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WHAT HAPPENS TO ORIGINATOR MEDICINES WHEN (GENERIC) FOLLOWERS ENTER THE PUBLIC MARKET

BACKGROUND and OBJECTIVE

Many pharmaceutical companies claim that because of existing European national pricing regulations, namely the widespread policy of external reference pricing (i.e. the policy to compare and base prices of medicines to those in other countries) some medicines, especially originator products that went off-patent, disappear from the public market. The Euripid quality assurance team is working on analysing the effects of external price referencing in different countries. We investigated the likelihood and – potentially – the duration until originators disappear from national public markets once generic followers enter the market.

METHODS

We extracted panel data from the Euripid database for seven selected active ingredients that play a major role in national public medicines markets. The chosen active substances (atorvastatin, clopidogrel, donepezil, omeprazole, olanzapine, paroxetine, valproic acid) were basically marketed in all countries according to registration databases. All strengths, presentations and pack sizes were considered. For the purpose of this analysis, we defined public market as publicly funded reimbursable medicines (irrespective of the actual reimbursement rate). Euripid database currently contains information on reimbursable medicines from 28 European countries, for some countries back to the year 2010. We checked if originators of the mentioned substances were marketed at different periods commencing with their first appearance, the latest being May 2016 and if relevant – when they had been delisted.

RESULTS

In 2016 the originator brand was not reimbursed

- ◆ for atorvastatin in Poland and Estonia,
- ◆ for clopidogrel in Czech Republic, Estonia, Hungary, Poland and Slovakia
- ◆ for donepezil in eight countries,
- ◆ for omeprazole in 13 countries,
- ◆ for olanzapine in Estonia, Latvia, Poland and Slovakia,
- ◆ for paroxetine in six countries,
- ◆ for valproic acid in Bulgaria, Iceland and Estonia.

Regarding timelines, no explicit, direct 1:1 connection could be established between the time of generics entering the market and the delisting of originator brands. Whereas we can find countries (e.g. Estonia or Czech Republic) where originators disappeared as early as 2010 or 2011 there are examples like clopidogrel in Hungary where the originator stayed in the national formulary despite a number of generics was listed for more than six years.

CONCLUSIONS

The likelihood that an originator product is delisted from a national formulary (reimbursement or positive list) after generic followers enter the market is high, but the time for delisting varies considerably from immediately till never.

This fact might be stimulated by the policy of external pricing but even more by internal referencing of medicines or tender-like procedures as in Denmark where the lowest priced products take the market. In the case of olanzapine and atorvastatin almost 2,500 different medicines with this active ingredient were marketed in the 28 surveyed countries, many of them much cheaper than the originator.

The country with the highest likelihood for an originator not to be listed in a national formulary is Estonia. This needs to be considered as serious indicator for access barriers as, e.g. there was also not generic version of olanzapine reimbursed in the outpatient sector at time of analysis.

Furthermore, we found that some manufacturers shaped their dissemination strategy by applying for inclusion of own generic versions of their products in national formularies. Therefore, e.g., atorvastatin is marketed by Pfizer® as reimbursable generic version in the Czech Republic, Austria, Hungary, Ireland or Switzerland.



FACTBOX EURIPID

- ◆ **EURIPID Collaboration** is a voluntary and strictly non-profit cooperation between mostly European countries on building up and maintaining a database with information on national prices of medicinal products in a standardised format.
- ◆ EURIPID database contains data on official prices of publicly reimbursed, **mainly outpatient medicinal products** that are published by national authorities in line with the Transparency Directive 89\105\EC.
- ◆ Access to the database is exclusively available to the **European Commission** and for **national competent authorities for pricing and reimbursement of medicinal products**, who agreed on the rules of the collaboration and who participate actively.
- ◆ Currently data of **29 countries** are available in the database, 28 European countries went into the analysis.
- ◆ **More than 10 000 000** price references of medicinal products
- ◆ **Price Types:** Ex-factory Price (Ex-Fact), Gross Retail Price (GRP), maximum price
- ◆ Researchers may apply for price data on aggregated level to euripid@oep.hu

