



Ethical Medicines Industry Group (EMIG) Response to the Gowers Review of Intellectual Property

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Executive Summary

About EMIG

- The Ethical Medicines Industry Group (EMIG) represents emerging pharmaceutical companies supplying medicines to the NHS.
- This submission outlines EMIG's views on the issues in the scope of the review that relate to the pharmaceutical industry and our members.
- We are aware that few changes in relation to supplementary protection and parallel trade could be made by the UK in isolation and we would support the UK in any discussions that it may enter into with the EU authorities.

Supplementary Protection Certificates (SPCs)

- EMIG considers that SPCs are a desirable and necessary right afforded to the pharmaceutical industry and in part address the inherent disadvantage of the patent procedure for the pharmaceutical industry as compared to proprietors of non-pharmaceutical products.
- EMIG suggests that the 5-year maximum on SPCs should be reviewed should regulatory requirements, particularly in relation to clinical trials, lead to longer development periods.
- The draft regulation on medicines for paediatric use provides for a further six-month period of protection added to the SPC. Given the extensive extra work needed for clinical research involving children, this is inadequate reward for the level of investment involved in establishing indications for children, and consideration should be given to an extension of this period.
- Orphan medicine protection is closely related to paediatric medicines. However, in the UK, an anomaly exists within the current legislation which allows specials to be used instead of the licensed product. We request that consideration should be given to the specials legislation being amended to deal with this anomaly.

Parallel Imports / International Exhaustion

- The price disparities between EU member states, which cause parallel trade, are substantially the result of the pricing and profit controls imposed by member states and other factors, rather than the pricing decisions of the companies themselves. EMIG asserts that a simple system whereby pharmacists advise the NHS when a parallel imported product is dispensed might be considered.
- EMIG would appreciate any pressure the UK Government can place on the EU authorities to moderate the strict application of Article 28 in the light of the absence of pricing freedom and would be pleased to supply data on the affect of such trade on individual member companies.
- EMIG endorses the currently held position that international exhaustion has no application to medicinal products.



1. Introduction

The Ethical Medicines Industry Group (EMIG) was established in 1985 as the forum for the emerging pharmaceutical sector in the UK. We are proud to have 35 member companies and our aim is to represent their views on industry issues that directly affect them. We represent some of the most innovative, emerging biosciences companies of the future.

EMIG represents the smaller and medium-sized pharmaceutical companies supplying medicines to the NHS and welcomes this opportunity to comment on the significance of certain intellectual property rights to its members. The specific issues upon which we intend to comment are supplementary protection certificates and parallel trade/international exhaustion of rights.

To some extent, the interests of EMIG members in these areas are similar to those of the major pharmaceutical companies. However whilst the larger companies typically base their business on so-called 'blockbuster' drugs, our members are more commonly involved in developing and supplying specialty medicines for smaller patient populations. In some cases therefore there is a difference in emphasis in certain respects.

We recognise that few changes in relation to supplementary protection and parallel trade could be made by the UK in isolation and we would be pleased to support the UK in any discussions that it may enter into with the EU authorities in order to push forward any of the issues which require action at that level.



2. Supplementary Protection Certificates and Related Rights

In this section, we will address the issue of supplementary protection a little more broadly than only addressing the supplementary protection certificate afforded under Council Regulation (EEC) No 1768/92. We feel it is important to bring into the equation other similar forms of protection of value to companies dedicated to improving medicines. In particular, we would like to address supplementary protection for paediatric medicines and the protection afforded to orphan products.

Supplementary Protection Certificates (SPCs)

SPCs have been widely used in the UK. It was recently reported that 268 SPCs have been granted. Members of EMIG are among those companies that have sought SPC protection.

We consider that SPCs are a desirable and necessary right afforded to the pharmaceutical industry and in part address the inherent disadvantage of the patent procedure for the pharmaceutical industry as compared to proprietors of non-pharmaceutical products in that the latter do not require marketing authorisations and are theoretically able to start generating income from the patent as soon as it is granted.

The SPC protection formula of one half of the time between patent application and first marketing approval (subject to a maximum of 5 years' post-patent protection) by implication envisages a development period typically of 10 years.

EMIG suggests that the 5-year maximum on SPCs might need to be reviewed should regulatory requirements, particularly in relation to clinical trials, lead to longer development periods.

Paediatric Extension to SPCs and Orphan Medicines

The draft regulation on medicines for paediatric use provides for a further six-month period of protection added to the SPC if information arising from a completed paediatric investigation plan is incorporated into the Summary of Product Characteristics (SmPC). Given the extensive extra work that will be involved and the well-documented and substantial issues involved in clinical research involving children, EMIG believes that this is inadequate reward for the level of investment involved in the development of such drugs, and consideration should be given to an extension of this period.

EMIG calls for further consideration to be given to the case for an extension of the period of protection afforded to products achieving new paediatric indications.

Orphan medicine protection is closely related to paediatric medicines. The 1999 EU Regulation on orphan medicinal products¹ offers 10 years' market exclusivity to those intending to market qualifying medicinal products. Member states are obliged under

¹ (Regulation EC/141/2000) ("Orphan Regulation")



this EU legislation to encourage the development of orphan products. However, UK legislation³, allows the supply of 'specials' (unlicensed medicinal products supplied under the doctor's specific responsibility). Non-legally binding MHRA guidance (Guidance Note 14), but not the UK legislation itself, states that an equivalent of an available licensed product should not be available on a specials basis. For orphan or other speciality products, the fact that specials can legally be used instead of the licensed product can substantially prejudice the benefit of the protection otherwise afforded under the EU Regulation.

EMIG believes that further consideration should be given to reviewing the specials legislation to deal with this anomaly.

² Schedule 1 of the Medicines for Human Use (Marketing Authorisations etc) Regulations 1994 (1994/3144)

³ Schedule 1 of the Medicines for Human Use (Marketing Authorisations etc) Regulations 1994 (1994/3144)



3. Parallel Importation/International Exhaustion

Parallel Trade within the EU

Article 7.1 of Directive 89/104/EEC on trademarks provides that:

“The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent”.

Under Article 7.2 it is stated that:

“Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market”.

European Court of Justice (ECJ) case law has substantially restricted any “legitimate reasons for the proprietor to oppose further commercialisation of the goods” and relabelling, repackaging and rebranding are permitted if the importer would otherwise be hindered in selling the parallel imported products in the market of import.

The opposition of the pharmaceutical industry, including EMIG members, is well known to the strict enforcement of ‘free movement’ principles within the EU. The price disparities between member states, which cause parallel trade, are substantially the result of the pricing and profit controls imposed on member states rather than the pricing decisions of the companies themselves. Other factors, such as the fact that the bulk of the price difference is retained by traders, rather than patients or end-purchasers (including the NHS), and the affect on British jobs, also drive this opposition.

Some of the problems with parallel imports could be addressed with a simple system whereby pharmacists advise the NHS when a parallel imported product is dispensed might be considered.

EMIG would support any pressure the UK Government can place on the EU authorities to moderate the strict application of Article 28 in the light of the absence of pricing freedom for medicinal products in most EU member states and would be pleased to supply data on the affect of parallel trade on individual member companies.

Parallel Importation from outside the EU

Outside the EU, the position on international exhaustion has largely been a result of case law involving ‘designer goods’. In summary, it is settled that national trademark rights can be used to prevent importation of goods into the EU from outside the EU.



In addition, the obvious public safety dimension in the EU regulatory regime over the sale of medicinal products renders free sale within the UK and the EU of medicinal products coming from outside the EU wholly inappropriate, particularly bearing in mind international regulatory regimes of differing severity and the risks of counterfeiting.