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Celesio Policy Position

Pharmacist-Led Generic Substitution – Benefits for Healthcare Systems

April 2017

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