British Association of European Pharmaceutical Distributors – Written Evidence (UST0019)

Introduction

1. The British Association of European Pharmaceutical Distributors (BAEPD) is the professional organisation representing 16 companies engaged in the parallel import of licensed medicines into UK, all of whom possess the appropriate licences granted by the Department of Health and Social Care ("DHSC") through the Medicines and Healthcare Products Regulatory Agency ("MHRA"), the competent UK national regulatory authority, and, where applicable, for centrally-authorised medicinal products, by the European Medicines Agency ("EMA").
2. These licences authorise the specific Company to whom such approvals have been given, to source licensed prescription pharmaceuticals, inter alia, from any member state within the European Economic Area (EEA) and to distribute such products into the supply chain in the United Kingdom, normally either to the retail pharmacy, the dispensing general practitioner, hospitals/clinics or to other appropriately licensed wholesalers. This activity is known as Parallel Distribution and is only legally permissible because of a legal principle known as "regional exhaustion of rights", the relevant region in this case being the EEA (see below).
3. Member companies engaged within the Parallel Pharmaceutical Distribution Industry (PPDI) purchase licensed prescription medicines from whichever country has the lowest price or highest availability and distribute them in a country where the price is higher. A considerable saving therefore is achieved by the Health Service providers (and the Government) in the UK, a saving which helps in the drug cost containment programme, while enabling added value to be realised within the sector. The PPDI also enables shortages of medicines in the UK to be remedied by importing into the UK medicines which could not otherwise be sourced from domestic routes, thus ensuring that patients do not suffer from the non-availability of the medicines that they need.
4. The PPDI is primarily concerned with ensuring that the high standards of public health and safety as laid down and enforced by the relevant authorities within the MHRA are maintained. To this end, the BAEPD members comply with the Code of Operational Conduct ('Good Parallel Distribution Guidelines') operated by the pan-EU parallel distributor representative association, Affordable Medicines Europe, of which BAEPD is a member, and to which all member companies must adhere.

5. We are delighted to provide a submission to the Select Committee with regards to the UK-US Trade Negotiations. Given the interests of our members this submission focuses only on the issue of healthcare, and in particular drug pricing. Our submission will be that low prices for drugs are essential to support the Pharmaceutical Supply Chain and it is primarily the continuation of the regional exhaustion of rights regime which enables this. Accordingly, any negotiations with the US regarding health and drug pricing cannot be divorced from the parallel discussions with the EU regarding exhaustion of rights and indeed the general discussions taking place within the UK and co-ordinated by the Intellectual Property Office into the most appropriate exhaustion of rights regime post Brexit.

Parallel Distribution

6. 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 (and/or healthcare systems) enjoy lower prices as a result.

7. As explained in the introduction, parallel distributors of medicines buy them 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 Member States, and not the European Commission itself, have competence over national pricing, resulting in a wide range of strategies and, consequently, of discount levels. Some countries are able to negotiate lower prices with manufacturers than others, so that drug prices can vary substantially across the EU.

8. Parallel Distribution has operated safely and effectively in Europe for more than 40 years and Parallel Distribution in medicines is highly regulated, with all importers requiring appropriate EU and/or national licences to trade. The total EU market in parallel distributed medicines is estimated at a little over €5 billion, of which the UK received approximately 10%, and around 45 millions of such imported packs are dispensed in UK each year.

<u>Exhaustion of Rights</u>

9. As the Committee will appreciate, Parallel Distribution is only possible because of the doctrine of exhaustion of Intellectual Property Rights (IPR).
10. Through its membership of the European Economic Area (EEA), the UK is currently part of a <u>regional-level</u> Intellectual Property Rights (IPR) exhaustion regime, which means that goods marketed in the EEA cannot be barred from being resold/distributed

across the Member States on the basis of IPR, and rights holders having the ability to control imports from outside the EEA.

11. If the UK were to leave the Single Market at the end of the transitional provisions without a deal, it could potentially be able to alter the current regime to either a national or an international regime. The UK's current no-deal preparation papers cite an unreciprocated IPR exhaustion regime as a potential default, whereby parallel imports into the UK from EEA could continue, but the EU may not grant reciprocal rights for parallel exports from the UK.

12. With national exhaustion, once a product is first sold in the UK with approval from the IPR holder, the rights holder cannot stop the products being re-sold within the UK. However, IPR holders are able to prevent re-sale within the UK of any goods that were not first placed on the market in the UK, thereby restricting parallel imports of products from another country. This would defeat the business model under which parallel distributors of medicines currently operate. It would also mean that the prices of medicines in the UK would increase substantially since the manufacturers' prices would no longer be constrained by parallel imports.

13. Contrastingly, under international exhaustion, once the IPR owner (or another with approval from the IPR holder) puts the goods on the market outside of the UK, the rights holder loses their exclusive right after the first distribution of the product, meaning they cannot prevent parallel imports from abroad.

14. The BAEPD's view has been that the key priority in the current negotiations with the EU to secure a deal by the end of the transitional provisions on 31 December 2020, and thus avoid a hard Brexit, must be to retain the existing benefits enjoyed by the UK through the regional exhaustion of rights regime. As we have explained, this regime provides costs reductions to the NHS for the supply of medicines as well as alleviating medicine shortages where they arise.

The Pharmaceutical Chain

15. In order to provide the Committee with some context for our submissions we believe that it would assist you to explain a little more about how the Pharmaceutical Chain works in the UK.

16. The UK pharmaceutical chain can be divided into two distinct channels, both serviced either directly by the manufacturer/importer, or via wholesale intermediaries:

- The primary care market which refers to the community sector, including retail pharmacy and dispensing sectors; and
- The secondary care market which refers to the hospital sector.

Primary Care Market

17. Typically, in primary care a patient will take a prescription written by a GP to a retail pharmacy. The pharmacy will dispense the medicine identified in the prescription with the patient paying a prescription charge, if applicable. In remote areas where a retail pharmacy may not be available, dispensing doctors may dispense the medicines, which they prescribe.

18. Pharmacies are reimbursed by the NHS for the medicines which they dispense. The reimbursement is based on the Pharmaceutical Price Regulation Scheme (PPRS) – an agreement between the DHSC and the ABPI (representing the manufacturers) – and the UK Drug Tariff, the catalogue of agreed prices for each molecule dispensed in UK. Essentially there is free pricing for new active substances, but PPRS seeks to limit the overall profit a manufacturer may make, after allowing for certain costs, especially research and development costs. Price increases on existing products must be negotiated and agreed with the Government. The PPRS is reviewed every five years, most recently in 2019. The PPRS review can impose price cuts on medicines on the Drugs Tariff in the review process.

19. Full reimbursement is given for medicines on the Drugs Tariff under PPRS.

20. On receiving a patient's prescription, a pharmacist may have a choice of medicines to dispense, depending on whether:
    - The medicine is prescribed generically (i.e. using its INN (International Non-proprietory Name) name) or as a branded medicine: and
    - There is a generic equivalent available.

21. If the medicine is prescribed by reference to a brand, the pharmacist may only supply the branded product available on the market or as a parallel import. Accordingly, <u>parallel imports provide the only alternative to the branded product supplied by the manufacturer in the UK</u>. This is a crucial point and the loss of access to the parallel imported product would effectively eliminate competition in the supply of branded pharmaceuticals in the UK and drive up prices.

22. The pharmacist and the wholesaler have strong incentives to substitute brands with parallel imports due to the reimbursement system used in the UK. The Government operates what is called the "clawback" system. Pharmacies are reimbursed the full list price of the domestic brand drug according to the Drugs Tariff, irrespective of the source of the product dispensed, or the price actually paid. However, the Government assumes that pharmacies are able to obtain discounts and to buy a certain proportion of their sales using cheaper parallel imports and generics and therefore adjusts the reimbursement to each pharmacy through the Discount Recovery Scheme ('clawback') in the following year. Clawback is calculated on the basis of a discount inquiry applied to a representative sample of medicines supplied across the NHS. This clawback is applied whether or not the pharmacy uses parallel imports and generics. It currently averages out at around 10% of pharmacy reimbursement income.

23. The medicine will be purchased by the pharmacy either from a wholesaler or where the manufacturer operates a Direct to Pharmacy Scheme (DTP), direct from the manufacturer via a logistics provider.

24. There are currently only three national full line pharmaceutical wholesalers – Alliance Boots, McKesson (formerly AAH) and Phoenix in UK. The remaining so called 'short line wholesalers' operate on a regional basis and will supply only certain products rather than a complete range.

25. Approximately 97% of all pharmaceutical products supplied to the UK market are subject to DTP or some form of Reduced Wholesaler Scheme (RWS) under which the manufacturer only supplies a limited number of wholesalers.

26. Short line wholesalers stock a narrow range of medicines (around 2,000 lines) and concentrate on generics, parallel imports and popular branded medicines. These are generally faster moving products that can be sold in large quantities. It is estimated that there are more than 2,000 licenced short line wholesalers in the UK varying significantly in size and in the range of products stocked.

27. In the last decade, the move to DTP and RWS has led to most manufacturers moving away from supplying all full line wholesalers which has led to a reduction in the number of full line wholesalers from 11 to 3 since 2007.

28. Vertically integrated pharmacy chains are generally supplied by their group's wholesaler (for example Lloyds is supplied by

McKesson/AAH) they can also order from other sources if necessary.

29. There are a number of buying groups within retail pharmacy who are able to use their substantial purchase power to obtain bigger discounts from manufacturers and from parallel importers sourcing product from elsewhere in the EU.

Consequences of loss Regional Exhaustion of Rights Regime and Parallel Trade in Medicines

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

31. Wholesalers and retail pharmacy would cease to have access to cheaper parallel imported alternative products. This would result in the current level of clawback, worth around £100 million per annum, to be unsustainable since pharmacy would no longer have access to PIs. In fact the benefit of parallel imports to pharmacy is significantly higher than the amount of the clawback, so that the Government would also be forced to increase the level of funding to support pharmacy which is already under pressure from rising costs and the additional severe drain on finances caused by Covid-19 economic measures,

32. Furthermore, manufacturers who are free to set their own prices under the Drug Tariff (subject to 5 yearly review as described above), would no longer be subject to the competitive constraining effect of supply through parallel imports.

33. Parallel imports also provide an alternative source of product where shortages arise in the local supply chain from manufacturers.

34. In some cases, products are not available from the manufacturer in the UK, for example where the originator Marketing Authorisation has lapsed or been withdrawn for commercial reasons, and can only be sourced through parallel imports. There are recent multiple examples during the current Covid-19 crisis where crucial access to medicines was only available in the UK because of parallel imports. If desired we can provide further information for the Committee.

35. 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 parallel imports 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 participation in EU/EEA regional exhaustion of rights is essential.

Medicine Shortages

36. Medicines shortages are a known world-wide phenomenon, emanating from many sources, such as globalisation, manufacturing compliance issues, economic/commercial marketing decisions, quota systems, and just-in-time delivery mechanisms. It is already observed in UK as a result of the proliferation of DTP and reduced wholesaler models implemented since 2007

37. Certain scenarios of the possible Brexit outcomes have the additional potential to exacerbate medicines supply for UK in January 2021 and beyond. If a 'hard Brexit' ensues, then UK, as a third country, will have limited access to EU manufactured medicines (presently the whole UK markets imports some 37m packs per month from EU sources), and new border controls are likely to introduce lengthy delays into the supply chain. Furthermore, in such a scenario, and without a binding solution on trademark rules, the supply of parallel imports into UK from EEA would also become more difficult

38. As is mentioned above, certain medicines are only available via parallel imports.

39. The European Medicines Agency has already announced that centrally-approved products, marketed under its regulatory control, will not be available for UK after 31 December 2020, absent any intervention or contingency arrangements from the UK DHSC and the MHRA.

40. The implications therefore for UK patients are potentially dire, and could lead to severe supply shortages in early 2021 and beyond.

41. Had it not been for the transitional provisions enshrined within the Withdrawal Agreement, following the UK's departure from the EU at the end of January 2020, exhaustion of rights would have immediately ceased 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 would no longer result in the product or service being in free circulation within the EU. However consistent lobbying from the BAEPD has at least resulted in the status quo being preserved in the transitional provisions at least until 31 December

2020 and given the unfortunate coincidental timing of the Covid-19 pandemic this has enabled crucial medicines to remain available to UK patients at reasonable prices. This has, we believe, saved countless lives during the Covid-19 crisis.

42. Beyond that date however no one yet knows what the outcome will be with potentially catastrophic consequences for UK patients and the NHS.

Impact of the above on UK -US Trade Negotiations

43. Although we have no knowledge of the detail of the negotiations with the US, it is widely rumoured that an objective of the US negotiators is to ensure parity of medicine prices. That would mean that medicine prices in the UK would need to rise rather than US prices will fall.

44. In recent years the regulatory apparatus of the US pharmacy chain has focussed largely on medicine safety. However, the US regulators have failed to emphasise cost-effectiveness when it comes to both new and existing medicines. The cost of US medicines is significantly higher than those in the rest of the developed world and this is primarily due to limited competition between the pharmaceutical companies there.

45. If medicine prices in the UK are to remain at the levels that they are now it is essential to retain the competition afforded by Parallel Trade and the regional exhaustion of rights regime referred to above. Conversely adopting a national exhaustion of rights regime would play into the hands of the US negotiators as it would remove competition here in the pharmaceutical sector and drive prices up to the levels in the US.

46. For the reasons set out above we cannot support the abolition of the regional exhaustion of rights regime. It would have catastrophic effect not only on millions of patients in the UK which will be denied access to life saving medicines, but it will also exacerbate the cost of providing medicines generally to the NHS.

47. We would be delighted to work with the Committee going forward to preserve the status quo in the interest of UK patients and to do our own bit to try to save the NHS.

26 June 2020