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# Why do some countries approve a cancer drug and others don't?☆

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ABSTRACT

The term drug reimbursement describes the policy system that determines whether or not a drug is entitled to reimbursement within the healthcare system. Countries make different decisions regarding which cancer treatments to routinely provide. As a result, depending on the cancer drug-indication and the country assessing it, the decision can be Favourable, Favourable with restrictions or Non-Favourable. The main objective of this paper is to describe the differences in drug reimbursement decisions on cancer drugs across 10 European countries. This aim is achieved through testing a number of hypotheses that can explain the differences in these specific reimbursement decisions. First of all, we collect data on cancer drug decisions for 10 European countries, from 2002 to 2014. Secondly, the hypotheses are tested on this database. The results show that Social Health Insurance systems tend to take more Favourable decisions than the tax-based systems, that cost-effective drug-indications have a higher probability of reimbursement and that other countries are more likely to make a Favourable decision if NICE also make it. Moreover, our findings also corroborate that an economic evaluation requirement reduces the number of Favourable decisions, and that, during the global financial crisis, the number of Favourable decisions has been reduced, compared to Non-Favourable and restricted. To sum up, characteristics of the drug reimbursement system, drug particularities and the socioeconomic situation are the main factors determining the differences across countries.



## Introduction

The term drug reimbursement describes the policy system that determines whether or not a drug is entitled to reimbursement within the healthcare system. The decisions taken by each healthcare system have an impact on the society, as they determine which drugs are made available for the patients. These are extremely important decisions, which mix the clinical and economic evidence with ethical judgements. Drug reimbursement encompasses the entire process from the submission of a reimbursement request to the final decision. In the last stage of the process, countries make different decisions regarding which treatments to routinely provide. As a result, depending on the drug-indication and the country assessing it, the decision can be Favourable, Favourable with restrictions or Non-Favourable.

Drug reimbursement has attracted attention from several authors, due to the different systems that exist. Various comparative analyses have been published recently [1–5], describing the different national models in the world. Due to these differences, depending on the drug-indication and the country assessing it, the final decision of reimbursement can differ across countries [3,6]. There are a number of descriptive and comparative studies analysing these differences [7–10] and some of them also include an empirical analyses [11–16]. These last studies are mainly based on the decisions taken in UK by either the National Institute for Health and Care Excellence (NICE) or the Scottish Medicine Consortium (SMC). Furthermore, none of these empirical studies have specifically analysed decisions on cancer drugs.

In particular, even if the European countries have common objectives for Health Technology Assessment (HTA) systems, the process is not homogenous. The operative processes and the organisations work differently across these countries. Our main objective is to describe the differences in drug reimbursement decisions on cancer drugs across 10 European countries. We explore a number

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of hypotheses that can explain the differences in these specific reimbursement decisions. The overall hypothesis of this paper is that there are differences in cancer drugs decisions across Europe related to the characteristics of the drug reimbursement system, the drug particularities and/or the socioeconomic situation.

The paper is structured as follow. Hypotheses section defines the main hypotheses. The third section describes the data on cancer drugs reimbursement decisions. In Testing the Hypotheses section, the hypotheses are tested on the cancer database. Finally, these results are discussed in the last section.

## Hypotheses

The overall hypothesis of this paper is that there are differences in cancer drugs decisions across Europe related to the characteristics of the drug reimbursement system, the drug particularities and/or the socioeconomic situation.

(1) The health system implemented in each country has an effect on the reimbursement decision. This first hypothesis is that the proportion of Favourable decisions (without restrictions) is higher in Social Health Insurance (SHI) systems than in tax-based systems. In the latter, the taxes collected are not only to be used for drug reimbursement, so there is an intrinsic competition for these funds.
(2) Countries with higher Public Health Expenditure (PHE) per capita tend to accept more drugs into the system than the countries with lower PHE per capita.
(3) A cost-effective drug-indication has a higher probability of reimbursement than a non-cost-effective one. Some authors have empirically tested this hypothesis during the last decade [11–16]. Their results were positively related with the previous statement.
(4) NICE is one of the most important HTA agencies around Europe. Their HTA analyses are considered among the most complete and strict. Thus, regardless of whether a country's decision precedes or follows a NICE decision, other countries will tend to say yes to drugs for which NICE make a Favourable decision (without restrictions). Whereas, they will be less likely to say no when NICE make a Non-Favourable decision.
(5) When the reimbursement decision-making requires an economic evaluation, the proportion of Favourable decisions is lower then when it is not required. This requirement differs across countries.
(6) Due to the global financial crisis, many austerity measures have been implemented in Europe. As a consequence, we anticipate proportionately fewer Favourable decisions, and more restricted and Non-Favourable decisions.

## Database

The sample includes the pharmaceutical technology appraisals for cancer drugs that have been appraised in 10 European countries from January 2002 until November 2014. Our database collects the drug reimbursement decisions on 161 drug-indications for the 10 countries selected: Belgium, France, Germany, Netherlands, Poland, Portugal, Spain, Sweden and United Kingdom (England and Scotland analysed separately). These countries were selected because they each have a well-defined HTA process and publicly available information on their drug reimbursement procedures.

During the last decade, many new cancer drug-indication pairs have been appraised. The drugs selected to enter into our study were classified under "malignant disease and immunosuppression" on the SMC website. SMC was the starting point because it appraises all the licensed drugs. However, the SMC list was validated, checking NICE decisions for any additional cancer drug-indication. After this process, the number of drug-indications was 161.

**Table 1**
Decision data by country (sources).

| Country | Institution/database | Data source |
|---|---|---|
| England | NICE | HTA decisions from the NICE website. |
| Scotland | SMC | HTA decisions from the SMC website. |
| Sweden | TLV/NLT | HTA decisions from the TLV/NLT website. Validation from the TLV team. |
| Belgium | RIZIV INAMI | HTA decisions from the INAMI database (online). Validation of the data and information on MEA from the INAMI team. |
| Portugal | INFARMED | HTA decisions from INFARMED database (online). Information on the MEA from the INFARMED team. |
| Poland | AOTM | Database created by AOTM. |
| Spain | BOTPLUS | Database created by EASP and UCLM from BOTPLUS. Validation of data by GENESIS. |
| Germany | G-BA | HTA decisions from the G-BA website. Only decisions from 2011 onwards (AMNOG) |
| Netherlands | CVZ/MoH | Information on decisions provided by MoH. |
| France | HAS/MoH | Database created by the URC-ECO. |

*Source:* own construction.

Table 1 reports the data source for each country. For some countries, all drug reimbursement decisions were publicly available through their websites, but for others, assistance was required from the National HTA Agencies or the National Government.

### *Decision outcome*

The decision outcome describes the final decision regarding the adoption of the technology: Non-Favourable, Favourable with restrictions and Favourable. A decision is considered to be restricted only when it differs from the indication detailed in the marketing authorisation, for instance, when a positive recommendation is limited to a sub-group of those identified in the marketing authorisation, but it is not considered restricted when the recommendation is to purchase at the lowest acquisition cost.

Moreover, in order to capture all possible decisions, the decision variable has two other categories: non-submission and non-assessed. The first category collects the decisions where the reimbursement body asked the manufacturer to make a submission and it failed to do so. Under this category, there are only decisions from NICE and SMC, as the other countries do not document this information. The non-assessed category collects the drug-indications that have not been assessed by each country.

**Table 2**
Decision outcome total.

| | Decisions (all countries) |
|---|---|
| **Non-Favourable** | **123 (7.75%)** |
| **Restricted** | **191 (12.04%)** |
| **Favourable** | **561 (35.35%)** |
| Non-submission | 43 (2.71%) |
| Non-assessed | 669 (41.16%) |
| **Total** | **1587 (100%)** |

*Source:* own construction.