POTENTIAL IMPACT OF PRICE ADJUSTMENTS IN GERMANY ON OTHER EUROPEAN COUNTRIES: A SIMULATION MODELING EXERCISE (PHP188)

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Abstract: International Reference Pricing (IRP) is a key cost-containment tool for health care payers across the world. IRP may apply either fixed or flexible rules to calculate the price of branded drugs. Typically there is no negotiation between manufacturers and the IRP body. In the context of the German AMNOG price negotiations and the role of Germany as a key reference country, there is dearth of evidence on the potential cross-border impact of the AMNOG law. Our objective was to simulate the potential impact. Methodology: An IRP tool (Orange) was used to simulate scenarios of price agreements for a new branded drug between the German Head Association of the Statutory Health Insurance Companies and the manufacturer. The impact of price agreements on other European countries was evaluated based on existing IRP rules as defined in the Orange tool. All prices were initially set at 100 euro to limit the impact to Germany only. Results: A 50% price decrease in Germany would lead to a range of reductions across Europe. The largest impact would be in France, Romania, Russia, Slovenia and Luxembourg (50% decrease) followed by Norway, Greece (17%), and the Netherlands (13%). Switzerland, Ireland, Denmark and Austria would be only marginally impacted by a price reduction in Germany. In contrast, with a price increase in Germany of 25%, a limited impact in other countries was observed. Such an increase would lead to 6% price rise in the Netherlands, 4% in Switzerland, 3% in Ireland and Denmark, and 1% increase in Austria. Conclusions: Price negotiations in Germany could potentially impact the price of new branded therapies in numerous other countries. Ongoing downward pressure on pharmaceutical prices could ultimately have a negative impact on innovation and drug development in Europe.

The Act on the Reform of the Market for Medical Products (Arzneimittelmarkt-Neuordnungsgesetz – AMNOG) of 22 December 2010 put an end to free pricing for new drugs in Germany. (1)

The Act requires that new products are subjected to an early evaluation of their additional benefit by the Federal Joint Committee (Gemeinsamer Bundesausschuss – G-BA) after being launched on the market:

- If it is not possible to prove any additional benefit versus the comparative therapy previously identified by the Committee (existing standard therapy), the pharmaceutical is allocated to a reference price group with comparable active ingredients. If there is no such reference price group, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband – GKV-SV) negotiates with the pharmaceutical company on a refund rate which does not lead to higher annual therapy costs than the expedient comparative therapy.

- If an additional benefit is proven to exist, the National Association of Statutory Health Insurance Funds negotiates with the pharmaceutical company a supplement on top of the price of the expedient comparative therapy.

While the AMNOG procedure is being completed, the price set by the pharmaceutical company itself applies to the new pharmaceutical, but only for one year.

International Reference Pricing (IRP) is a key cost-containment tool for health care payers across the world. IRP may apply either fixed or flexible rules to calculate the price of branded drugs. Typically there is no negotiation between manufacturers and the IRP body. (2)

OBJECTIVES: In the context of the German AMNOG price negotiations and the role of Germany as one of the most referenced countries worldwide, there is dearth of information on the potential international impact of the AMNOG Act. We carried out pricing simulations to assess the potential impact of new drug pricing in Germany as a result of the AMNOG Act on other countries that reference Germany either formally or informally. See Graph 1.

METHODS: The publicly available IRP rules were screened and evaluated systematically and based on these findings an IRP tool called “Orange” was developed. We employed the Orange tool to simulate scenarios of price agreements for a new drug between the German Head Association of the Statutory Health Insurance Companies and the manufacturer and to evaluate the potential impact of these price agreements in other countries. See Graph 2.

RESULTS: Currently Germany is being referenced by more than 20 countries worldwide, including Austria, Canada, Denmark, Egypt, Finland, France, Greece, Ireland, Israel, Italy, Japan, Luxembourg, the Netherlands, Norway, Romania, Russia, Slovakia, Slovenia, South Korea, Switzerland and Taiwan.

We simulated a hypothetical price dataset for a new branded drug X with all prices set at 100 euro to limit the impact to Germany only. We assumed the drug would be launched in all markets evaluated.

In the first simulation we assessed the impact of a 25% price drop in Germany on other markets, with a focus on Europe. The results suggest that such a reduction would lead to a range of decreases elsewhere. The largest impact in Europe would be in France, Romania, Russia, Slovenia, Luxembourg (-25%), followed by Norway and Greece (-8.33%), Netherlands (-6.25%), Switzerland, Ireland and Denmark. See Graph 3.

A price drop of 50% in Germany would proportionately double the impact in most countries. See Graph 4.

Assuming that the new drug had solid evidence supporting a significant additional benefit that resulted in a 25% increase in the price in Germany, the simulation results demonstrated a limited impact. The model predicted a modest 0.25% increase in the Netherlands, 4.17% in Switzerland, 2.78% in Ireland and Denmark, and about 1% increase in Austria. However, since IRP rules are used by payers as a cost-containment tool, it is not clear whether such price increase would indeed be implemented.

CONCLUSIONS: Given the widespread use of international reference pricing the AMNOG Act will likely have significant repercussions beyond the pricing of new drugs in Germany. This could ultimately lead to a downward spiral on pharmaceutical prices with a subsequent negative impact on innovation and drug development in Europe. Further research with real case examples is needed to understand the actual influence of AMNOG internationally.

Graph 1: Countries referencing Germany for prices of branded drugs.

Graph 2: The IRP model used to run the analyses.

Graph 3: Price reduction by 25% in Germany and impact on prices in other countries.

Graph 4: Price reduction by 50% in Germany and impact on prices in other countries.

References

Disclaimer: B. Stoykova was a freelance consultant at the time of this project and the content of this poster does not in anyway represent the views of her current employer.