

## Pharmaceutical Sector Inquiry – Preliminary Report

### Fact Sheet

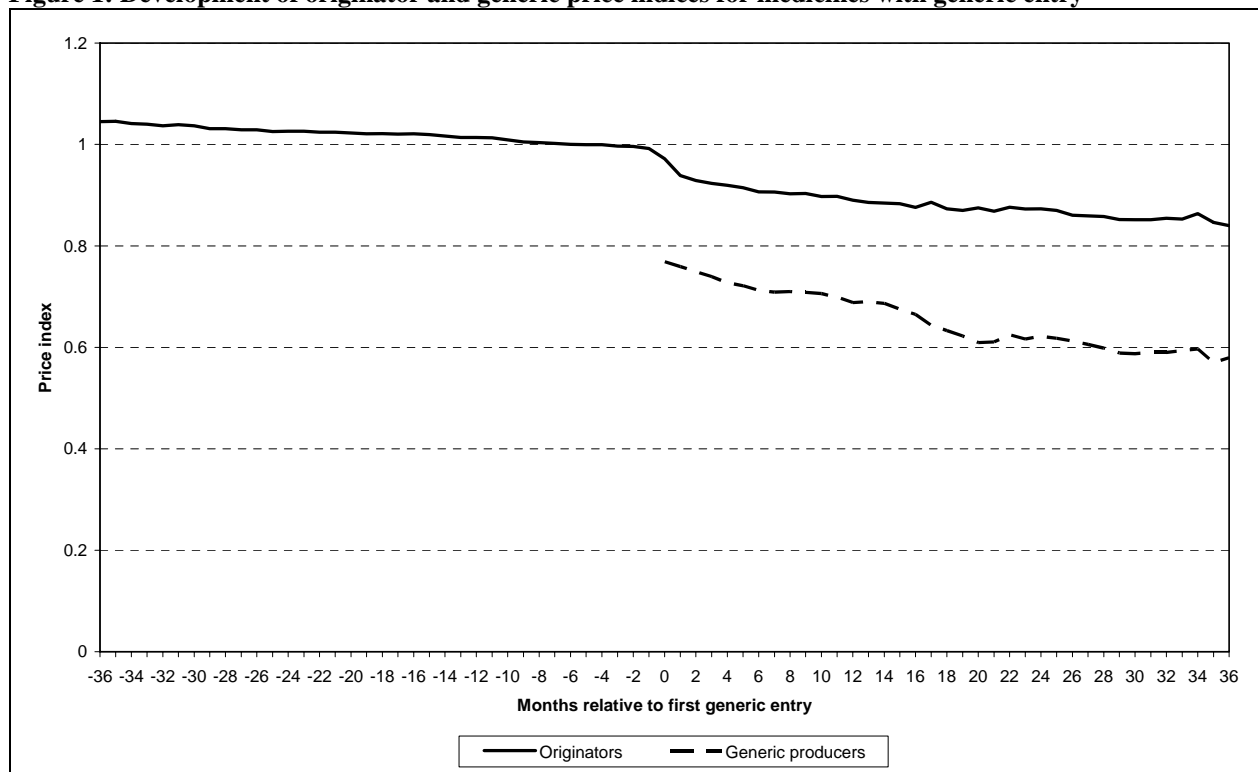
#### "Prices, time to generic entry and consumer savings"

### Price Decreases after Generic Entry

In 2007, each European citizen spent on average approximately €430 on medicines. In total, the market for medicines was worth over €138 billion at ex factory prices and approximately €214 billion at retail prices. This corresponds to 2% of the GDP.

Based on a sample of medicines that faced generic entry in the period from 2000-2007, the European Commission's report found that generic medicines enter the market at a price that was, on average, about 25% lower than the price set by originator companies prior to loss of exclusivity (e.g. due to patent expiry and loss of data exclusivity). Prices of generic medicines, after they have been available on the market for two years, are on average 40% lower than the former price of the medicine of the originator company. Also the average prices of originator companies go down. These developments are illustrated by Figure 1.

**Figure 1: Development of originator and generic price indices for medicines with generic entry**



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

Note: The originator price index is set equal to one 6 months before loss of exclusivity.

The overall impact of generic entry is significant, offering European patients better access to safe, innovative and affordable medicines, as well as reducing the burden carried by national health systems. In markets where generic medicines become available, average savings to the health system (as measured by the development of a weighted price index of originator and generic products) are estimated at almost 20% one year after the first generic entry, and about 25% after two years (EU average). The inquiry highlights considerable variations around this average in the various EU Member States and across medicines.

## **Market Shares**

Generic entry does not just affect price. It also affects companies' market shares. Generic companies attained about 30% market share (in volume terms) at the end of the first year and 45% after two years. Further, it appears that the decrease in price levels allows for more consumers being able to afford the medicine.

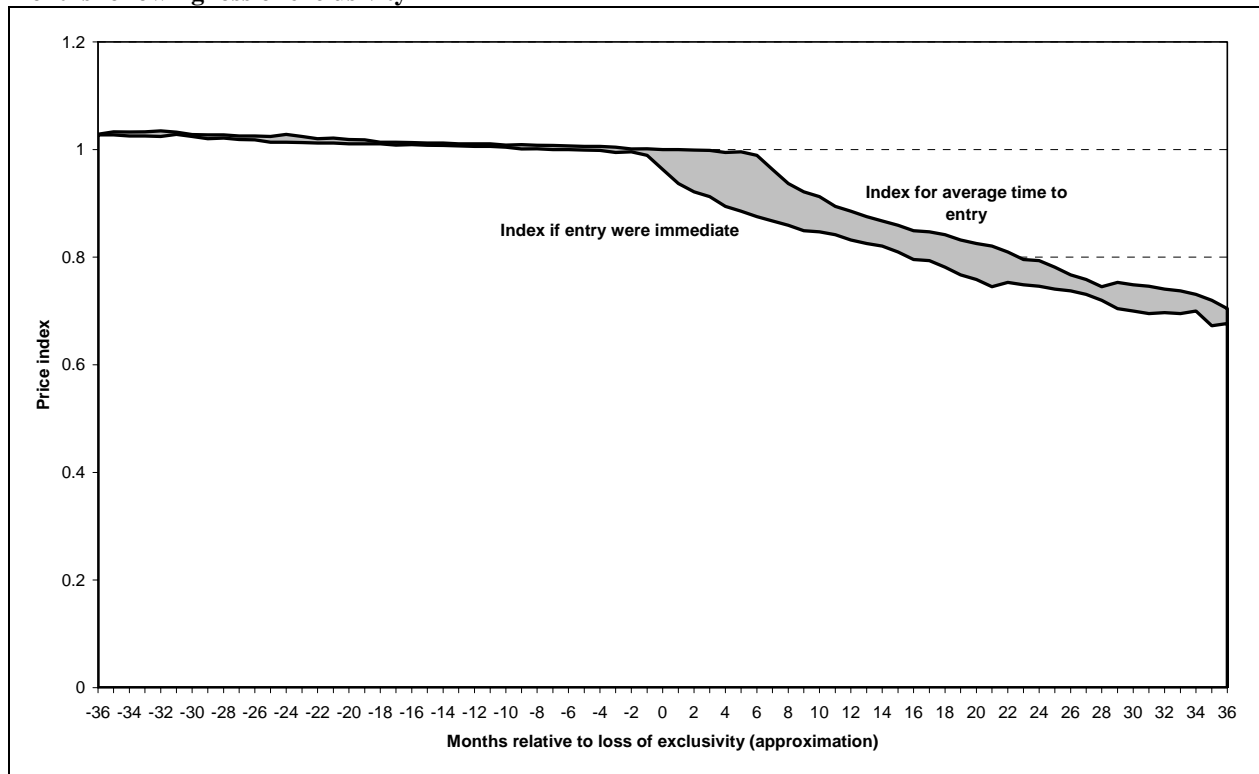
## **Time to Generic Entry**

Often generic entry occurs later than could be expected on the basis of the statutory loss of exclusivity of the originator product. The average time gap between the date on which the originator medicines lost exclusivity and the date of first generic entry was more than seven months (on a weighted average basis for the whole sample). Also for the highest selling medicines, for which rapid entry matters most, it took about four months on average before market entry.

## **Loss of Potential Savings**

Based on a sample of medicines that faced generic entry in the period 2000 to 2007, the sector inquiry has analysed the additional savings that could have been obtained over this period had generic entry taken place earlier. These savings can be illustrated by Figure 2 below. The line on the left ("Index if entry were immediate") depicts the price development of medicines if generic entry occurs at the time the medicines lost exclusivity, whereas the line on the right ("Index for average time to entry") depicts the situation where the medicines faced first generic entry only after a hypothetical time gap of 7 months (which is the average for the EU). The shaded area, the difference between the two curves, gives an approximation of the forgone savings related to late generic entry.

**Figure 2: Development of average price indices if entry were immediate and for generic entry after seven months following loss of exclusivity**

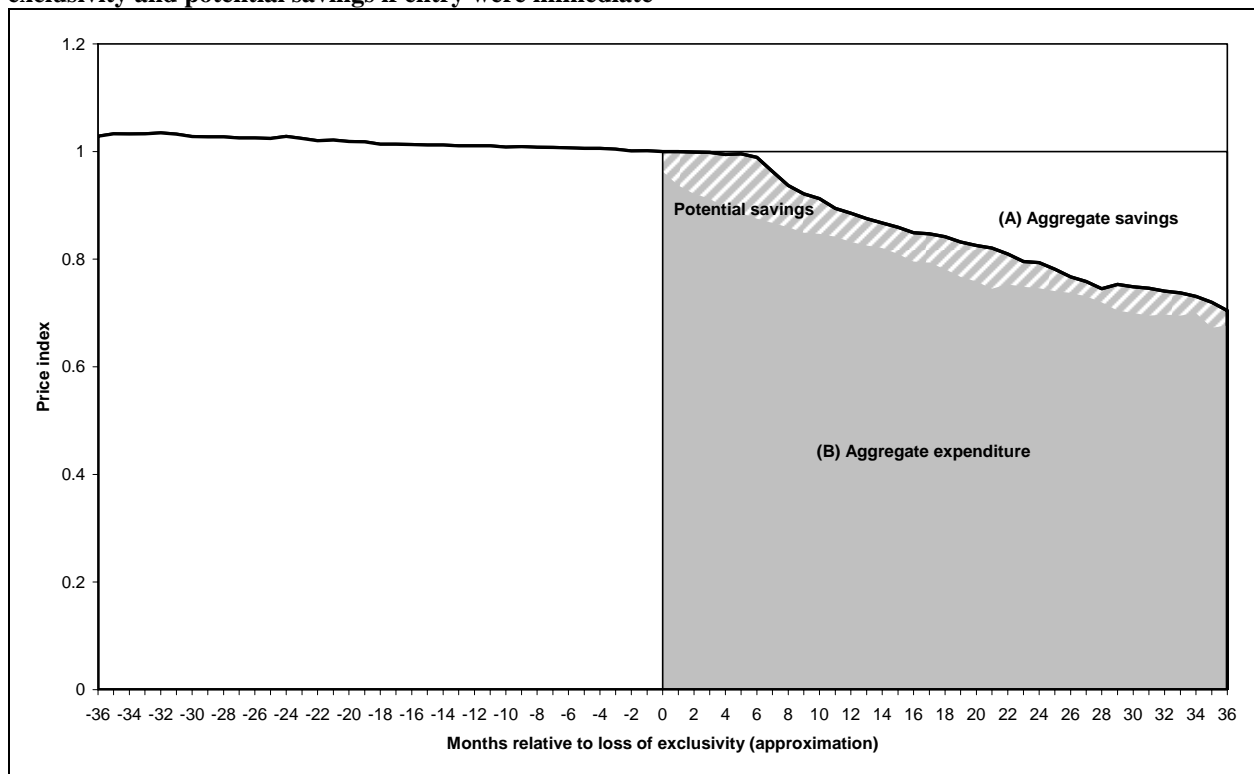


Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

The sector inquiry has estimated that aggregate expenditure on the sample of medicines analysed, which was about €50 billion over the period following loss of exclusivity<sup>1</sup> (indicated by grey area B in Figure 3 below), would have been at least €15 billion higher without generic entry (white area A). The potential savings attainable in case generic entry had taken place immediately upon loss of exclusivity of the originator medicine, could have led to additional savings of about €3 billion (shaded area). In other words, the generic savings could have been 20% higher. This is a conservative estimate..

<sup>1</sup> .At retail prices. Values evaluated at constant (pre-expiry) volumes The estimate is based on 17 Member States, where sufficient observations were available.

**Figure 3: Aggregate expenditure, savings in case of generic entry after seven months following loss of exclusivity and potential savings if entry were immediate**



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

Econometric analysis suggests that a number of factors have an influence on the observed pattern and effect of generic entry, e.g. the turnover of the originator medicines before the expiry of the patent/data exclusivity or the regulatory environment. For instance, Member States which oblige pharmacists to dispense the cheapest generic medicines whenever possible appear to show earlier entry and greater savings for their health budgets. Likewise, generic uptake seems to be faster and ultimately generic prices seem to decrease more in Member States which do not impose a price cap, e.g. a fixed percentage reduction on the originator product price, on generic companies entering the market.

For further information on the Pharmaceutical Sector Inquiry, please consult:  
<http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>