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Funding Pressures Impact Non-Originator Drugs In Germany, France and Italy

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Pressure on public finances has led national governments across Europe to seek better control over healthcare expenditure. Healthcare funding pressure varies from country to country. However, pharmaceutical products are generally seen as a prime area where savings can be achieved. One way governments are looking to contain this area of expenditure is through shifting pharmaceutical consumption away from expensive branded products towards cheaper non-originator drugs (i.e. generics and biosimilars). This results in a tension between:

- Favourable regulatory environments to encourage the use of non-originators, which are overall positive for non-originator pharmaceutical products
- Governments' expectation that these products will be considerably cheaper than their originators, which is putting pressure on pricing

This note focuses on three of the largest European pharmaceutical markets. It compares how these two aspects interact and impact non-originator products sold on the retail market (i.e. through pharmacies).

Key Findings

- **Whilst the 3 countries are seeking to create a favourable regulatory environment for the consumption of non-originator drugs, their efforts result in different outcomes; Germany having the most favourable environment and Italy the least favourable**
- **Reimbursement mechanisms putting pressure on price are varied; they include targeted direct price cuts (France, Italy), exclusion of products with limited medical benefit from reimbursement (France), public tenders and additional rebates (Germany)**
- **Each country uses its own approach, as a result, national efforts to contain expenditure lead to varying impacts on individual non-originator products**

Legislative and regulatory initiatives creating a favourable environment for the consumption of non-originator drugs

Non-originators generic and biosimilar drugs are much cheaper than their originator products. Public payers across the three countries have sought to create favourable environments to increase their consumption with varying degrees of success. Germany has the most favourable legislative and regulatory frameworks for generic market penetration and is the most likely to encourage the use of biosimilars in the future. There are also some positive signals from France, where the regulator's position on the substitution of biosimilars has been slightly relaxed. In Italy, legislative efforts to reform the remuneration of pharmacies and incentivise the distribution of generics have not made any progress and the regulatory framework for biosimilars has not yet been adapted.

	Legislative and Regulatory Tools Encouraging the Use of: Generics	Biosimilars
Germany	• High penetration rate due to successful implementation of past regulatory and legislative arrangements, including automatic substitution in pharmacies, financial incentives for prescribers, and prescribing guidelines	• Prescription targets for biosimilars are in the process of being developed at *Länder* (regional) level • It is possible that national legislative or regulatory changes will lead to automatic substitution of biosimilars, however, there are outstanding safety concerns
France	• Government initiative in 2015 to increase prescription and delivery of generic drugs • No further regulatory or legislative changes expected at present	• Since 2016, the French Medicines Agency (ANSM) opened the way for substitution for biosimilars under certain conditions
Italy	• Possible reform of pharmacist remuneration aimed at increasing the share of generic drugs delivered in retail pharmacy • However, the reform has been pending for several years and is unlikely to pass	• No specific plans at the moment, but the Italian Medicines Agency (AIFA) is leading internal discussions on how to increase the use of biosimilars

Reimbursement mechanisms are putting pressure on price

Germany: the increased use of rebate contracts for generics by sickness funds is likely to expand to biosimilars in the medium-term

The latest reimbursement reform in Germany was adopted in March 2017 with the 'Act to Strengthen the Provision of Medicines to the SHI'. The Act particularly targets the pricing and supply of innovative drugs and did not significantly address generic or biosimilar pharmaceutical pricing.

However, sickness funds of the SHI are increasingly asking pharmaceutical companies to agree to 'rebate contracts'(*Rabattsverträge*) for generics. Such contracts are set-up for an average period of 2 years following a tendering process. Companies are asked to agree additional discounts with the sickness funds. Whilst contracts do not guarantee sales volumes, pharmacies are required to deliver the product which is on the rebate contract of a patient's sickness fund. There are 113 sickness funds and over 27,000 rebate contracts. So far, the number of biosimilars on rebate contracts is limited. However, as more versions come onto the German market, sickness funds may also seek rebate contracts for some of them.

France: saving efforts involve generic price cuts and removal from reimbursement list

France is seeking to eliminate long term recurrent deficits in its social security system (which funds the SHI). The draft social security funding law 2018, which includes the SHI budget, confirms the direction of the past few years. The SHI's budget growth will be limited to an average of 2.3% a year until 2022. In 2018, this will require over €4bn in savings, €480m of which will come through pharmaceutical pricing reductions.

There will be two ways to achieve this:

- The Healthcare Products Economic Committee (CEPS) will continue to review generic prices and negotiate reductions with the pharmaceutical industry. However, further to the 2016 negotiations which led to wide-ranging reductions for 600 products, the CEPS is likely to focus on specific therapeutic areas
- The Health Authority (HAS) determines whether a product is reimbursed by the SHI based on its added medical benefit. It is likely to be asked to review products in selected therapeutic areas and remove drugs whose medical benefit is considered insufficient. In recent years, such reviews have been carried out for analgesics and Alzheimer's drugs

Italy: funding constraints, spending caps and targeted price cuts to generics

Italy's finances are under significant pressure due to high levels of public debt, leading to savings across all areas of public spending, including healthcare. For pharmaceuticals, annual expenditure is capped. Pharmaceuticals sold in hospitals and in retail each have their own spending cap. The retail sector has managed to keep expenditure within the limits of the cap but the hospital sector has consistently exceeded them, meaning that the industry had to repay some of the overspend back to central government.

Although the situation is more positive in the retail sector, the Italian Medicines Agency (AIFA) was instructed to make targeted price cuts to selected generic therapeutic areas. There are currently no indications that AIFA will be required to repeat this.

The impact of national responses to funding pressure should be considered on a case-by-case basis

Responses to healthcare funding pressure in Germany, France and Italy are leading to a mixed outlook for non-originator products due to the tension between increased market share and reduced prices.

Whilst the objective to make savings on pharmaceutical expenditure through the increased use of non-originator drugs is similar, approaches by national governments vary. As a result there are limitations to drawing a general regulatory and reimbursement outlook for generic and biosimilar products in Europe. The impact on the same product is likely to be different across the three countries. It depends on the balance of the tension between increased consumption and price reduction, as well as some specific characteristics (e.g. therapeutic area) of the generic or biosimilar product.

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