uptake. Community pharmacists have an important role to play where they are enabled and encouraged to substitute cheaper equivalent medicines for expensive originators.

Celesio therefore calls on national policymakers to set the appropriate legislative framework to favour generic substitution by pharmacists and calls on EU-level policymakers to support this process. This should include:

- Legalisation of generic substitution in those few countries that still do not allow it
- Prescribing focused on substitutable INN
- Mandatory substitution where clinically suitable, or at least default substitution so that patient has to pay the difference if they want the reference product
- Removal of barriers to effective substitution and, where appropriate, the introduction of incentives for the pharmacist
- A balanced approach to patient safety, availability of medicines on the market and cost, so that generic substitution is a common responsibility whose benefits are shared by all parties
- Support for pharmacists to make substitutions of biomedicines, where patient safety and equivalence has been established
- Adequate remuneration of each player involved in distributing generics to retail pharmacies.

About Celesio

Celesio is a leading international wholesale and retail company and provider of logistics and services to the pharmaceutical and healthcare sector. Our proactive and preventive approach ensures that patients receive the products and support that they require for optimum care. With more than 36,000 employees, Celesio operates in 13 European countries. Every day, the group serves over 2 million customers – at about 2,150 pharmacies of its own and over 5,500 participants in brand partnership schemes. With 109 wholesale branches, Celesio supplies more than 50,000 pharmacies and hospitals every day with up to 130,000 pharmaceutical products.

Celesio Markets in Europe

Facts and Figures

Please see our online Supporting Material at www.celesio.com/generic-substitution

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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