

Good reasons for confidential drug prices

DEBATT

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The price alone is insufficient to assess whether a new drug is too costly.

For many years, manufacturers have been permitted to offer confidential discounts in tenders for pharmaceutical drugs and vaccines in Norway. The establishment of the National System for Managed Introduction of New Health Technologies in the Specialist Health Services in 2013 allowed for confidential pricing, also in the process of methodology assessment of drugs funded over the hospital budget. In 2016, Section 6 of the Medicines Act was amended to also permit confidential discount agreements for drugs financed by the National Insurance System (1). As a result of these changes, confidential discount agreements have now become widespread.

In parallel with these changes, the Storting has adopted clearly defined prioritisation criteria, requirements for health technology assessment of all drugs prior to procurement and a considerable increase in the staffing of the Norwegian Medicines Agency and the Norwegian Hospital Procurement Trust (2, 3). The introduction of drugs for use in the health services is under better control than ever before. Paradoxically, the call for transparency around the discount agreements for drugs indicates that the distrust in these processes has rarely been as great as now.

Cost effectiveness must be the basis

On 3 March last year, Kjersti Toppe, Centre Party member of the Storting, put forward a member's bill to require publication of discounts on drugs (4). She argues that confidential drug prices make any documentation or debate on fair prioritisation impossible (5). This is

incorrect. Publication of drug discounts provides little insight into whether giving priority to a course of treatment is appropriate or not. Cost effectiveness must be the basis for decisions on priorities. Such analyses involve scientific evaluation of costs and efficacy, with price included as one among multiple elements. 'Costs' also include other so-called direct costs linked to administration, monitoring and treatment of adverse events. Additional to these are indirect costs, such as the time spent on treating the patient and travel time for the patient and next of kin. In the same process, incremental total cost is assessed in relation to the incremental health outcome that the treatment produces. This is done on the basis of clinical studies, which are often extrapolated beyond the duration of the study to estimate long-term effects with the aid of statistical methods.

The relationship between incremental cost and incremental outcome constitutes the incremental cost-effectiveness ratio (ICER), which informs us about the extra costs for a quality-adjusted extra year of life. The Storting has decided that this ratio shall be a central measure for prioritisation. The figure is always discussed and frequently cited in the reports from the Norwegian Medicines Agency. A new drug may be cost-effective, and even cost-saving, with a higher price than the drug that it replaces.

Two examples

The cost-effectiveness ratio and the underlying analyses are relatively complicated to understand. It is far easier to relate to the price of drugs, but it can also be misleading when it comes to prioritisation. Two examples:

Last year, the Decision Forum concluded that a drug used for treatment of acute lymphatic leukaemia (ALL) was cost-effective (6). Price per package was NOK 116 221.60, the expected annual price was NOK 1 034 630. Previously the same year, the forum decided that a drug for treatment of metastatic breast cancer was not cost-effective (7). Price per package was NOK 42 603.80, expected annual price NOK 555 370.90.

While the drug for treatment of acute lymphatic leukaemia had a lower cost-effectiveness ratio than the drug for treatment of breast cancer, the fact that the authorities have a higher willingness-to-pay threshold for the leukaemia product is also part of the assessment. This is due to the weighting of the degree of severity, based on expected loss of future good years of life. In these examples, the price of the drug alone provides little information as to which drug should be prioritised, but rather the reverse.

Confidence in the bureaucracy

A comprehensive system for introduction of new interventions in the healthcare services has been established. The Norwegian Medicines Agency has 180 days to assess whether the publicly known criteria for prioritisation have been met, based on documentation from the manufacturers. This is followed by a process that involves the Ordering Forum, Norwegian Medicines Agency, the Hospital Procurement Trust and the Decision Forum before a decision is made. The call for publication of the prices that have been negotiated therefore comes close to representing an expression of distrust in the above actors who participate in the preparation of a basis for decision-making.

Previously, the public had access to most drug prices, but less insight into the decision-making process, the criteria on which it was based and the total cost connected with prioritisation. Drugs were financed through different schemes based on a varying degree of assessment. Today, the public still knows the maximum price of a drug, but not always the discount that the authorities have negotiated. On the other hand, the public has access to the basis for assessment of all new drugs, the criteria they have to fulfil and their degree of cost-effectiveness.

Kurt Brekke, chief economist in the Norwegian Competition Authority, has claimed that both theoretical and empirical material indicates that publication may cause the unit prices for medicines to rise (8). It is obviously difficult to conduct good-quality studies of

the effect of confidential pricing agreements. However, as pointed out by Professor Morten Dalen at the Norwegian Business School, likely outcomes are not made less likely by being impossible to prove (9).

Confidentiality provides enterprises with an opportunity to differentiate prices between countries with varying ability or willingness to pay. Pfizer in Norway aims to make our drugs available to Norwegian patients as quickly as possible. Confidentiality is a key precondition for providing us with latitude in the process of health technology assessment.

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Published: 11 March 2019. Tidsskr Nor Legeforen. DOI: 10.4045/tidsskr.19.0106

Received 1.2.2019, accepted 7.2.2019.

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