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**This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.**

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI advocates for access to essential treatments that satisfy the priority health care needs of a population.
- HAI Europe promotes better access to medicines by advocating for EU trade policies that are coherent with the EU's commitments on health and development; by campaigning for changes to the EU's internal market laws that hamper access to medicines in Europe; by advancing EU actions on the exploration of new models of medical innovation.
- HAI Europe is committed to ensuring the rational use of medicines through greater controls on medicines promotion, independent medicines information, greater patient involvement in the reporting of adverse drug reactions so that harmful or ineffective medicines are identified more quickly, thereby reducing the threat to public health.
- HAI Europe advocates for the highest levels of transparency, independence and accountability in all aspects of pharmaceutical policy and regulation, as well as the wider participation of patients and consumers in decisions that will affect their health and wellbeing.

## Summary

HAI Europe welcomes this opportunity to respond to the public consultation on Directive 89/105/EEC on the transparency of measures regulating the pricing and reimbursement of medicines (Transparency Directive). Price transparency is key to improving the affordability of medicines and the sustainability of healthcare systems. Yet, contrary to its title, the current Transparency Directive fails to mandate the open access to medicines prices across EU member states.

Secrecy around the prices that health authorities and insurers pay for medicines, and the price determination process, limit opportunities for price comparisons. Without knowing what others

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are paying, procurers are not empowered to negotiate for the lowest price. Informed price negotiation can be an effective way to control medicines expenditure without constraining health services in the face of shrinking public health budgets. Price transparency and information exchange are key to attaining equitable access to affordable medicines in Europe.

### *Medicines prices: A veil of secrecy*

Price information is not always available to procurers or those determining prices. Specifically, the catalogue or virtual prices that are listed and publicly accessible may not reflect the real transaction price due to a number of strategies.

Price transparency can be reduced in several ways. Companies can list high prices while granting rebates or discounts to purchasers, on the condition that the actual price will not be publicised. This often happens between insurers and pharmaceutical companies in Germany. Companies can also offer bonuses, providing a larger number of units than stated in the contract, in exchange for maintaining the listed price.<sup>1</sup>

These are also examples where a lack of transparency exists as to the real price paid due to other factors. Certain policies and regulations can affect the final price. The use of pay-back is a mechanism through which companies agree to return revenue over a predetermined level to public institutions in the form of annual lump-sums. This is a risk-sharing mechanism that requires companies to return a certain part of their “excess” revenue to the purchaser if sales exceed a previously determined target. This mechanism is used in Hungary, France, and Italy.<sup>2</sup>

These strategies distort the cost of the medicine in question. In many cases, the price stated is higher than the actual transaction price. Without knowing when rebates, discounts, and pay-back mechanisms have been applied, it is impossible to make well-informed decisions about procurement prices.<sup>3</sup>

### *The price transparency EU citizens need*

Price transparency empowers pricing officers when negotiating for lower prices (and hence lowers health system spending on pharmaceuticals), equips healthcare professionals with the knowledge to make informed prescribing and dispensing decisions, and most importantly lowers the price that patients and consumers pay.

European patients and consumers need to know the price of a medicine and what they have to pay. The public need to be able to access a portal where they can compare the price of all available medicines. With this information, they can make informed cost-effective decisions about their treatment.

Health care providers need to know the costs of medicines, and in particular, what patients will have to pay to obtain the medicines they need. This information can guide healthcare professionals to make cost-effective prescribing and dispensing decisions.

Procurers, pricing officers and others need to know the true prices of medicines, rather than catalogue or list prices. Procurers at national and institutional levels need a database of centralized information on the prices of medicines throughout the European Union. Only with this information will those tasked with buying or determining prices be equipped to negotiate effectively with manufacturers for the most competitive price.

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<sup>1</sup> Espin J, Rovira J and Olry de Labry A. (2011) External Reference Pricing (working paper in review series on pharmaceutical pricing policies and interventions) Forthcoming publication by WHO/HAI Project on Medicines Prices and Availability.

<sup>2</sup> Idem.

<sup>3</sup> Idem.

### *The role of the Transparency Directive*

The Transparency Directive should mandate the creation of an online database to compare prices across Member States (procurement prices, reimbursement prices, patient prices etc). This tool should be publicly accessible and updated annually by the European Commission, based on information that is collected from Member States.

The World Health Organisation (WHO) has already established a centralised price information exchange in the Western Pacific region.<sup>4</sup> The website provides comparative information on procurement prices for selected medicines across the Western Pacific Region, empowering countries to be better equipped when negotiating with suppliers and making medicines more affordable. It is hoped that this initiative will be widened to include procurement prices for all medicines purchased by governments in the region, as well as patient prices and reimbursement prices.

Arrangements between governments and the pharmaceutical industry, such as price discounts, unpublicized rebates or price-volume agreements should be made public.

Buyers need to negotiate medicines prices based on comparative data. The Transparency Directive should mandate the transparency of procurement prices as an essential tool to ensuring affordable medicines and sustainable healthcare systems in Europe.

### *No undue delays in pricing and reimbursement decisions*

Immediate generic entry to the market after a patent has expired leads to lower prices. The onset of generic competition has been reported to yield on average a 20% price reduction one year after the first generic entered the market. Medicines prices continue to drop on average 25% of their original price after two years of competition.<sup>5</sup> Considering the potential for savings, generic medicines should not face any undue delays in reaching the market once they have met quality, safety and efficacy criteria.

### *Maintain the freedom of public authorities to provide demand-side measures*

The Directive relating to medicinal products for human use currently prohibits company incentives to doctors that may promote the prescription of a specific product. The European Court of Justice has upheld the ruling that health authorities are free to offer financial incentives to induce doctors to prescribe the lowest priced medicine in a therapeutic class, provided that the measures abide by the provisions in the Transparency Directive. HAI Europe supports this interpretation and application of the Transparency Directive. HAI Europe maintains that the freedom of public authorities to offer incentives that deliver lower prices is essential to meeting public health needs with finite health resources.

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<sup>4</sup> Price Information Exchange (PIE) website of the Western Pacific Region of the World Health Organisation.  
URL: [www.piemeds.com](http://www.piemeds.com)

<sup>5</sup> European Commission (EC) Directorate General for Competition (DG Competition), 'Pharmaceutical Sector Enquiry - Final Report' 2009, p. 28.