Working Paper 1 – External Reference Pricing

Executive Summary

The high price of medicines is a major concern for policy-makers, insurers and patients. High prices can make medicines unaffordable, compromising equitable access to them, and threaten the financial sustainability of public health systems. This applies especially to new high priced medicines which are protected by exclusive market rights, such as patents and data protection.

From the early seventies, most industrialized countries began creating mechanisms aimed at containing pharmaceutical costs in the face of rising prices and limited health service budgets. Price control is one of the oldest and still more widespread forms of pharmaceutical costcontainment, but even in the narrower context of direct product price control, there are a large number of modalities and variations in the way price regulation is designed and implemented.

In recent years, many countries have introduced the practice of External Reference Pricing (ERP), where the national regulated price is derived from or somehow related to those in a „basket" of reference countries. ERP is defined in this paper as "The practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country". There are many modalities of ERP with varying combinations of methods for choosing or calculating external reference prices and also many ways to apply ERP in practice. Therefore, assessing the impact or merit of ERP, in relation to other pricing approaches, can be difficult.

A literature search revealed few published articles on ERP. Therefore, in order to gain a greater understanding of how ERP is applied in a variety of low and middle-income countries, a survey was undertaken in a sample of countries currently using this mechanism. The countries stated that they combine between two and five criteria to set prices along with ERP.

The use of ERP appears to be more justified for countries which have limited technical capacity or the resources required for more complex price regulation mechanisms such as pharmacoeconomic analysis. Countries need to consider the appropriateness of ERP along with all other options for attaining efficient medicine prices, including promoting price competition through the introduction of competitive policies – especially in the case of off-patent medicines – as well as other price regulation options. The application of ERP should be objective and transparent, in order to provide opportunities for assessing its effects, make decision-makers accountable, reduce uncertainty for the pharmaceutical industry, and diminish the risk of discrimination and corruption.

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