Brexit – Medicines, Medical Devices and Substances of Human Origin Inquiry

Submission of the British Association of European Pharmaceutical Distributors (BAEPD) to the Health Committee of the House of Commons

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1. WHAT IS BAEPD

The British Association of European Pharmaceutical Distributors (BAEPD) is the industry body currently representing 14 of the largest licensed parallel distributors in the UK. These companies represent around 90 per cent of the UK repackaging capacity for parallel imported medicines. The BAEPD is responsible for the promotion, protection and development of the interests of its members importing pharmaceuticals into the United Kingdom from elsewhere within the European Union, and for fostering the highest professional standard of practice and conduct amongst its members

2. KEY CONSIDERATIONS FOR COMPANIES, HEALTHCARE SERVICES AND REGULATORY BODIES IN THE UK

2.1. Customs Arrangements and Tariffs

It is essential to avoid the reintroduction of routine customs control and tariff barriers to ensure timely and cost effective supply of medicines to patients in the UK.

The introduction of a "hard" border with a new customs regime will result in delay and expense in dealing with medicines which will require inspection and approval.

Tariffs on pharmaceuticals would seriously impede the import of medicines into the UK which constitutes approximately 90% of all medicines prescribed in the Health Service.

2.2. Medicines Regulation and Licensing

The development of pan European regulatory rules over the past 40 years has created a genuine free market in which medicines can be freely traded with the minimum cost and delay. This has provided great benefits to the NHS and to patients in ensuring security of supply whilst at the same time guaranteeing the lowest prices. In addition, great strides have been made in eliminating the risk of counterfeit product coming into the supply chain which put patients at risk.

It is of great importance that these benefits are not lost to the UK. This would happen if we do not ensure that our regulatory rules maintain equivalence with the European framework.

2.3. Parallel Trade

Parallel distribution occurs when products are purchased in one EU Member State where they are less expensive and transported for resale to other Member States where they are more expensive, in competition with the same product sold by the manufacturer or its local licensee. Many products are parallel distributed in the EU,

for example clothing, domestic appliances, and motor cars. Parallel distribution increases competition in the market and consumers enjoy lower prices as a result.

3. THE NATURE OF PARALLEL TRADE

3.1. Parallel distributors buy medicines in other EU Member States at a cheaper price. They move these medicines to the destination market, repackage them to comply with national regulation and linguistic needs, and sell them at a discount to the standard local price. This is possible because unlike many products sold in Europe, drug prices are negotiated individually with governments. Some countries are able to negotiate lower prices with manufacturers than others, so that drug prices can vary substantially across the EU.

3.2. Parallel trade exists throughout a wide range of commercial sectors but has been particularly significant in relation to the trade in pharmaceutical products in which parallel trade has been a very important factor within the EU for more than 40 years.

It is well established that parallel trade in pharmaceuticals has created enormous benefits throughout EU/EEA. In relation to the UK, for example:

a) PI has led to direct savings for the NHS in the period 2004 – 2009 of €986.2 million[i]

b) These direct savings benefit the Department of Health and the Exchequer through the UK claw back mechanism in which a percentage of the assumed pharmacy margin from parallel imports is deducted from payments due to retail pharmacy. The claw back is estimated currently at around £100 million per annum.

c) There are also indirect savings derived from the competitive effect of PI on originator prices. For branded in-patent pharmaceuticals, parallel trade represents the only price competition in the market and the presence of PI constrains manufacturer's behaviour in negotiating price levels with the Department of Health. It is estimated that list prices for drugs in the UK are at least 3% less than they would have been without the existence of parallel trade. A study by the Health Economics Consortium at the University of York[1] in 2003 found that such savings were difficult to measure but were likely even larger than the direct savings in the UK market.

d) Some proprietary medicines are only available in the UK exclusively through PI so without the presence of PI these products would not be available in the UK at all. Furthermore, the sudden absence of parallel imported products from the UK market in a post-Brexit scenario, is likely to create shortages for

[1] West P, Mahon J. Benefits to payers and patients from parallel trade. 2003. York, York Health Economics Consortium.

patients in wide range of medicinal products, as manufacturing capacity cannot be quickly adjusted to fill such a void (presently some 25m packs of PI medicines are dispensed annually in UK)

e) Without PI, pharmacy revenues will fail to compensate retail pharmacy from the loss of the benefits, which it currently receives from lower priced PI products. Accordingly, there will be a need for Government to pay more to maintain UK pharmacies' viability.

f) The loss of the PI industry would result in a direct loss of an estimated 3,000 jobs in BAEPD member constituencies alone. Additionally, the demise of parallel importer companies would have significant economic impact on ancillary suppliers and service providers in their local environments.

4. THE POST BREXIT OPTIONS ON PARALLEL TRADE IN PHARMACEUTICALS

5.1. Following the UK's departure from the EU in March 2019, exhaustion of rights will immediately cease to apply in relation to trade from the UK into the EU of 27 Member States since the sale of the product or service into the UK market will no longer result in the product or service being in free circulation within the EU[2].

5.2. On the assumption that Section 12(1) Trademarks Act 1994 will remain in place post Brexit, the doctrine of exhaustion of rights will continue to be applied by the English Courts in respect of "… *goods which have been put on the market in the European Economic Area under that Trademark by the proprietor or with his consent*".

5.3. However, this asymmetric application of the doctrine exhaustion of rights applies only in relation to trademarks. Section 60 Patent Act 1977 provides that importing patented goods into the UK constitutes a patent infringement even if the goods have been lawfully manufactured abroad. This will not apply where the patent owner has himself marketed the goods abroad whether directly or through a licence. In those circumstances he cannot sue for infringement of his UK patent unless he can prove that the defendant had notice, at the time of purchase that the goods were sold subject to a condition limiting the rights to import into the UK.

5.4. If the UK were to lose the benefit of exhaustion of rights within the EU/EEA following Brexit, the only competitive constraint on manufacturers substantially increasing the prices of branded pharmaceuticals would be lost and prices to the NHS would inevitably rise.

5.5. Wholesalers and retail pharmacy would cease to have access to cheaper parallel imports. This would result in the current level of clawback (which the NHS currently recovers from pharmacies to take account of parallel trade worth at least £100 million

[2] See Silhouette International –v- Hartlauer (1998) ECR i-4799; Lebago ECR i-4103; Zino Davidoff and Levi Strauss (2001) ECR I 8691

per annum), being unsustainable since pharmacy would no longer have access to PIs. In fact the benefit of PI to pharmacy is significantly higher than the amount of the clawback, since pharmacies recover significantly more savings from PI than they have to pay in clawback. Pharmacies are already under pressure from deregulation and proposal from Government to cut support. **The loss of PI may well lead to a significant loss of community pharmacies**. In the circumstances the UK Government would also be forced to increase the level of funding to support pharmacy which is already under pressure from rising costs etc.

5.6. Furthermore, manufacturers who are free to set their own prices under the Drugs Tariff would no longer be subject to the competitive constraining effect of supply through PI.

5.7. PI also provides an alternative source of product where shortages arise in the local supply chain from manufacturers.

5.8. In some cases products are not available from the manufacturer in the UK and can only be sourced through PI.

5.9. The structure and operation of the UK pharmaceutical supply chain and the pricing arrangements set by the Department of Health have developed on the basis that PI within the remainder of the EU/EEA is in place. **If we are to ensure that a system which has worked so effectively for so many years continues to operate, the retention of UK participate in EU/EEA regional exhaustion of rights is essential.**

5. THE POST BREXIT ALTERNATIVE TO PARALLEL TRADE

5.1. If the UK were to decide to remain within the Single Market, or were able to negotiate an equivalent arrangement under a bilateral free trade agreement with the EU, then acceptance of the application of the exhaustion of rights within the EEA plus the UK would be implicit. This would mean no change from the current regime and would offer the best solution for the industry, the preservation of jobs and the NHS in ensuring that we maintain the most competitive prices for pharmaceuticals.

5.2. However, the Government has indicated that the UK will not seek to remain in the Single Market but will nevertheless seek to achieve, "*the greatest possible access to the single market through a new, comprehensive, bold ambitious free trade agreement*".[3]

5.3. If the UK does not remain within the Single Market and fails to achieve a Free Trade Agreement providing for the continuation of the EEA Regional Exhaustion of Rights, it will be necessary to consider what unilateral approach the UK could adopt on the issue for the future.

[3] Speech of Theresa May February 2017

International Exhaustion

5.4. Prior to the UK joining the EU, English law permitted a degree of international exhaustion. This was because it was generally recognised that:

a) parallel trade is desirable since it limits the ability of the right owner to partition the world market into individual countries. In this way intra band competition is encouraged leading to a reduction in consumer prices.[4]

b) the primary function of a trademark, and indeed other IP rights, is to prevent the parallel importation of goods which are not genuine. On this reasoning, if the product is lawfully placed on any market by the right owner or with his consent, the consumer interest is protected and the right holder has achieved his first sale so that the IP right owner requires no further protection.

5.5. The World Trade Organisation (WTO) Agreement on Trade Relating Aspects of International Property Rights (TRIPS) expressly leaves it to each Member State the freedom to address exhaustion of intellectual property rights.

5.6. In the USA the Supreme Court delivered an important judgment on the application of the exhaustion of rights in the case of *Impression Products Inc –v- Lexmark International* Inc ('the Lexmark Case') in May 2017. In that case the US Supreme Court found:

a) That Lexmark exhausted its patent rights in the subject products the moment it sold them and that there was no right for Lexmark to retain patent rights it had elected to sell;

b) That the exhaustion of rights extended to sales of subject products outside the USA and imported into the USA for resale.

5.7. The approach in Lexmark follows the jurisprudence of the Supreme Court in copyright. In *Kirtsaeng –v- John Wiley and Sons Inc* in 2003, the Court held that the first sale doctrine (the equivalent of exhaustion of rights) applied to goods manufactured abroad with the copyright owner's permission and then imported into the US. The same principle is applied under US law to trademarks where a reseller of trademarked goods imported from outside the USA does not infringe US trademark rights so long as the imported goods have not been altered so as to be materially different from those originating from the trademark owner.

5.8. The UK could adopt international exhaustion for some or all IPR's as in the USA thus admitting into the UK all products and services incorporating IPR provided that the IP right in question have been placed on a market by the IP owner or with his consent. Such a measure might be qualified to exclude those products where there

[4] Revlon Inc v Cripps & Lee Ltd (1980) FSR 85 (CA) out of Colgate Palmolive Ltd v Maxwell Finance Ltd (1989) RPC 497 (CA).

are significant differences in the characteristics or quality of the products to avoid issues of confusion for the consumer. **The presence of significant intra brand competition from imports would guarantee that UK consumers pay the lowest prices whilst IP owners would still have their first sale rights protected.**

5.9. However, in relation to medicines, a major obstacle to adopting international exhaustion is the regulatory framework. The manufacture and distribution of medicines within the EU is tightly regulated. All manufacturers, wholesalers and retailers of pharmaceuticals are licensed under an EU wide regime which provides for strict rules designed to ensure patient safety and to reduce, if not eliminate the costs of counterfeit products entering the supply chain. EU Directive 2011/62 (the Falsified Medicines Directive (FMD) will introduce an EU wide register of pharmaceuticals which will track all pharmaceuticals from manufacture to patient dispensing through an FMD hub based in Brussels with national hubs established in each Member State. The UK is an active participant in the development of FMD. It is assumed that notwithstanding Brexit, the UK will continue with its participation in the EU based regulatory scheme for pharmaceutical products.

5.10. On the basis that the UK continues with its participation in the EU pharmaceutical regulatory framework, the unilateral adoption by the UK of EEA wide international exhaustion or global international exhaustion would have no impact from a regulatory perspective as regards parallel trade with the EEA. However, the unilateral adoption of international exhaustion by the UK is likely to complicate the relationship within the EU in relation to parallel exports from the UK into the EEA. There will be concern that the UK should not provide an entry point into the EU in respect of products not qualifying under the EU exhaustion rules. **There is a danger that a unilateral adoption of international exhaustion might therefore complicate, if not seriously compromise, negotiations for the UK remaining within the current EU/EEA regime.**

5.11. Furthermore, the need to align measures to secure patient safety and prevent counterfeiting would give rise to significant regulatory issues which would make the application of exhaustion of rights to trade with non EEA countries difficult. This is because all countries will have different regulatory arrangements for pharmaceuticals within their domestic markets. It has taken the EU 40 years and the creation of a centralised administration to create an integrated European market for pharmaceuticals. Can we afford to embark on a similar journey with all other countries with whom we wish to trade?

5.12. The EU experience is not, of course, entirely analogous with a unilateral decision to adopt international exhaustion. We are concerned with parallel trade <u>into</u> the UK

rather than imports and exports from the UK. Accordingly the primary regulatory issue would be that of ensuring that PI products from outside the EU are substantially equivalent to a product for which there is a market authorisation in the UK. This role is already undertaken by the MHRA in relation to EEA products and it is possible that the MHRA's role could be extended to cover imports from non EEA countries. However, the MHRA currently struggles with its capacity to regulate EU trade into the UK. Enlarging the MHRA's role to cover global trade in pharmaceuticals into the UK would require a very substantial increase in resources for the MHRA.

5.13. BAEPD's view is that the key priority must be to retain the existing benefits enjoyed by the UK through the well-established regional regime of exhaustion of rights within the EU. Although BAEPD does not oppose the idea of international exhaustion in principle, it would be very difficult, costly and time consuming to implement. BAEPD therefore believes that it should not be allowed to obstruct the essential need to secure the maintenance of the principles of exhaustion of rights between the UK and the remainder of the EU of 27.

BAEPD

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