FORUM


# Generic Drugs: Market Access and Pricing in Europe

*Peter Wittner*

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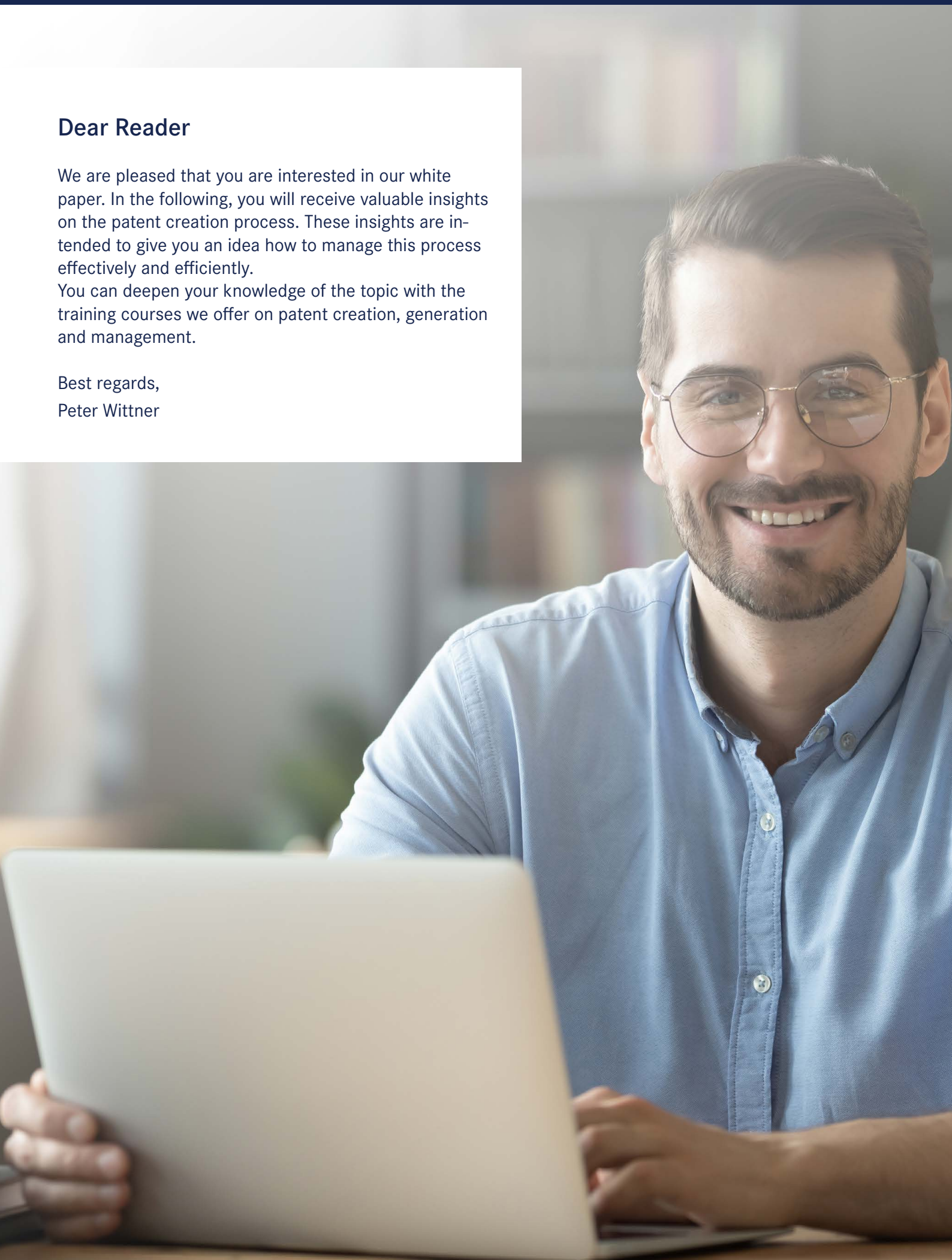
Best regards,
Peter Wittner



# Market Access & Pricing in the EU

The generics industry is an unpredictable environment that is constantly changing.

It is probably quite realistic to also describe the generics business as a Darwinian world where companies need to evolve to survive. Those that do not evolve will be overtaken or eaten by more efficient competitors that do know how to do. The motto is „Evolve or become extinct“!

What if part of the survival strategy requires us to move from the comfort of our familiar home market into another national market as part of our expansion?

Thinking about such a move will prompt questions such as:

- Is it the same as our home market?
- Are prices higher or lower?
- Is there free pricing – or will our products be tied into reference price groups?
- Are pharmacists allowed to substitute?
- Can we sell the same products – or do we need to change our product range?

A deeper understanding can help you to understand how markets differ – and how to avoid being swallowed by a larger competitor in the Darwinian generic jungle.

# Overview of generic markets in Europe

Generic Markets in Europe have similarities and differences. This means that you have to adjust your generic product range for each european market. For example a range of branded generic products can work well in one country but lose most of its value in another where products are mostly sold as unbranded generics. In addition, prices can vary quite significantly.

The summary and the illustration below may help you to get a first overview of similarities and differences in France, Germany, Spain, the UK and Italy.


**About the author**

**Peter Witttner** is an independent consultant specialising in the commercial aspects of generics and biosimilars with nearly 40 years‘ pharmaceutical experience. The major part of this has been spent in the generic industry. He was Managing Director for the UK subsidiary of the Indian generic leader Ranbaxy. Before that, he was head of the European Sales & Marketing departments of the UK generics companies Evans Medical and H.N. Norton, which later became part of IVAX and then Teva.

## Summary of generic policies by country

**Summary of generic policies by country**

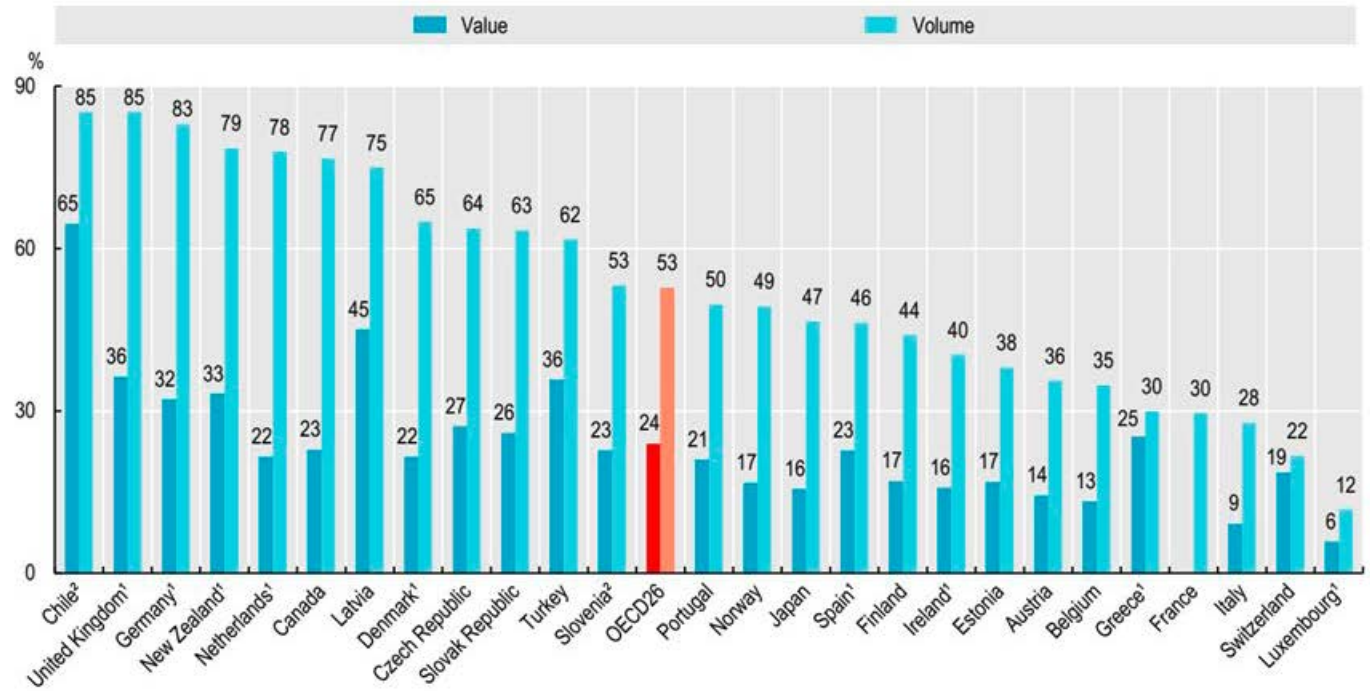
| Country | Generic pricing system | Reference pricing used? Internal and/or external? | INN prescribing by doctor / Generic substitution by pharmacist? | Length of pricing process |
|---|---|---|---|---|
| **France** | Prices are regulated | **Internal** – 60% discount from brand price + Positive List<br>**External** – None | Allowed, but not compulsory / compulsory substitution; patient can refuse | 60 days for P+R combined process |
| **Germany** | Free pricing | **Internal** – None (but many generics sold by tender) + Negative List<br>**External** – None | Allowed, but not compulsory / physician can overrule substitution; patient can refuse | 14 days for P+R; combined process |
| **Italy** | Prices are regulated | **Internal** – Originator (-20%), then based on price of lowest competitor + Positive List<br>**External** - none | Obligatory / pharmacist must offer; patient can refuse | 120 days for P+R combined process |
| **Spain** | Prices are regulated | **Internal** – Originator (-40%), then based on price of lowest competitor<br>**External** - none | Obligatory / pharmacist must offer | 30 days for P+R combined process |
| **UK** | Free pricing | **Internal** - None<br>**External** - none | Allowed, but not compulsory / prohibited | Immediate |

***Sources:*** Medicines for Europe, local generic trade associations



## European generic markets in a global comparison

Figure 9.7. **Share of generics in the total pharmaceutical market, 2019 (or nearest year)**




1. Reimbursed pharmaceutical market, i.e. the sub-market in which a third party payer reimburses medicines. 2. Community pharmacy market.
Source: OECD Health Statistics 2021.

## Legislative background

Pharmaceuticals (including generics) are governed in Europe by Directive 2004/27/EC. The legislation has produced winners (mostly the generic industry) and losers (mostly the branded R&D companies). These were the consequences of the directive:

1. Changes regarding the Data exclusivity (period during which generic applicants cannot refer to originator‘s data). At that time the period varied from 6 years in some countries to 10 in others. Nowadays this applies uniformly for 8 years.
2. Introduction of the so-called „Bolar clause“, which allows generic development work during the patent period.
3. European Reference Product: The Directive made possible to use even withdrawn brands as a reference in the european market.
4. Harmonisation of the Summary of Product Characteristics which led to a reduction of delays in registering generics in other countries.
5. Sunset Clause – allows cancellation of registration for products not marketed for 3 years.

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