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Stakeholder preferences about policy objectives and measures of pharmaceutical pricing and reimbursement ☆, ☆☆

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Abstract

Objective: Policy objectives, such as cost-containment and reward for innovation, can be conflicting, and different stakeholders are likely to prioritise policy measures with regard to their objectives differently. The study elicits preferences of different stakeholders in European countries about policy objectives and pharmaceutical pricing and reimbursement measures in accordance with their preferred objectives.

Methods: Representatives of eight stakeholder groups (patients, consumers, competent authorities for pharmaceutical pricing and reimbursement, public payers, research-oriented industry, generic medicines industry, pharmacists, doctors) from the 28 EU Member States were invited to express their preferences about seven policy objectives and 16 measures in a web-based questionnaire. The replies were analysed through a Multi-Criteria Decision Analysis (MCDA), using an outranking method based on the ELECTRE III algorithm.

Results: Based on 81 valid responses showed that nearly all stakeholders attributed highest priority to equitable access to medicines. Overall, stakeholders considered pharmaco-economic evaluation as the most appropriate policy measure to achieve policy objectives in accordance with their preferences. Value-based pricing and a transparent reimbursement process were ranked second and third. Across all groups, low preference was given to external price referencing (EPR) and co-payments, whereas stakeholders had differences in assessment on tendering, generic substitution and differential pricing.

Conclusions: The overall negative assessment of the commonly used EPR policy suggests a possible need for change in current pricing practice. However, positions about alternative

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pricing options differ considerably across stakeholders. It is recommended to further explore the motivation of the stakeholders for their assessments in a qualitative research project.

Introduction

At national level, policy-makers face several challenges when trying to design the most appropriate mix of pharmaceutical policy measures. These include an ageing population, managing the introduction of new, premium-priced medicines, the need to prescribe more rationally, ensuring equitable access to medicines, the balance between granting timely patient access to medicines and the need for sound pharmaco-economic evaluations as basis for informed decisions. A rational selection of medicines to be reimbursed, based on cost-effectiveness criteria, added value and need, is required in order to ensure sustainable funding despite tight budgets in times of a global financial crisis [1–6].

Personalised, or targeted, medicines in which a medicine and its companion diagnostic, frequently a medical device, are applied [7,8], are, another challenge for policy-makers since medical devices are typically not addressed by pricing and reimbursement policies [9,10]. Furthermore, the increase in pharmaceutical innovation, particularly in high-income countries [11], is likely to be over-estimated, partially due to different methodological assumptions [12]. A World Health Organization (WHO) report highlighted several pharmaceutical gaps for which innovation would be needed [13].

In the light of these challenges, policy-makers are required to balance their policies to account for different, partially conflicting policy objectives. In the European Union, the policy objectives of '(1) timely and equitable access to pharmaceuticals for patients all in the European Union (EU), (2) control of pharmaceutical expenditure for Member States, and (3) reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development' were defined as core values which need to be balanced when Member States implement pharmaceutical pricing and reimbursement policies [14].

Policy-makers can use a range of policy options that address different aims, different stakeholders and different products (e.g. orphan medicinal products, generics). A common pricing policy in European countries is external price referencing (EPR), which is defined as 'the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price' [15]. As of early 2015, 25 of the 28 EU Member States (all except Denmark, Sweden und UK) and the European Free Trade Association (EFTA) countries Iceland, Norway and Switzerland apply EPR for a range of medicines in the out-patient sector (typically on-patent medicines) and/or as supplementary decision criteria in the pricing and reimbursement process [16–18]. In contrast, value-based pricing (VBP) is rarely used as an integrative pricing and reimbursement policy: it has been applied as a key pricing method in Sweden for more than a decade but in no other European country [19]. England had planned to introduce it in 2014 [20] but eventually refrained from doing so. At the same time, VBP elements, such as pharmaco-economics and Health Technology Assessments (HTA), are increasingly being used in a supplementary way in European countries though EPR remains the major pricing policy there [21]. To grant access to new, often high-cost medicines with limited evidence, new arrangements such as managed-entry agreements (MEA) have been made in several European countries [22]. Other policies are applied for generics and biosimilars. A few countries (e.g. Denmark, Germany, Netherlands) introduced tendering and tendering-like models for generics, such as the preferential pricing policy in the Netherlands in which reimbursement is exclusively granted to the winning bidder of an active ingredient [23,24]. Tendering in the out-patient sector may also be applied to further medicines beyond generics, as this is the case in smaller countries (e.g. Cyprus) [25]. Pricing and reimbursement practices are supplemented by demand-side measures, to enhance a more rational use of medicines or to increase generics uptake. In the European Union, except for Austria, all Member States introduced either generic substitution or INN prescribing, and some countries have both policies in place [17,26].

The pharmaceutical industry has been calling for the implementation of differential pricing (DP). This policy, also known as 'tiered pricing', 'equity pricing' and 'Ramsey pricing', is 'the strategy of selling the same product to different customers at different prices – in the case of (reimbursable) medicines, prices would vary among the countries according to their ability to pay' [15]. DP is not applied within the EU market yet, also for legal limitations. Its experience has been limited to specific groups of medicines (particularly vaccines, contraceptives and anti-retrovirals) in low-income countries for which procurement is provided by international funds and organisations [27,28].

Stakeholder preferences on pharmaceutical policy measures are solely known in an anecdotic, incomplete way, when, for instance, a stakeholder group advocates in favour or against specific policies. However, their preferences have never been analysed systematically.

Against this backdrop, this study aims to survey preferences of relevant stakeholders in European countries on policy objectives and pharmaceutical pricing and reimbursement measures in accordance with their preferred objectives and to analyse them with regard to similarities and differences across groups.

Methods

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