PRICE ANALYSIS OF NEW MEDICINAL PRODUCTS REIMBURSED IN ITALY AND GERMANY

Giorgio Casilli1, Dario Lidonnicì1, Martina Isernia1, Matteo Morichi1, Mareike Konstanski2, Ulrike Kuchenbecker2, Thomas Mittendorf2, Elena Paola Lanati1

1MA Provider, Milan, Italy; 2Xcenda GmbH, Hannover, Germany

Background
The launch sequence and submission to HTA authorities become more and more relevant with innovative, high-priced drugs, in terms of planning, since it may affect pricing strategies.

Objectives
Aim of the study was to analyse the impact of price negotiations and compare the outcomes of the process in Italy and in Germany.

Methods
Price information of 82 newly reimbursed medicinal products (January 2015 to June 2019) were available for Italy and Germany. Analyses were conducted according to their orphan status1, therapeutic area, innovative status2 and reimbursement class (based on Italian criteria). For Italy/Germany, published ex-factory prices at date of launch (Official Gazettes/Lauertaxe3, including mandatory temporary reductions4) were compared with net prices including confidential discounts after price negotiation (tracked by regional public tenders/Lauertaxe). Finally, we made a comparison of the ex-factory and net/reimbursed prices5 between the two countries.

Figure 1. Italian vs German ex-factory price.

Results
Compared to Germany, the Italian ex-factory price was on average 22% lower (Figure 1).
Subgroup analysis showed that Italian vs. German ex-factory price was -27% for orphan drugs (n=25), -20% for oncological drugs (n=27), -15% for innovative drugs (n=23) and -26% for other drugs (n=32). Analysing prices after negotiation processes, Italian net price resulted on average 23% lower than German reimbursed price (Figure 2).
Subgroup comparison (Italian vs. German net/reimbursed price) showed -21% for orphan drugs (n=25), -24% for innovative drugs (n=23), -19% for oncological drugs (n=27) and -24% for other drugs (n=32).
Price negotiation yielded to discounts amounting to -25% on average in Germany and -24% in Italy (Figure 3).

Figure 3. Negotiated discounts on Italian ex-factory price vs negotiated discounts in Germany.

Interestingly, if the reimbursement in Italy (i.e. the negotiation with AIFA) was granted before the G-BA decision (German negotiation), prices in Italy resulted on average -55% lower than German launch price (data not shown).

Conclusions
Our analysis highlighted that negotiated discounts in Italy are higher than in Germany leading to lower prices of reimbursed drugs.
Even if International Reference Pricing is not a key determinant of the Italian reimbursement system, it may affect AIFA’s decision-making process on pricing negotiation.
Since Germany is almost always the first country in EU where a new product is launched, German price can be set as a starting point for Italian price negotiation. This becomes also more relevant in the case AIFA approaches the price negotiation after the G-BA assessment. Companies should thus carefully plan their launch sequence and design accurate access scenarios, being difficult and almost impossible to reset the price afterwards.

References
5. http://www.g-ba.de/

via Vincenzo Monti 3
20123 Milan - Italy
tel +39 02 8906882
fax +39 02 8909827
e-mail | info@maprovider.com

piazza San Salvatore in Lauro 10
00186 Rome - Italy
tel | fax +39 06 68006614
e-mail | info.roma@maprovider.com

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