Ensuring Equal Access to Medicines in the European Union following EU Marketing Authorisation through Centralized Procedures

Cooperation in the field of medicinal products within the European Union has over the years led to greater interaction between Member States and various joint initiatives. The assessment of new medicines on quality, safety and efficacy is one of them. Over the last 50 years Member States and the European Commission have worked together to build trust, harmonized procedures and a strong scientific backbone resulting in the pharmaceutical system as we know it today. The EU cooperation on marketing authorization of medicines is one of the most successful examples of EU cooperation.

The European Medicines Agency (EMA) is respected all over the world and is considered to be one of the most efficient EU Agencies. The organization operates as an 'assembly line' in which medicines are scientifically assessed by experts from the Member States. Meetings and procedures are organized in such a way that 98% of all requests for marketing authorization are finalized within the legal deadlines. This facilitates that new, innovative and potentially life-saving medicines can be examined efficiently. It also ensures companies of reliable, stable and professional evaluation of their products. EMA also ensures a rapid response by EU and national authorities whenever public health is at risk due to unanticipated side effects of medicines that are already on the market.

This efficient system allows (and in some cases requires) pharmaceutical companies to submit a new medicine within a single centralized European marketing authorization procedure. After a positive assessment by EMA of a new medicinal product, marketing authorization is usually granted for the entire EU market, granting access to all EU Member States. However, such marketing authorization does not mean that the authorized medicinal product automatically becomes available in all EU member states and for all EU citizens.

The reason for this is twofold. First, companies are obliged to bring products to the market in Member States with the right packaging, labelling and product descriptions in the required national language. Second, as reimbursement decisions are a national competence, pharmaceutical companies have to follow national procedures regarding reimbursement in each individual Member State. However, prior to the reimbursement phase, pharmaceutical companies are actually currently free to decide if and in which EU member states they want to bring a product to the market. Many companies follow a marketing strategy with a specific order according to which products are introduced in these national markets. And in too many cases and in particular in smaller national markets, a product that has obtained an EU marketing authorization is introduced with serious delay or not at all.

In the EU regulatory framework, several legal instruments exist that address to some extent the access to and availability of medicinal products. Article 81 of Directive 2001/83/EC states that marketing authorization holders that actually place a medicinal product on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State in question are covered[1]. However, it is not further clarified what this actually means in practice or what the consequences are when a company does not fulfil this obligation. Furthermore, according to article 13 of Regulation 726/2004/EC a centralized marketing authorization is valid throughout the EU[2]. Pharmaceutical companies need to notify the EMA of the dates of actual marketing of the medicinal product in the Member States. Marketing authorization holders also need to inform the EMA if a product ceases to be placed on the market, either temporarily or permanently. The regulation also includes a sunset clause that stipulates that any authorization which is not followed by the actual placing of the medicinal product on the internal market within 3 years, or that is no longer actually present on the market for 3 consecutive years, ceases to be valid (articles 14.4, 14.5). The reference to 'placing on the market' in this instance refers to placement of one presentation/ pack size of the product anywhere on the internal market and not on individual national markets.

The EU's so-called Transparency Directive (Council Directive 89/105/EEC) aims to ensure the transparency of measures established by EU countries to regulate the pricing and reimbursement of medicinal products through national health insurance systems[3]. It defines a series of procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the EU's Internal Market. The Directive is a peculiar instrument under EU law because it lies at the interface between EU responsibilities for the Internal Market and national competences in the area of Public Health in accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU). The Directive contains various time frames in which member states have to make their decision on reimbursement of the pharmaceutical product. However, nothing is said about any time frame in which companies are expected to introduce their products on the market.

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; OJ L 311, 28.11.2001, p.67.
[2] Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying own Community procedures or the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; OJ L 136, 30.4.2004, p.1.
[3] Council Directive 89/105/EC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems; OJ L 40, 11.2.1989, p.8.

The fact that various European Countries have to wait until pharmaceutical companies introduce their products on the various national markets, or – even when requested –never introduce these at all is unacceptable. Whilst fully respecting the division of competences between the EU level and Member States, this situation has to be improved. Therefore the Netherlands proposes to start a dialogue with Member States, the European Commission, marketing authorization agencies (including EMA), the national medicines regulatory agencies, the pharmaceutical industry and patient organizations to seek for ways forward and find solutions for this issue. For the sake of all European patients and citizens, and for the industry as well.