AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

TRANSPARENCY DIRECTIVE REVISION

POSITION PAPER

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POSITION PAPER ON REVISION OF THE TRANSPARENCY DIRECTIVE

Affordable Medicines Europe strongly support an ambitious revision of the Transparency Directive. It is a key objective for our sector to bring more affordable medicines to healthcare systems and patients across the EU. The current lack of transparency of medicines prices is one of the key obstacles to reach this objective. We therefore called for real transparency in prices of medicines.

Ensuring a competitive pharmaceutical market in the EU

The main goal of the Transparency Directive is to ensure that competition is preserved and encouraged in the EU market. Just as the Transparency Directive, parallel distribution is based on the principle of free movement of goods. Parallel importers find products that are less expensive in one Member State and import to a Member State where prices are generally higher. They then sell the medicines at a lower price than that offered by the pharmaceutical companies in the importing country. This spurs competition and bring significant savings to healthcare systems and patients.[1] Unfortunately the current Directive fails to efficiently secure competition due to a number of factors, such as secret price agreements, which by their 'voluntary' nature are not in scope of the current Directive, lack of transparency in public procurement, the market for generic medicines being out of scope of the Directive, and long timeframes.

Affordable Medicines Europe call for a revision of the Transparency Directive that takes the following four key aspects into consideration.

The Directive must include voluntary/secret agreements

The current Directive does not include voluntary agreements. The 2013 proposal for revision (COM(2013) 168 final), specifically excludes voluntary agreements from its scope. In some Member States (e.g. Germany), voluntary agreements between e.g. health insurers and pharmaceutical companies are a key component in setting the prices of medicines. In fact, in Germany alone, more than 50% of all procedures are concluded through co-called 'voluntary' agreements.2 Hence, these agreements are already part of the formalised pricing procedures.

In Sweden, "side agreements" with secret refunds have been growing in importance since 2014. Here, the Dental and Pharmaceutical Benefits Agency (TLV) coordinates negotiations between companies and the Regional County Councils (SKR). In the agreement between the Swedish government and SKR on government grants for the pharmaceutical benefits, the government and SKR share the refunds that the managed entry agreements generate.

Another example of such agreements is the so-called 'rebate contracts', which are not disclosed. This means that list-prices are known, but the actual price paid by the health insurer is unknown. The lack of transparency on voluntary agreements makes it impossible for parallel importers to know at what prices they may bring products to the market at more competitive prices. This reduces the downward pressure on

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[1] *Mendez, S. J. (2016). Parallel Trade of Pharmaceuticals: The Danish Market for Statins. Melbourne: Melbourne Institute of Applied Economic and Social Research. Retrieved from https://melbourneinstitute.unimelb.edu.au/downloads/working_paper_series/wp2016n08.pdf, Enemark, U., Pedersen, K., & Sørensen, J. (2006). The economic impact of parallel import of pharmaceuticals. Odense: University of Southern Denmark. Retrieved from https://pdfs.semanticscholar.org/92f1/eb32d32370ea06ae76abd7d009d7759e62ce.pdf, Posada, P. (2019). Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases. Madrid: NERA Economic Consulting, and Verband der Ersatzkassen. (2019, April 16). Keine Streichung der Importförderklausel für Arzneimittel. Retrieved from https://www.vdek.com/presse/pressemitteilungen/2019/streichung-importfoerderklausel-arzneimittel.html.*

[2] *BPI Pharma-Daten 2019, page 62, https://www.bpi.de/fileadmin/user_upload/Downloads/Publikationen/Pharma-Daten/Pharma-Daten_2019_DE.pdf.*

prices brought on by competition. In this case, the lack of transparency potentially stabilises prices at a higher level than the market would otherwise have dictated.

Another example of voluntary agreements is the UK Pharmaceutical Pricing Regulation Scheme (PPRS). This voluntary scheme implements a system of retrospective volume discounts. Any spending of the NHS above an agreed cap will be paid back to the NHS which leads to a subsequent discrepancy from the list price at an unknown level. According to the industry association, the payback amounts to around one million pounds per day.

The number of secret agreements between public authorities and pharmaceutical companies is growing in a number of Member States.[3] Examples of such agreements in which prices remain untransparent are claw-backs, secret price discounts e.g. for new molecules and patented medicines, and cost-volume contracts. There is a tendency to suggest that the 'rebates' given are equal to savings. However, this is not the case, as most often pharmaceutical companies start price negotiations at fictively high levels, only to give 'rebates' based on this. By the lack of transparency, every Member State may think they have struck "the best possible deal", while in fact, they have not. The savings are as fictive as the initial list-price proposed.

Finally, since External Reference Price systems applied by many Member States are based on list prices, setting a fictitiously high list-price in e.g. Germany, upon which a 'rebate' is then given to German health insurers, allow pharmaceutical companies to keep the reference prices high (the list-price), translating into higher price levels in other Member States.

A similar procedure is applied in Italy, where a given MAH and the national agency agree to a price similar to the one in other Member States and which is published in the Official Gazette accordingly. In fact, the parties agree on a secret discount during these negotiations which will only be indicated in a confidential document agreed and signed between the two parties. In the Netherlands, there are two forms of secret agreements on patented products. The government negotiates secret agreements with MAH's where the public price is higher than the real price. This so called "sluis" procedure is applied before the product enters the market in case the costs of the product is in total more than 40 euro million per year or when the costs are more than 50.000 euro per year per patient. Furthermore, insurance companies can negotiate secret agreements with manufacturers regarding reimbursement prices leading to deviations of the real prices from the listed prices.

Definition of voluntary/secret agreements

In order to effectively include voluntary/secret agreements a clear and unambiguous definition must be established taking into account the different forms on national level. We propose the following definitions:

"Secret agreements are concluded between competent authorities/public purchasers or private entities acting on behalf of public authorities and the marketing authorisation holder providing discounts or other benefits which are kept confidential."

"Voluntary agreements are concluded between competent authorities and the marketing authorisation holder for a medicinal product which are not mandatory nor represent the only possibility for the medicinal product to be included in the health insurance systems, and which aim to reimburse a medicinal product under specific conditions which are kept confidential."

Recommendation:
Voluntary/secret agreements in all forms must be included in the scope of the Directive. A concise definition of voluntary/secret agreements is key in this aspect.

[3] *In Bulgaria, 216 million BGN (approx. 110 million euro) were announced to be saved due to secret agreements in 2019. In 2020, more than 80 MAH were invited to make secret agreements with the insurance fund. In Romania, the budget allocated for secret cost-volume contracts in 2019 was 4,49 billion leu (approx. 965 million euro) for 44 contracts including 25 medicines. In Sweden, there are secret "side agreements" for 50 medicines to date. Pharmaceutical companies will pay 2.9 billion SEK (approx. 282 million euro) in bonus for medicines covered by side agreements between companies and regions for 2020.*

The Directive must include public procurement

In many Member States, public procurement of medicines provides transparency of the prices paid for medicines. However, this is not the case for all Member States, which constitute a significant barrier to more efficient competition in these countries. Especially parallel importers are discouraged from participating in tendering if winning prices are not known over time. This is due to the fact, that in effect having no transparency on prices over time, makes it very difficult for parallel importers to know if e.g. investing in a parallel import license of the given product is relevant.

In its 2012 Impact Assessment the Commission assessed that public procurement mainly affects generics and represents 8% of the market.[4] However, since then, this volume has increased and today patented medicines also play a more prominent role in the tendering. Hence, in an upcoming revision of the Transparency Directive, the advantages of including public procurement in the scope of the Directive should be reassessed and recognised. For those Member States where the winning prices are already transparent, such an inclusion would have no practical implication.

Recommendation:
The winning prices of public tenders should be transparent and accessible to all market players.

Generic medicines should be included in the scope of the Directive

Whereas generic producers do not enjoy the monopoly granted by a patent, this does not mean that the market for generics is sufficiently transparent in all instances to ensure the most efficient competition. For example, generic tender prices in the Netherlands are mostly only known by the manufacturer and the insurance company. In most cases the list price is still high and there are secret discounts.

Generic prices differ significantly across Member States and cannot be explained by e.g. income levels. As an example, generics are substantially lower priced in Denmark, Sweden, and the Netherlands than in Greece, Czechia and Italy.[5] A common feature for the lower priced countries is a transparent procurement regime for generics. Hence, the inclusion in the Transparency Directive of generics may bring such significant economic savings to Member States without such transparency.

Recommendation:
The Directives scope should be extended to include generic medicines.

A revision must introduce shorter timeframes

Today the long timeframes on pricing and reimbursement decisions, often several hundred days, are inhibiting the access to medicines for patients. Significantly reduced time limits may help improve access for patients as well as economic efficiency gains via new medicines entering the market more rapidly. While setting timeframes may always be considered arbitrary, we suggest a timeframe of 60 days should be sufficient for authorities and other bodies to make the appropriate assessments on which basis a price can agreed or set.

Recommendation:
The time limit for pricing and reimbursement decisions for new medicines entering the market should be set to maximum 60 days.

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[4] *European Commission, SWD(2012)30 final, p. 7, para. 4.2., Tendering*
[5] *Analysis by IQVIA and the Swedish Dental and Pharmaceutical Benefits Agency (TLV):* https://www.tlv.se/download/18.2fd33a7716a01b3e195b7bfe/1555315650846/internationell_prisjamforelse_2018.pdf*, p. 6.*

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Affordable Medicines Europe represents Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition for patented medicines and a supplementary layer of product safety. We represent 125 companies in 23 EU/EEA Member States. These members account for approximately 85% of the total parallel import market volume in the EU/EEA. Membership in Affordable Medicines Europe is exclusive to companies holding a wholesale (GDP) license (export and import). All importing members furthermore are GMP licensed.

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