ADVANCING THE SINGLE MARKET FOR MEDICINES
GIRP Position Paper

1. The Single Market

The single internal European market was one of the primary stated purposes of the 1957 Treaty of Rome. The arrangements for Europe which were envisaged in the Treaty of Rome entailed a common external tariff; the abolition of internal customs duties; the removal of distortions to competition; the harmonisation of relevant laws; the adoption of a common agricultural policy; the freedom of movement for persons, goods, services and capital; and the creation of various supranational bodies to execute the Treaty's ambitious purpose.

The Single European Act represented the first major revision of the Treaty of Rome. It led to the establishment of the Single Market, in its current form, which is now at the heart of the European Union. Over the years, the European institutions and the Member States relentlessly worked to draft and adopt a network of Regulations and Directives. Such work was needed to rid Europe of the technical, regulatory, bureaucratic, and protectionist barriers that hindered internal free trade and free movement. With the removal of such obstacles national markets were opened and undertakings were permitted to compete more effectively.

Today the Single Market comprises of more than 500 million human beings who will require, on more than one occasion perhaps, access to health services, treatments and medicines. In this respect Article 152 of the EC Treaty deals with enhanced cooperation between the Member States and generally has the objective of improving the level of public health for all European citizens.

2. Why is there no Single Market for medicines in Europe?

Notwithstanding, the progress already made, much work still needs to be done in the area of the free movement of medicines. GIRP acknowledges that medicines are special goods. They are an integral part of all public health strategies as they are necessary for the protection of the health and wellbeing of every citizen. Irrespective of their financial capacity the national governments of the Member States of the European Union must ensure that the safety and efficiency of medicines is continually guaranteed.

However, GIRP believes that a balance is to be found between the needs of governments and healthcare systems to contain health care spending and the need to provide the most efficient and innovative medicines to all European citizens through the advancement of the Single Market for medicines. GIRP calls on all decision makers and stakeholders to embrace the objective of advancing the Single Market for medicines in Europe and to help finding a balanced way forward.

The EMA (European Medicines Agency) was established and began its activities in 1995. Today the EMA has an over 20-year track record of ensuring efficacy and safety of medicines for humans and animals across Europe, and promoting research and innovation in medical science. Its mission statement includes the aim of "applying efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission. To achieve this mission a European system for a centralized authorization procedure for innovative medicinal

products was introduced, which allows for a single marketing authorization to be granted to new products valid throughout the European Union. Its ultimate aim should be that every European citizen has equal access to the most innovative medicines. Since its inception, the EMA has issued close to 1000European marketing authorisations for medicines for human use.

Many believe that centrally registered medicines can freely circulate Europe wide. However, none of the almost 1000products for human use, which have received a central marketing authorisation, can circulate freely throughout the European Union, without first having to acquire additional authorisations.

The constraints to the free circulation of centrally registered medicines arises through national pricing and reimbursement decisions, which have to be taken before the product can be placed on the market. Furthermore, national laws require specific information to be placed on the package of the medicines before the product can be dispensed in their territory, such as a national registration number, for example the "Pharmazentralnummer" in Germany or the "Vignette" in France. Adaptations to these national requirements are a pre-condition for placing the product on the market.

In order to adapt the package to the national requirements and to bring a centrally authorised product to the market in a Member State, a manufacturing authorisation is necessary for each Member State in which the product is brought to the market. As this is not the business of pharmaceutical full-line wholesalers, the markets remain therefore regional or national at the uttermost.

3. Consequences of the non-existence of a Single Market for medicines

3.1. Parallel trade

Financing of healthcare and reimbursement of healthcare costs are a national competence in the EU and therefore there are 28 different healthcare systems throughout the EU, each regulated and operated according to different frameworks.

Parallel trade is a consequence, on one hand of different ex-manufacturers' prices throughout the EU Member States and on the other hand of quite different legislative situations in the 28 Member States.

Price differences between the Member States give rise to this activity and the existence of parallel trade is the proof of the non-existence of a Single Market for medicines in the European Union.

The Member States of the European Union have adopted a rather ambivalent attitude towards parallel trade. They have been in a constant state of tug-of-war in an attempt on the one hand to protect innovation and on the other to curb national expenditure by promoting parallel trade. Evidence of such can be identified in the Member States of the European Union, where for example in Germany pharmacies are obliged by law to dispense a set percentage of parallel imported products to patients and wholesalers by jurisdiction to have all parallel imported products on stock. In the United Kingdom a claw back mechanism is closely linked to parallel trade. In this respect the percentage amount taken by the government through the claw back mechanism is highly dependent on the fluctuations in the volumes of parallel trade.

The French authorities even issue licenses for exporters, whose business is limited to the export of medicines from France. Exporting licences (distributeurs en gros à l'eportation) are granted by the Agence Française de Sècurité Sanitaire des Produits de Santé (AFSSAPS), which belongs to the French Ministry of Health. The detailed requirements are laid down in French legislation (Code de la Santé, Art. R 5106 §7).

Even for centrally registered EMA products, which have already received a central marketing authorisation, a procedure has been established by the EMA granting an additional 'parallel distribution' authorisation to parallel traders who wish to bring innovative medicines registered through the centralised process to the national markets.

3.2. Delays in market access

Major delays occur in several Member States with respect to access to the most innovative medicines for Europe's citizens. In theory no reimbursement decision is necessary before a product can be placed on the market. However, in practice, in some countries, due to the unique national requirements for packaging, it is practically impossible for a manufacturer or a wholesaler to distribute a pharmaceutical product prior to a reimbursement decision, as in many cases the publication of information on reimbursement on the pack is mandatory.

The current price setting systems, which results in price differentials for medicines, between the Member States, results in a lack of price predictability for manufacturers. If there was a system in place for a European freely set price by the industry then new innovative products would be able to be launched as soon as they were approved, thus allowing access to markets at a faster pace.

4. Suggested measures to develop a Single Market for medicines in Europe

As a first step, GIRP suggests two measures, which will improve the efficiency of the pharmaceutical supply chain, as well as guarantee the immediate access to the most innovative medicines for all EU citizens.

4.1. Separation of ex-factory price setting and reimbursement decision

It is evident that there are significant differences between and even within Member States in relation to both pricing and reimbursement with respect to the time it takes to obtain a decision. The most common reason for delay to the market is the need to negotiate the public price and the reimbursement status for products. Although companies are ready to launch their products immediately after the European Commission's final decision, the lack of pricing and (or) reimbursement approval seriously hinders patients' access to these products.

The issue of pricing and reimbursement for EMA registered products should therefore be separated. In case of a detachment of pricing and reimbursement, products could be immediately placed on the market (with a European or a multi country package including all necessary national requirements) after the centralised marketing authorisation has been granted. Pharmaceutical manufacturers should be able to price an ex-factory status of their medicines for the whole European Union market. Due to the principle of subsidiarity, Member States would then have to decide upon the public price and the reimbursement of the product. Derogations should be applied for Member States where the access to the market is not possible prior to a reimbursement decision. According to these derogations, a pharmaceutical product could access the market prior to a reimbursement decision based on a freely set ex-factory price.

4.2. A European package

The information specific to a Member State has to be accommodated in the boxed area (the so-called 'blue box'), which appears on one side of the medicine pack. Manufacturers at the production level (or pre-wholesalers contracted by the manufacturers to do this), should have the right to make the necessary adaptations to the 'blue box' in accordance with the national requirements of an already standardised package, without having to obtain an additional manufacturing authorisation, so that the same medicines can be traded throughout the European Single Market. The existence of a single manufacturing authorisation valid for the entire European Union granted by the EMA, together with the marketing authorisation, could be a first step towards a Single Market for medicines and would guarantee immediate access to the most innovative medicines for all European citizens.

5. Conclusions

GIRP is fully committed to advancing a genuine Single Market for medicines. In achieving this aim, a Single market for centrally registered products could be reached as a first step and then the system can be extended to products which are mutually recognised throughout the European Union.

However, GIRP would like to stress that a pre-condition to advance the Single Market for medicines is a free manufacturer price throughout the European Union.

With a Single Market for medicines firmly established, no repackaging and (or) re-labelling would be necessary and new possibilities offered by labelling exploited.

A Single Market for medicines in Europe would result in immediate market access for all European citizens to the most innovative medicines. Similar to other sectors, a genuine Single Market for medicines will present new opportunities which will lead to a greater level of wellbeing for citizens in Europe

GIRP
European Association of Pharmaceutical Full-line Wholesalers
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Annex

GIRP

GIRP, "Groupement International de la Répartition Pharmaceutique Européenne" or in English "European Association of Pharmaceutical Full-line Wholesalers", is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. Founded in 1960, GIRP represents the national associations of over 750 pharmaceutical full-line wholesalers serving 33 European countries, including major pan-European pharmaceutical wholesaling companies. GIRP members employ about 140.000 people and distribute medicines with an annual value of over 100 billion Euro.

The pharmaceutical full-line wholesalers achieve a general public mission as they contribute to global improvement of health. Therefore, their distribution activities are being developed to the benefit of all in the communities they serve. Above all, GIRP is a communication platform and focal point between its member organisations and all players in the health care sector, providing information and co-coordinating informed opinions on all matters relevant to the efficient and safe distribution of medicines throughout Europe.

Members of GIRP are required to: (i) carry a full range of products continuously, (ii) ensure product availability to patients within a matter of hours continuously, (iii) create and maintain quality standards that ensure the safety and integrity of the medicine when delivered to the retail pharmacist.

The significance of rapid availability of medicines has a heightened importance in today's world where events such as the threat of bio-terrorism attacks or sudden viral disease outbreaks require rapid response.

GIRP members have a network of warehouses providing several daily and, in some cases, overnight deliveries to hospitals and retail pharmacies. Members employ state-of-the-art information technology and physical infrastructure to undertake this service with a level of intensity, sophistication, quality and efficiency required by manufacturers, pharmacies, hospitals and government health authorities.

GIRP members also play a role as an information conduit and supplier to industry players. This information is not only a critical analysis tool for industry participants, but plays a vital role in allowing wholesalers to efficiently effect withdrawal of a defective product from the market.

Parallel Trade

Germany

Obligation for full-line wholesalers to stock parallel imported products:

According to a decision of a German Court in 1995 (BGH, 21st February 1995, KVR 11/94), importers of medicines are regarded as manufacturers of medicines and pharmaceutical full-line wholesalers are obliged to buy medicines which have been re-imported into Germany in accordance with § 129 SGB V or those products which are parallel imported by importers of medicines.

Obligation of pharmacies to dispense a set percentage of parallel imported medicines:

In Germany dispensing of parallel imported products is in accordance with § 129.1.2 SGB V and § 5 of the framework contract under § 129.2 SGB V. Following the law, parallel imported products are products which are:

- licensed;
- registered in the IFA database;
- identical with the prescribed product concerning dosage, pack size and pharmaceutical form; (re- or parallel imports)
- which fulfil all requirements coming out of the SGB;
- where the price of the product is at least 15% below or at least 15 EUR below the price of the "original" product.

All partners within the framework of the contract agree on an import quota. This quota defines the amount parallel imported products a pharmacy must dispense. This quote is currently defined as 5% of revenue.

United Kingdom

In the UK the claw back mechanism and parallel trade are directly linked. The government in the United Kingdom can at anytime adjust the claw back amounts. For example, if there is a drop in the parallel import market volume then the Government can reduce the amount it will take through the claw back mechanism, however if there is a rise in the volume of parallel import trade then the Government can increase the amount taken through the claw back system.

France

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