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# ACHIEVING FASTER PRODUCT LAUNCH: HOW DO YOU OBTAIN NON-REIMBURSED PHARMACEUTICAL PRICES ACROSS EUROPE?

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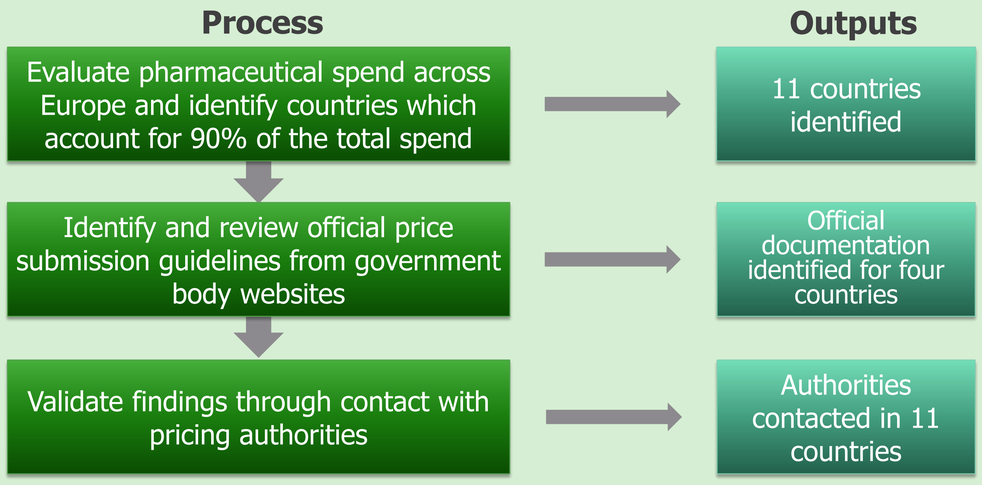
## Introduction

- Approximately one in four prescription-only medicinal products are paid out of pocket by EU patients, whereas the rest is funded by the health care system or compulsory health insurances via reimbursement procedures.[1]
- For reimbursed products, the price setting process for new pharmaceutical products are clearly defined across EU markets with information being readily accessible.
- There is a lack of published information concerning the pricing processes for non-reimbursed prescription-only medicinal products.
- The objective of this research was to determine national price submission procedures across Europe required for launch and patient access for non-reimbursed prescription-only medicinal products.

## Methods

**Figure 1. Project process and outputs**




- To determine markets for inclusion within this study, Organisation for Economic Co-operation and Development (OECD) pharmaceutical spend data across Europe (based on 2012 [or latest available year]) was utilized to identify the countries that account for 90% of European pharmaceutical spend.
- Only countries covered by the centralized marketing authorisation procedure of the European Medicines Agency (EMA) were included in the analysis.
- 11 countries, covered by the EMA, were found to represent 90% of European pharmaceutical spend.
- National price submission procedures for non-reimbursed prescription-only medicinal products across these 11 countries were analysed.
- Pricing authorities were contacted to obtain additional information related to price setting if ambiguities existed.

## Results

**National price submission procedures for non-reimbursed prescription-only medicinal products across 11 European countries**

- Price submission procedures were classified as: full price submission process; abridged price submission process, or no price submission (Figure 2).
- Nine of the 11 countries mandate submission of pricing documents (Table 1).
  - Six countries require a full price submission to the national pricing authority.
  - Three countries ask for an abridged pricing submission (i.e. price notification).
  - Two countries have no price submission or notification requirements.
- Negotiations with pricing bodies for non-reimbursed prescription-only products are limited, enabling manufacturers to have control over the price setting.

**Figure 2. Countries grouped by price submission process**

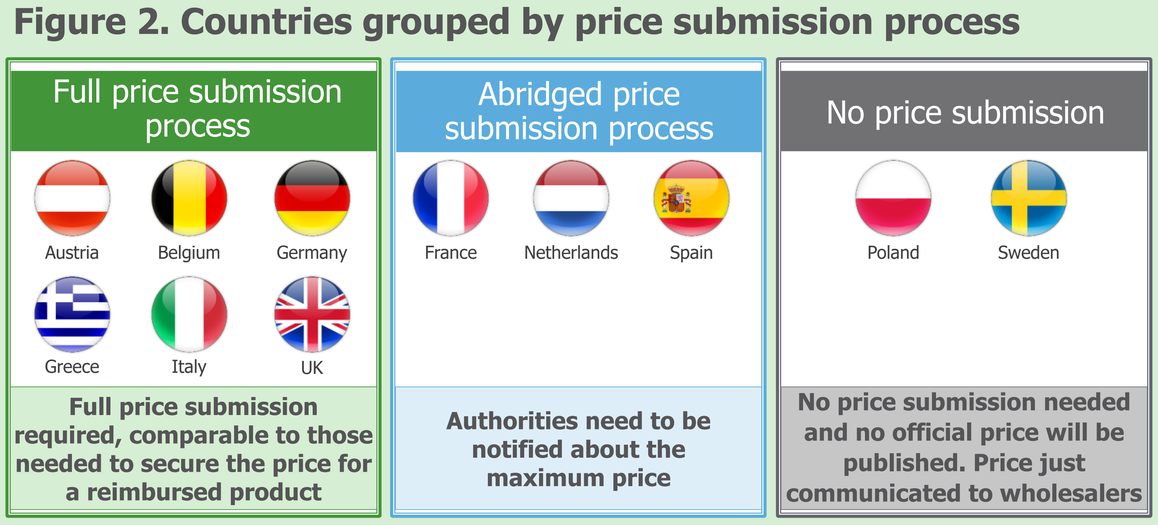



**Table 1. Price submission procedures across 11 European countries**

| | Country | Price level to be submitted | Pricing body | Prices publicly available |
|---|---|---|---|---|
| Full price submission | Austria | Ex-factory | The Federal Ministry of Health, Family and Youth (BMG) | No |
| | Belgium | Ex-factory | Federal Public service of Economic affairs | Yes |
| | Germany | Ex-factory | Lauer Taxe, Rote Liste | Yes |
| | Greece | Ex-factory | National Organization for Medicines (EOF) | Yes |
| | Italy | Ex-factory | Italian Medicines Agency (AIFA) | Yes |
| | UK | Pharmacy selling price | UK Department of Health | Yes |
| Abridged price submission | France | Ex-factory | L'Agence nationale de sécurité du médicament et des produits de santé (ANSM) | No |
| | Netherlands | Wholesale selling price | Z index | Yes |
| | Spain | Ex-factory | Ministerio de Sanidad Asuntos Sociales e Igualdad Subdirección de Calidad de Medicamentos | No |
| No submission | Poland | N/A | Ministry of Health | No |
| | Sweden | N/A | Dental and Pharmaceutical Benefits Agency (TLV) | No |

## Discussion and Conclusion

- The majority of countries require submission of pricing documents for non-reimbursed prescription-only medicinal products prior to product launch. As a result, the prices of these products are placed on official drug lists, which raises physician awareness of product availability.
- Typically, price submission processes are less burdensome for non-reimbursed products when compared to reimbursed products. Nevertheless, they are still time and resource intense to achieve a successful outcome.
- It is important for manufacturers to actively manage international prices, as several non-reimbursed markets require prices from other EU countries to be declared during the pricing process.
- With more freedom over prices manufacturers need to consider patient willingness to pay when determining the optimal non-reimbursed price levels.
- Health technology assessments for non-reimbursed prescription-only medicinal products are undertaken in some markets . This has not been included within this scope and could be a further area for research.
- Typically, time to patient access is faster for non-reimbursed prescription-only products compared to reimbursed products, but it is likely that the revenues will be lower, as patients may have lower willingness to pay.
- Whilst seeking a non-reimbursed launch price in Europe can be an optimal strategy for certain therapy areas, manufacturers should ensure such an approach optimizes revenues when compared to a reimbursed approach.

## References

1. Organisation for Economic Co-operation and Development (OECD), http://stats.oecd.org/

ISPOR 21st Annual International Meeting, 21-15 May 2016, Washington, USA