

Paying for (expensive) drugs in the statutory system: An overview of experiences in 13 countries

Nikolentzos A, Nolte E, Mays N

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Summary

Introduction

The advent of new and expensive drugs creates challenges for health systems about how to make these new treatments available under the statutory system given inevitably limited resources. While these treatments have the potential to be effective for some individuals, through, for example, extending a patient's life by months or even years, their overall cost-effectiveness may be questionable and health systems may decide not to pay for these under the statutory system. Yet, patients may still wish to access these drugs and be willing to pay out of pocket to have them.

We here provide a rapid review of how countries have addressed this issue. We present an overview of policies in 13 countries on the funding of licensed pharmaceuticals under the statutory system describing the process of decision-making used by the main actors (regulators/health authorities) involved in the system for reimbursement of pharmaceuticals. The countries reviewed in this report include 10 European countries (Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Spain, Sweden, and Switzerland), plus Australia, Canada and New Zealand. These countries are characterised by different types of health systems: (i) national health service systems, and (ii) health insurance systems (social or private).

The report has been informed by several key sources: (a) an iterative search of the published literature using bibliographic databases (PubMed and Web of Knowledge), of the world wide web using common search engines (Google, Yahoo), and of governmental and non-governmental agencies/organisations of the literature on general pharmaceutical policies in the countries in question; and (b) information provided by country informants in response to a detailed questionnaire (included in the Annex to this report).

The report is broadly in two parts. We begin with an overview of the key observations on pharmaceutical policies in different countries with a particular focus on policies on funding new and/or expensive pharmaceuticals under the statutory system. This is followed by a table summarising the main characteristics of pharmaceutical policies in 13 countries, including general principles of decision-making on new drugs under the statutory system; the use of positive and/or negative lists; policies on co-payments for pharmaceuticals; time between licensing and reimbursement-decisions; the role of cost-effectiveness criteria in decision-making; examples for drugs that have been rejected for funding under the statutory system along with some general information about the systems included in this review. Part 2 of the report provides detailed assessments of each of the 13 countries reviewed here.

Key findings

1. All 13 countries have established national bodies separate from the Ministry of Health which either have an advisory role (Australia, Canada, France and the Netherlands) or have a regulatory function and make decisions on behalf of the Ministry of Health (Denmark, Finland, Germany, Italy, New Zealand, Norway, Sweden, Spain and Switzerland) about the reimbursement of new drugs under the publicly funded/statutory health system. It is worthy of note that the Ministry of Health remains the final decision-maker in some countries.
2. Federal states, such as Canada or Germany, vary in how decisions on reimbursement are taken. Thus, in Germany, decisions are taken by a federal level committee with representatives of the main health system stakeholders (Federal Joint Committee) whose decisions are binding on all statutory health insurance funds once approved by the Federal Ministry of Health. In Canada, where each Province has ultimate responsibility for health care, the majority of the jurisdictions follow the recommendations of the Common Drug Review undertaken by the national expert committee CEDAC. However, Provinces are not required to follow these recommendations and Quebec makes its own decisions without reference to recommendations from CEDAC.
3. The typical process for deciding whether a new drug should be paid for as part of the statutory system of a country includes the Ministry of Health (or an arm's length body of the Ministry of Health responsible for drugs) approving the list or formulary, after they have received advice from a specialised scientific committee or separate body (usually this is part of a national medicines agency and/or an independent organisation).
4. Cost-effectiveness is an overt criterion in decision-making on the reimbursement under the statutory system of new drugs in Australia, Finland, the Netherlands, New Zealand, Norway, Sweden and Switzerland. However, decision-making does not always depend exclusively on the cost-effectiveness evidence. Other criteria, such as the therapeutic value, effectiveness and efficacy of the drug may play a more important role. In most other countries the evaluation of cost-effectiveness of a new drug is not yet a formal requirement, but it is increasingly used in decision-making (i.e. Denmark, France, Germany).
5. Time from licensing to regulatory approval for reimbursement under the statutory system varies. In Germany, for example, drugs are automatically eligible for reimbursement by the statutory health insurance funds as soon as they are licensed, while in France the time between market authorisation and reimbursement approval may take an average of 16 months.
6. New drugs have to be included in *positive lists* in Australia, Canada, Denmark, France, Finland, Italy, the Netherlands, New Zealand, Norway, Spain, Sweden and Switzerland. In contrast, in Germany, reimbursement is automatically granted once market approval has been obtained. However, Germany has introduced an explicit *negative list* for pharmaceuticals which are not eligible for reimbursement under the statutory system, such as inefficient drugs.
7. Several countries have made special arrangements for the reimbursement of expensive drugs under their positive list (e.g. Australia, Canada, the Netherlands, and France). Access to these drugs is granted on the basis of specific criteria as to who is eligible to receive treatment, how the treatment is to be funded, and who is going to deliver and administer the treatment (for example Australia's Highly Specialised Drugs Program and the Special Authority Program).

8. The availability of new and in most cases expensive drugs (especially cancer drugs) under the statutory system has lately received considerable public and media attention in several countries. In addition, there have been cases where media attention has been sought by those lobbying for inclusion of a new drug in order to increase the pressure on the decision-making bodies to allow for the funding of new but expensive drugs (e.g. in the Netherlands). Competing private insurers in the Netherlands have on several occasions taken advantage of the media debate by including expensive drugs in their reimbursement schemes for marketing reasons.
9. In terms of specific drugs not being reimbursed by the statutory system, information is hard to obtain since few countries have transparent procedures. This point has previously been made in the Transparency Directive by the European Council (European Council 89/105/EEC). In brief, the European Council was concerned about the transparency of the methods used by the EU member states when determining the price and reimbursement level of pharmaceutical products under the statutory system, and indicated that both processes should not exceed 180 days. It further noted that when member states decide not to reimburse a specific pharmaceutical product under the statutory system, the process of coming to this decision should also be made transparent and the relevant authorities should be in a position to provide detailed information on the process to relevant actors and the public. The lack of access to this kind of information was noted by several key informants. To our knowledge, only Australia, Canada, New Zealand and the Netherlands provide accessible and transparent information about the decision-making process and the specific pharmaceuticals rejected from their positive lists as well as reasons for inclusions.

In conclusion, pharmaceutical policies in the 13 countries reviewed for this report vary considerably, largely reflecting countries' institutional, political, social and historical contexts, which determine the weight given to the views of the local pharmaceutical industry and more importantly how susceptible governments and other health system actors are to external pressures (media and general public opinion) in terms of their reimbursement decision-making processes. Tensions between authorities, whether governmental or non-governmental, responsible for reimbursement decisions and the pharmaceutical industry regarding reimbursement issues are seen in most countries.