

EAHP STATEMENT ON SUSTAINABLE AND EQUITABLE ACCESS TO MEDICINES

The immediate concern of any hospital pharmacist is to ensure that every patient within the hospital receives the medications they need in order to improve or stabilise their health status and relieve pain and suffering.

For this reason, hospital pharmacists have a direct stake in the efficient functioning of the medicines supply chain, and the operation of medicines reimbursement systems that enable patients in hospitals to benefit from sustainable and equitable access to the medicines they require.

In recent years, the growing problem of medicines shortages^[1], and the effects of austerity measures in reducing public expenditure^[2], have thrown into question the effectiveness of present systems for medicines reimbursement in Europe^[3], and the prospect of significant change in the way Governments and health systems approach this matter is either already underway^[4], or are subject to open discussion^[5].

Accordingly, to assist that discussion, the European hospital pharmacy profession conveys its views on some key aspects of the debate, from the perspective of health professionals intimately involved in matters of medicines selection, procurement, distribution, supply, manufacture, reconstitution and administration: the secondary care sector's experts in medicines.

CURRENT TRENDS IN MEDICINES PRICING AND ACCESS

Austerity and emergency measures related to medicines pricing

In a time of severe public spending restraint in many European countries, ushered in by the global financial crisis of 2008, the public expenditure costs associated with medicines has come under greater scrutiny^[6]. EAHP voices its concern at examples of policy responses in this area that appear short-sighted and detrimental to patient care, including increases to the financial burdens placed upon individual patients for meeting the costs of their medicines and other health services

As well as raising issues of equity and fairness (measures that might be said to disproportionately effect those on low incomes), this policy response raises a number of health risks, including the risks of

- lower patient adherence to their medications due to cost concerns^[7], with consequent negative impacts on health outcomes^[8]; and,
- patients and families turning to unauthorized routes of medicines supply, such as unregulated internet sites^[9], with the inherent dangers of obtaining and using harmful falsified products^[10];

Increasing the incurred costs of medicines for those in need can justifiably be considered a 'tax on ill health'. EAHP considers that health provision in Europe should continue to be viewed as a collective endeavor, and therefore urges policy makers to exercise restraint and responsibility in the allocation of medicines cost burden.

The operation of external reference pricing

The use of some form of external reference pricing (ERP) to inform decisions on prices of new (innovative) pharmaceutical products is increasingly normal in the European context^[11]. However, the manner in which the reference pricing is conducted can vary greatly, including the number and nature of countries referenced. Whilst ERP can be effective in reducing price, some concerns have been expressed that it creates an incentive for manufacturers to delay launch of a product in certain countries or negotiate confidential discount and rebate schemes harming system transparency^[12].

EAHP does not take a position as to whether ERP is a positive or negative development in relation to patient access to medicines. However it considers transparency in the systems of medicines reimbursement used within countries to be an important objective in view of the amounts of public money involved, and to aid effective scrutiny and improvement of public policy in the area of medicines access.

Health Technology Assessment, value based pricing and other innovations

Moves by Governments over the last decades to achieve a better match between the reimbursement price for medicines, and the evidence of their value and benefit, is generally welcomed as an advance in evidence-based policy. However scrutiny of the evaluation methodologies must be maintained and ongoing to ensure the balance of considerations from the patient perspective is appropriate. EAHP also recommend, for the purposes of prudent and well-informed public policy, that the expertise of the hospital pharmacist in areas such as pharmacoeconomics be leveraged and well utilised within the development of value-based pricing approaches.

The transparency of orphan drug pricing models

The EU defines an orphan drug as either a medicinal product intended for a life-threatening or chronically debilitating rare disease or a medicinal product that would not be developed without incentives because its sales are unlikely to generate sufficient return on investment^[13]. For patients with rare diseases, access to orphan drugs can be crucial in terms of receiving effective forms of treatment.

EAHP highlights a need for health systems to utilise transparent and evidence-based approaches towards orphan drug pricing and reimbursement^[14]. This is important for wider stakeholder confidence in the system, and sustainability of overall medicines

access arrangements, especially in view of evidence that an increasing proportion of pharmaceutical expenditure is being spent on orphan drugs^[15]

European Governments successfully collaborated in the creation of the European Orphan Medicinal Products Regulation, with its stimulating impact on Orphan Drug research and development^[16]. EAHP now urges European inter-Government collaboration to develop robust, consistent systems for evaluating each new orphan drug at the time of pricing and reimbursement that give grounds for ongoing public confidence.

Generic tendering

Generic tendering is another mechanism being used by Governments to deliver reductions in the price paid for medicines. Whilst evidence suggests this approach can be effective in terms of delivering cost reduction^[17], EAHP holds strong concerns that without careful use, over-zealous use of the approach can, in certain circumstances, negatively impact the sustainability of the medicines supply chain for these products^[18]. With a ‘winner takes all approach’, anecdotal evidence suggests that suppliers do not always have the manufacturing capacity to meet the existing (or potential) need, and vulnerability to the supply chain is added if alternative suppliers drop out of the market due to the loss of tender^[19].

For these reasons, EAHP urges system payers to utilise appropriate impact assessment tools when conducting generic tendering that include consideration of the impacts on medicine supply chain vulnerability and sustainability.

SUMMARY POINTS

- Tilting the cost burden of medicines in greater degree towards patients can be detrimental to medication adherence as well as discourage individuals from seeking early advice from health professionals about symptoms. The results can be avoidable worsening of a health condition and avoidable hospital admissions. EAHP therefore advises European Governments against this policy response.
- Lack of transparency in the arrangements for medicines pricing can harm public confidence in the system and deter effective scrutiny of public expenditure. EAHP urges European Governments to strive for higher standards of transparency in the area of medicines pricing and reimbursement.
- Moves towards greater use of health technology assessment and evaluation of a new medicine’s benefit/value are generally welcomed in terms of achieving evidence-based policy. However, this is still an emerging approach and therefore scrutiny of the methodologies in use must be maintained, and decision-making processes kept open to outside analysis. The pharmacoeconomic expertise within the hospital pharmacist profession should also be leveraged in the policy development process.

- Whilst generic tendering can be a useful tool for Governments in the control of medicines expenditure, EAHP calls for care and attention to be applied in respect of its impacts on supply chain security. Appropriate assessment and respect of supply chain impact should be made when using this mechanism.

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