# The Legal Framework for Parallel Trade in Pharmaceuticals for Human Use in the European Economic Area

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## 1. Parallel Trade in the European Economic Area

The European Economic Area (EEA) is comprised of the member states of the European Community (EC) plus Norway, Iceland and Liechtenstein. The latter three are members of the European Free Trade Association (EFTA). In a referendum, Switzerland, the fourth member of the EFTA, chose not to participate in the EEA. All members of the EEA participate in the European Common Market. Norway, Iceland and Liechtenstein participate without having joined the EC. They however have agreed to enact legislation similar to that in the EC in all relevant fields of economic policy.

In certain fields of business (e.g. motor cars, petrol or pharmaceuticals) the European Common Market is fragmented by different national pricing for the same kind of product.

In the pharmaceutical business, there are two main reasons for price differences between member states: disparity in national prosperity and governmental price control in order to limit public health expenditure.
Disparity in national prosperity may result in different prices for the same pharmaceutical product in “poor” and in “rich” member states (e.g. Portugal and UK).
Governmental price control in varying degrees results in price differences for an identical product even between member states with comparable national prosperity (e.g. Austria and Germany).

The difference in price for certain goods in the member states of the European Economic Area is the driving force for parallel trade and creates the parallel trader’s profit.
Parallel trade in the European Common Market is a practice whereby a wholesaler buys products in a member state with comparatively low prices, and then imports them into another member state with relatively high prices. The parallel trading wholesaler is not appointed or licensed for this kind of business by the original supplier. He trades in parallel to the distribution network that has been established by the original supplier for placing the product on the European Common Market. In doing so, the parallel trader benefits from the free movement of goods within the EEA.

## 2. Harmonization of Product Related Law – a Precondition for Free Movement of Goods

The free movement of goods within the European Common Market would be hindered by fundamental disparities between the national regulations. Approximation of laws, therefore, has been agreed in Chapter 3 of the Treaty establishing the European Community[1] (EC Treaty) where for example it says in Article 94: "*The council shall …issue directives for the approximation of such laws…[which] directly affect the establishment or functioning of the Common Market*".

Especially the harmonisation of laws affecting the exhaustion of commercial property rights and the approximation of laws governing the authorization and manufacturing of drug products have been important for establishing a Common Market in pharmaceuticals.

### 2.1 Exhaustion of Commercial Property Rights

Pharmaceutical products are often protected by commercial property rights, namely by trademarks and patents. A patent is an exclusive right to use an invention by manufacturing and placing a product on the market. It provides the right to exclude others from making, using, offering for sale, selling, or importing the patented invention. A trademark is a distinctive name, phrase, symbol, design, picture or style. A trademark is used to distinguish a product from other products on the market and to inform about the origin and quality of a product. The owner of a registered trademark has the right to prevent others from using it in order to avoid that others benefit from his marketing efforts and from the reputation of his product.

The free trade within the Common European Market would be hindered if the owner of trademark or patent rights not only would be able to prevent others from placing his protected products on the market, but also would be able to prohibit the further trade in these products after he has already placed them on the market.

The Court also states this in several judgements[2,3,4]. For example it says in the judgement *Merck vs. Stephar* that *"the proprietor of an industrial or commercial property …cannot rely on that law to prevent the importation of a product which has been lawfully marketed in*

[1] EC Treaty: Consolidated Version of the Treaty establishing the European Community
[2] Case C-15/74 Centrafarm vs. Sterling Drug
[3] Case C-187/80 Merck vs. Stephar
[4] Case C-267/95 Merck vs. Primecrown & Case C-268/95 Beecham vs. Europharm

*another member state..."*and *"... to prevent the importation ...would be contrary to the aims of the Treaty*."

Therefore in all member states of the European Common Market, both patent and trademark rights are subject to EEA-wide exhaustion.

As mentioned in the preamble of Directive 89/104/EEC[5], the approximation of trademark law currently is "*limited to those national provisions of law which most directly affect the functioning of the internal market."*

The exhaustion of trademark rights is one of these provisions and therefore has been agreed by the member states in Directive 89/104/EEC where it says in Article 7 (1): "*The trade mark shall not entitle the owner to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the owner or with his consent"*

There is no equivalent provision concerning patent rights. Indirectly, however, the exhaustion of patent rights has been agreed by the member states in Article 30 of the EC Treaty, which allows "*prohibitions ...justified on grounds of … the protection of industrial and commercial property"* but also states that these prohibitions *"shall not constitute a restriction on trade between member states"*.

The EEA-wide exhaustion of patent rights has been confirmed by several decisions of the European Court of Justice. For example in the judgement *Centrafarm* the Court has stressed that a patent owner in a member state cannot exercise his national patent right to prevent the importation of goods that have already been legally placed on the market in another member state of the EEA[6]. This exercise of patent rights would be "*incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market*".

Hence, once the owner of a patent or trademark (or a licensee) has placed a batch of the product on the European Common Market, the commercial property rights for this particular batch are exhausted. As the commercial right of exclusiveness is limited to the first marketing within the EEA, the owner of the commercial property rights cannot prohibit further trading of the product. This also means that he cannot prohibit the parallel trade of the product within the EEA.

However, there are limitations to the principle of exhaustion, which are discussed in section 4.

[5] Directive 89/104/EEC to approximate the laws of the member states relating to trade marks
[6] Case C-15/74 Centrafarm vs Sterling Drug

## 2.2. Approximation of Pharmaceutical Legislation

Especially in the pharmaceutical business, major disparities in the national law would directly affect the functioning of the European Common Market. This problem is even addressed in the preamble of Directive 2001/83 [7]: "*Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products and such disparities would directly affect the functioning of the internal market. Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.*"

Triggered by the provisions of the EC Treaty during the last decades, an enormous harmonization of pharmaceutical regulations took place within the EEA.

Regulations concerning the marketing authorization

The criteria for the evaluation of quality, safety and efficacy of pharmaceuticals in the marketing authorization procedure have been harmonized. Also rules for a mutual recognition of national marketing authorizations between member states have been developed.

Directive 2001/83 describes these basic principles applicable to pharmaceuticals in all member states of the European Community. This Directive is a codex summarizing provisions already published in much earlier Directives e.g. in Directive 65/65/EEC, which has been published in 1965.

Further harmonization has been introduced by Regulation EC 2309/93[8], which establishes a European marketing authorization for certain products. This European marketing authorization is valid in all member states.

Regulations concerning manufacturing and quality control

In all member states, the Good Manufacturing Practice is mandatory for manufacturing including quality control. This is clearly stated in Commission Directive 2003/94/EC [9]: *"All medicinal products for human use manufactured or imported into the Community ... are to be manufactured in accordance with the principles and guidelines of good manufacturing practice*."

[7] Directive 2001/83 on the Community code relating to medicinal products for human use

[8] Council Regulation 2309/93 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

[9] Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human us

The quality control specifications for hundreds of substances as well as several test methods have already been harmonized and are published in the European Pharmacopoeia.
The governments have initiated this process in 1964 "*convinced that it is desirable and necessary to harmonize specifications for medicinal substances which, in their original state or in the form of pharmaceutical preparations, are of general interest and importance to the peoples of Europe*" [10]

Additionally, the need for approximation of pharmaceutical laws is mentioned in Directive 78/25/EEC[11] where it is said in the preamble that the disparities between the laws of member states concerning the colouring of medicinal products "*...tend to hinder trade in medicinal products within the Community ...*" and that these *"...disparities therefore directly affect the establishment and functioning of the common market."*

In summary, it may be said that those pharmaceutical products which comply with the harmonized European pharmaceutical law are comparable in terms of quality, safety and efficacy - regardless in which member state they have been manufactured and regardless which member state has granted the marketing authorization for them.
This consistency in pharmaceutical law is a precondition for the free movement of pharmaceutical goods within a European Common Market. Without free movement of goods, however, parallel trade within the European Common Market would be more or less impossible.

[10] Convention on the Elaboration of a European Pharmacopoeia, Strasbourg, 1964
[11] Council Directive 78/25/EEC on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products

## 3. Conflict between Free Movement of Goods and Protection of Public Health

Free movement of goods is a cornerstone of the EC Treaty[12] where it is addressed in Article 3: *"...the activities of the Community shall include...an internal market characterised by the abolition...of obstacles to the free movement of goods..."*
Also, Article 28 and Article 29 of the EC Treaty prohibit all "*Quantitative restrictions on imports [Article 29: on exports] and all measures having equivalent effect"* on the trade between member states.

Pharmaceuticals are not exempted from the principle of free movement of goods within the European Common Market. For pharmaceutical products, however, tension exists between the free movement of goods and the need to control the pharmaceutical business in order to ensure safety, efficacy and quality of the products.

This tension is even mentioned in the preamble of Directive 2001/83[13] where it says: "*The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health. However, this objective must be attained by means which will not hinder the...trade of medicinal products in the Community*."

When the quality, safety and efficacy of a pharmaceutical product have been sufficiently demonstrated by the applicant and when it is evident that the benefit of the product overwhelms the potential risks, then a marketing authorization is granted by the competent authorities. According to Article 6.1 of Directive 2001/83, no industrial pharmaceutical product shall be "*placed on the market of a member state unless a marketing authorization has been issued by the competent authorities ...* ".

Once the product has been placed legally on the market in a member state on the basis of a marketing authorization granted in compliance with EU law, then this product theoretically can move freely within the Common Market. However, for safety reasons, the import of a pharmaceutical product into a member state may be restricted by the health authorities, even for a product that has already been placed legally on the market in another member state.

[12] EC Treaty: Consolidated Version of the Treaty establishing the European Community
[13] Directive 2001/83 on the Community code relating to medicinal products for human use

The role of the health authorities in monitoring the trade in pharmaceuticals within the Common Market is also addressed in the Directive 2004/27 [14], where it says in Article 76 (3): "*Any distributor, not being the marketing authorization holder, who imports a product from another Member State shall notify the … competent authority in the Member State to which the product will be imported of his intention to import it."*

Article 30 of the EC Treaty[15] allows those restrictions and prohibitions on import or export, which are "*justified on grounds of …the protection of health and life of humans…*". The measures however shall obstruct as little as possible the free movement of goods and they shall not "*constitute ….a disguised restriction on trade between member states*".

In a recent paper the Commission gives guidance on the practical applications of the principle of the free movement of goods to the measures of the health authorities relating to parallel trade in pharmaceuticals[16]. The aim of these measures is to safeguard public health but to obstruct free trade as little as possible. Patients and healthcare providers shall take as much as possible advantage of the free trade within the Common Market but without risk for personal and public health.

The health authorities, therefore, have developed different measures to supervise the parallel trade between member states. These measures depend on whether a pharmaceutical product is on the market based on a European marketing authorization granted according to Regulation 2309/93 or based on a national marketing authorization granted in compliance with the principles of Directive 2001/83.

### 3.1. Parallel Trade in Centrally Authorized Products

A marketing authorization granted according to Regulation 2309/93[17], a so-called central or European marketing authorization is valid in all member states of the EEA. By definition, the product placed on the market in one member state is identical to the product placed on the market in another member state. It is identical in all aspects concerning the quality, safety and

[14] Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use
[15] EC Treaty: Consolidated Version of the Treaty establishing the European Community
[16] COM(2003) 839 final "Commission Communication on parallel import of proprietary medicinal products for which marketing authorization already has been granted"
[17] Regulation 2309/93:Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of medicinal products

efficacy – apart from linguistic differences in labelling and patient information and apart from differences in the country specific information (e.g. national pack size code for reimbursement) to be provided in the so-called blue-box[18].

In principle, a centrally authorized pharmaceutical product that has been placed on the market in one Member State can be imported by a parallel trader into any other Member State and placed on the market there - provided the labelling, the patient information and the blue-box have been adapted to the requirements of the importing member state.

In parallel trade in centrally authorized products, the marketing authorization holder and the marketing authorization number for the product remain unchanged. The marketing authorization holder is responsible for his product even when the product is the subject of parallel trade. The parallel trader is regarded as a distributor of the product. Therefore parallel trade in centrally authorized products often is called parallel-distribution.

Requiring a separate marketing authorization for the parallel-distributed product would be an unnecessary restriction of free movement of goods since according to Regulation 2309/93 the product is already authorized for marketing in all member states. The duty of the parallel trader to notify the EMEA about parallel-distribution, however, does not unnecessarily restrict the free movement of goods. Health authorities are obliged to monitor the trade in pharmaceuticals. Parallel-traded products are not exempted from this supervision. Therefore the EMEA requires a notification about parallel distribution of a centrally authorized product. This notification enables the EMEA to verify that the imported product is in compliance with the original marketing authorization. Additionally, as the EMEA informs the authorities in the importing member state about the parallel-distribution, the national health authorities are able to monitor the local activities of the parallel trader.

In summary, the notification serves public health and therefore is covered by the derogations of Article 30 of the EC Treaty. In the past, however, there was no strict legal basis for the notification and therefore sometimes problems of compliance have been reported[19]. This issue, however, is now addressed in the new Regulation 726/2004, which will replace Regulation 2309/93. In the preamble of Regulation 726/2004[20] it says: *"Furthermore, in*

[18] F2/BL D (2004) Notice to applicants: Guideline on the packaging information of medicinal products for human use authorized by the community; Annex "blue box"
[19] PERF III-EMEA/PERF/GMP/287/03 – Meeting Report: GMP-Workshop Oct. 2003
[20] Regulation EC 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

*order to create greater legal certainty it is necessary…to confer on the Agency powers to monitor the distribution of medicinal products authorized by the Community…"*
Greater legal certainty is provided by Article 57 of Regulation 726/2004 where "*checking that the conditions laid down in Community legislation…and in the marketing authorizations are observed in the case of parallel distribution…"* now is listed as one of the official tasks of the EMEA.

### 3.1.1. The Notification Procedure for Parallel Distribution

In order to assist parallel-distributors to fulfil their obligations, the EMEA has published a document[21] which describes the procedure for notification of parallel distribution of a product that has been authorized according Regulation 2309/93.
At least 3 months prior to marketing, the parallel-distributor shall submit a specific notification form[22] and provide the EMEA with the following information:
- Name of the parallel distributor and a copy of his wholesaler distribution authorization
- Name of the pharmaceutical product
- Name of the member state where the product is sourced, also called member state of origin
- Name of the member state where the product will be distributed, also called member state of destination
- Both mock-ups and electronic files of labelling and patient information leaflet
- Details of the person to contact in case of recalls and similar problems
- Certification that the original condition of the product is not affected
- Proof of payment of the administrative fee

Due to the fragmentation of the European Common Market in areas with different languages and different blue-box requirements, it is often necessary to repack a product before it is placed on the market in another member state.
In this case, the parallel-distributor has to submit the following additional documents:
- A copy of the manufacturing authorization for the repackaging site
- Details on the proposed repackaging
- A confirmation that the proposed pack size is covered by the marketing authorization.

[21] EMEA-H-30313-98-Rev. 2 Procedure for Notifications of Parallel Distribution of centrally authorised Medicinal Products, April 2003-Rev.2
[22] Form for Notification of parallel distribution of a centrally authorized medicinal product, 2004- Rev.3

In the past, the parallel distributor also had to provide the EMEA with a specimen of the proposed repackaged product[23]. Since May 2004, this practice has been changed and the EMEA no longer requests the submission of a specimen[24]. Submission of mock-ups of the proposed packaging material and leaflet is currently sufficient.

When there are no objections, the EMEA sends a notice saying that the regulatory check has been completed to both

- the parallel distributor
- the competent authorities of the member state of destination
- the holder of the original marketing authorization

Since May 2004, the parallel trader has additionally to sign a declaration that he has informed the patent owner (or the beneficiary of the patent) according to the "specific mechanism", which has been agreed in the Accession Treaty.

Further particulars regarding the "specific mechanism" are presented in section 7.

### 3.1.2. Post-Notification Obligations in Parallel Distribution

In the notification form, the parallel distributor has to sign the following declaration:

> *"I, the undersigned, undertake to ensure that the product information remains in conformity with the latest Commission Decision relating to the medicinal product. Should the product information (labelling and/or package leaflet) and/or any other aspect of this notification be amended, I undertake to submit a "notification of a change" to the EMEA."*

The parallel distributor is obliged to ensure permanent compliance with the current version of the product information as authorized by the EMEA. He has to include amendments (e.g. additional adverse side effects or urgent safety restrictions) made in the labelling and in the patient information leaflet of the original product equally in the labelling and in the patient information leaflet of the parallel-distributed product. Therefore, the parallel distributor must check regularly those EPARs (European Public Assessment Reports), which are relevant for his products. The EPAR for a product provides authorized versions of labelling and patient information leaflet in all official languages.

The parallel distributor has free access to the EPAR which is public information and is published on the EMEA website. The obligation to ensure that the product information is updated therefore does not result in a dependence of the parallel distributor on the marketing

[23] Form for Notification of parallel distribution of a centrally authorized medicinal product
[24] EMEA-Ho-2368-04-Rev 1 EMEA Post-Authorisation Guidance on Parallel Distribution

authorization holder. In the case *DePejper*[25] such dependence has been judged as an unnecessary restriction of free trade: *"... practices which make it possible for a manufacturer of the pharmaceutical product ... simply by refusing ... the documents relating to the medicinal preparation ... to enjoy a monopoly of the importing and marketing of the product, must be regarded as being unnecessarily restrictive..."*

In order to demonstrate permanent compliance with the original marketing authorization, the parallel distributor is required to send a notification of each update[26] in labelling and patient information to the EMEA.

The parallel distributor also is obliged to inform the EMEA about any other changes concerning the data package provided in the initial notification of parallel distribution – for example a change of the repackaging site or a change of the country of source.

If the parallel distributor does not fulfil his post-notification obligations, the EMEA can inform the member state where the parallel traded product is placed on the market of this non-compliance. Based on national drug law, the health authorities in this member state will decide on further actions[27]. The corrective actions range from inspection of the parallel distributor (in order to challenge his wholesaler license) to a recall of the product in order to prevent public health from risks caused by serious non-compliance of the product.

### 3.1.3. Parallel Trade with Iceland, Norway and Liechtenstein

Norway, Iceland and Liechtenstein participate in the Common Market although they did not join the European Community. Therefore specific rules concerning parallel trade with these countries have been published [28,29].

Iceland, Norway and Liechtenstein as Member State of Origin

The above mentioned EMEA notification procedures for parallel distribution also apply for parallel distribution of products coming from Iceland, Norway and Liechtenstein, provided the products correspond with the European marketing authorization.

Parallel distributors may consult the EMEA prior to submission of a notification to ensure that this correspondence exists.

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[25] Case 104/75 dePeijper
[26] Form for Notification of a change for parallel distribution of a centrally authorized medicinal product
[27] EMEA-Ho-2368-04-Rev 1 EMEA Post-Authorisation Guidance on Parallel Distribution
[28] EMEA/8518/00 Rev 1Guidance document for Industry, with regard to the extension of the centralized procedure, referral procedures, parallel distribution/import and pharmacovigilance requirements to Iceland and Norway
[29] EMEA-Ho-2368-04-Rev 1 EMEA Post-Authorisation Guidance on Parallel Distribution

Iceland, Norway and Liechtenstein as Member State of Destination

For import of centrally authorized products into Iceland, Norway and Liechtenstein, the national procedures for parallel import apply. The EMEA is not the competent authority and also Icelandic and Norwegian translations of the EPARs are not provided on the EMEA website.

### 3.2. Parallel Trade in Nationally Authorized Products

National marketing authorizations are granted according to the criteria described in Directive 2001/83 [30]. In principle, these criteria are identical in all member states. Nevertheless, pharmaceutical products that are based on independent national marketing authorizations may differ from country to country - even when they are marketed under the same trademark.

Therefore, a pharmaceutical product placed on the market in one member state is not automatically covered by a marketing authorization in another member state. In the case of parallel import, the national health authorities first need to check whether the imported product is identical or at least "sufficiently similar" to a national reference product.

This is in contrast to centrally authorized products. By definition these products are identical in all member states and therefore such a similarity check is not necessary.

The assessment of similarity between two authorized pharmaceuticals, one from another member state and one from the domestic market, is performed in a so-called simplified procedure.

#### 3.2.1. The "Simplified Procedure"

Normally an applicant for a marketing authorization has to submit a dossier presenting data on the quality, safety and efficacy of the product. However, the parallel trader usually has no access to this data package, which is property of the original marketing authorization holder.

Even after the expiry of the data protection period he only would be able to refer to the safety and efficacy data of the original product but not to the quality data package.

[30] Directive 2001/83 on the Community code relating to medicinal products for human use

In the *dePeijper* case[31] it has been ruled that national regulations for marketing authorization of a parallel import product are unnecessarily restrictive when they require documents that can be obtained only from the manufacturer or marketing authorization holder. Such national regulations would enable them to stop any parallel trade just by refusing access to these documents. National regulations to control parallel trade however "*are only compatible with the treaty to the extent to which they are necessary for an effective protection of health and life of humans*". Regulations are not compatible with the EC Treaty "*if the health and life of humans can be as effectively protected by measures which do not restrict intra-community trade so much."* Member states therefore have to choose those regulations to monitor parallel imports which obstruct the free trade as little as possible.

After the *dePeijper* case, the Commission published an opinion on how to proceed further with parallel imports of pharmaceuticals[32]. According to this Commission Communication, a marketing authorization for a parallel traded product shall be granted in a simplified procedure, which should not exceed 45 days. In the simplified procedure the member state into which the product is imported shall check if the parallel traded product is covered by a marketing authorization already granted for a reference product in that member state.

In the past also a "common origin" of parallel import product and domestic reference product has been a criterion in this simplified procedure. For example this is stated in §20a of the Austrian Drug Law[33] and in case *Kohlpharma*[34] also the German BfArM has argued that granting a marketing authorization for a parallel import "*is subject to the condition that the two medicinal products [imported product and the domestic reference product] have a common origin"*. "Common origin" here means that the products are manufactured by members of the same corporate group or are manufactured by independent companies but under a licence granted by the same licenser. The principle of "common origin" however recently has been challenged by the judgement *Kohlpharma* where the Court has stated that "*the restriction on the free movement of goods between Member States which results from the refusal to issue a marketing authorization [for a parallel import product] ...cannot be justified on grounds of protecting public health if that refusal is based solely on the fact that the two ...products do not have the same origin"*.

[31] Case 104/75 dePeijper
[32] Commission communication on parallel imports of proprietary medicinal products for which marketing authorization have already been granted, 1982
[33] Austrian Drug Law, §20a Genehmigung für den Vertrieb im Parallelimport;
[34] Case C-112/02 Kohlpharma vs. Chiesi

The Authorization granted in a "Simplified Procedure"

Two national marketing authorizations are involved in the simplified procedure:

- the marketing authorization granted in the member state of origin for the product which is now subject of parallel trade
- the marketing authorization granted in the member state of destination for the reference product

The simplified procedure however should not be confused with "mutual recognition procedure" and "abridged application procedure" where also two marketing authorizations are involved.

In a "mutual recognition procedure" the applicant requests a member state for recognition of a marketing authorization already granted by another member state. The applicant claims identity in all aspects of the summary of products characteristics (SPC) to the marketing authorization already granted.

In an "abridged application" the applicant claims "essential similarity" and bioequivalence to a reference product and consequently he refers to the safety and efficacy data of this reference product.

The marketing authorizations granted according to the above-mentioned procedures provide the right of first trade. This means that the owner of the marketing authorization has the right to place the product on the market.

An authorization for a parallel import product however only provides the right of second and further trade of a product that has already been placed on the market. The right of first trade for the parallel import product is linked inseparably to the marketing authorization for the product in the member state of origin and will not be granted to the parallel trader.

The parallel traded product is authorized for import and marketing in the member state of destination, provided the product has already been placed legally on the market in the member state of origin and provided the product is "sufficiently similar" to the reference product in the member state of destination.

With a marketing authorization granted according to the "simplified procedure", however, the parallel trader is not authorized to manufacture the parallel import product in order to place it on the market. He has to wait until the marketing authorization holder (or his licensee) has placed the product on the market in the member state of origin. Then the parallel trader can purchase this product, ship it to the member state of destination and place it on the market there.

The "Simplified Procedure" in Germany

In the EEA there is no harmonized approach for the assessment of a parallel import product in a simplified procedure. In judgement *DePeijper*[35] the Court has stated that *"...it is for the member states, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure and in particular how strict the checks to be carried out are to be*."

Hence the member states affected by parallel imports have developed their own national administrative operation procedures. National procedures for the assessment of parallel import products for example exist in France[36], Finland[37], in the Netherlands[38] and in Germany. In Germany, the simplified procedure is described in an announcement on the authorization of parallel imported pharmaceutical products within the framework of a simplified procedure[39]. The aim of the announcement is to speed up the assessment process for parallel import products in order to comply with the 45-days period required by the Commission Communication[40] on parallel import in 1982.

The applicant for a marketing authorization concerning a parallel import product has to submit a parallel-import-supplementary form[41] in addition to the application form in the Module 1.2 of the Common Technical Document. This parallel-import-supplementary form indicates the following additional information to the authorities:

- EEA member state of source
- Details on the imported product authorized in the EEA member state of source
- Details on the reference product authorized in the Federal Republic of Germany
- A declaration saying that solely the product mentioned in the form will be imported into and marketed in Germany.

[35] Case 104/75 dePeijper
[36] Décret no. 2004-83 du 23 janvier 2004 relatif aux importations de médicaments a usage humain et modifiant le code de la santé publique
[37] Administrative Regulation 2/1999 Parallel Import of Medicinal Products
[38] MEB-14-1.0 Parallel Import Authorisations
[39] Bekanntmachung über die Zulassung von parallel importieren Arzneimitteln im Rahmen eines vereinfachten Verfahrens" vom 06.11.1995 (BAnz. 1996, S. 398)
[40] Commission communication on parallel imports of proprietary medicinal products for which marketing authorization have already been granted; 06.05.1982 ; updated 30.12.2003 -COM (2003) 839-
[41] Zusätzliche Angaben für den Antrag auf Zulassung eines parallel importierten Arzneimittels gemäß "Mitteilung der Europäischen Kommission über Parallelimporte von Arzneispezialitäten, deren Inverkehrbringen bereits genehmigt ist" (Amtsblatt der EG vom 06.05.1982, Nr. C 115/5 ) sowie "Bekanntmachung über die Zulassung von parallel importieren Arzneimitteln im Rahmen eines vereinfachten Verfahrens" vom 06.11.1995 (BAnz. 1996, S. 398)

Additionally, the parallel importer is requested to submit documents necessary for a similarity check by the competent German authorities. However, in case the parallel trader is not able to present sufficient data to enable a decision on similarity, the German authorities will contact the authorities in the member state of origin.
The marketing authorization for the parallel import product will be granted by the competent German authorities only if therapeutically relevant differences between imported product and German reference product do not exist.

### 3.2.2. Sufficient Similarity

European pharmaceutical law does not provide an official definition of "sufficient similarity". The general rule is that switching between parallel import product and the reference product never should have critical consequences for the patient. Therefore the Dutch Medicines Evaluation Board requires that the patient information leaflets of both the parallel import product and the reference product must include identical information on indications, contraindications, side effects, dosage as well as methods and route of administration[42]. Pursuant to Dutch Drug Law "*... the parallel import product is authorised for the same indications, contraindications, side effects, posology, method of administration and route of administration as for the already authorised product. It can therefore be concluded that the package leaflet must also contain identical information in the sections covering the indications, contraindications, side effects, posology, method of administration and route of administration. This conclusion is also justified in the interests of public health, since prescribers and users should be able to expect the same information to be applicable to both a parallel-import product and the Dutch reference product."*

From case law it can be derived that certain differences between the parallel imported product and the reference product are deemed to be acceptable provided the active substance is identical and provided that the differences do not have a therapeutic effect.

In the case *Smith and Nephew*[43] the Court has ruled that a parallel traded product is sufficiently similar to the reference product if both products "…*have at least been manufactured according to the same formulation [which means: manufactured using the same excipients] and using the same active ingredient and ... also have the same therapeutic effects*…"

[42] MEB-14-1.0 Parallel Import Authorisations
[43] Case C-201/94 Smith and Nephew

However, according to the later judgement in case *Rhone-Poulenc Rorer*[44], also a product manufactured using different excipients can be sufficiently similar to the reference product - provided the difference in composition does not influence the therapeutic effect.
In *Rhone-Poulenc Rorer* the Court has stated that *"…it is permissible … to place the imported product upon the market …if …[the imported product] has the same active ingredients and therapeutic effect as medicinal product Y [the domestic reference product], but does not use the same excipients and is manufactured by a different manufacturing process…"*

Nevertheless, it has to be considered that differences in colour or appearance between the parallel import product and the reference product may be misleading for the patient. In Finland[45] for example it must be mentioned on the outer carton of the parallel import product if the appearance differs from that of the Finish reference product. Such a statement may help to avoid confusion and also may facilitate acceptance of those parallel imported products that look somewhat strange. In certain situations a member state even can refuse the marketing of a parallel import product because of different appearance if the confusion of the patient could result in a serious health risk. [46]

The Dutch Medicines Evaluation Board refers to differences in the breakability of tablets and their influence on compliance with the dosage recommendations given in the patient information leaflet[47]. If the parallel import product "*is not scored whereas the Dutch reference product is scored, it must be determined whether it will be possible to comply fully with the dosage recommendations given … for the Dutch reference product. If necessary, it should be stated in the package leaflet that it is not possible to administer certain dosages of the product."*

Differences in shelf life are addressed by the Finish National Agency for Medicines[45]: *"The shelf life accepted in the country of acquisition shall be accepted as the shelf life for a medicinal product subject to parallel import. However, it cannot be longer than the shelf life accepted for the medicinal product marketed in Finland."*
French authorities[48] accept differences in storage conditions only when the storage conditions for the parallel import product are more restrictive than those for the reference product – but

[44] Case C-94/98 Rhone-Poulenc Rorer
[45] Administrative Regulation 2/1999 Parallel Import of Medicinal Products
[46] EMEA-PERF-Acq-1367-02 Reflection Paper on Parallel Imports
[47] Dutch Medicines Evaluation Board in: MEB-14-1.0 Parallel Import Authorisations
[48] Décret no. 2004-83 du 23 janvier 2004 relatif aux importations de médicaments a usage humain et modifiant le code de la santé publique

not vice versa: «*L'étiquetage de la spécialité pharmaceutique bénéficiant d'une autorisation d'importation parallèle doit être identique à celui de la spécialité pharmaceutique ayant obtenu l'autorisation de mise sur le marché en France, sauf en ce qu'il comporte : ...les précautions particulières de conservation de la spécialité pharmaceutique bénéficiant d'une autorisation d'importation parallèle lorsqu'elles sont plus strictes que celles de la spécialité pharmaceutique ayant obtenu l'autorisation de mise sur le marché en France*. »
Also the Belgian authorities[49] identify differences in shelf life and storage conditions as those differences which have to be evaluated for potential risks: « … *les différences relatives à la durée de validité, aux conditions de conservation et à la composition en excipients vis - à - vis du médicament de référence sont telles qu'ils aient une incidence thérapeutique et/ou puissent entraîner un danger pour la santé publique*. »

According to the judgement *Ferring*[50] "*it must be held that if it can be demonstrated that there is in fact a risk to public health arising from the coexistence of the two versions such a risk may justify restrictions on the importation...*" On the other hand these restrictions on the importation do not comply with the EC Treaty *"when the health and life of humans can be protected equally effectively by measures less restrictive of intra-Community trade."*

Therefore, all differences between parallel import product and domestic reference product have to be evaluated from case to case for potential risks and for influence on the therapy.

### 3.2.3. Post-Authorization Issues

Renewals

Like other marketing authorizations, also the marketing authorization for a parallel import product is valid only for 5 years. An application for renewal must be submitted at least 3 months before the expiry of the current marketing authorization[51]. If the parallel trader does not apply or does not apply in due time for renewal then the license for the marketing of the parallel import product will expire automatically. However the renewal procedure for marketing authorizations in general is under revision. Article 24 of the Directive 2004/27[52], which amends Directive 2001/83, requires a first renewal after five years, but further renewals

[49] Arrete Royal relatif à l'importation parallèle des médicaments à usage humain et à la distribution parallèle des médicaments à usage humain et à usage vétérinaire
[50] Case C-172/00 Ferring
[51] Art. 24 of Directive 2001/83/EC; respective § 31 of the German Drug Law (AMG)
[52] Directive 2004/27 amending Directive 2001/83 on the Community code relating to medicinal products for human use

only for certain reasons: "*Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.*"

Variations

After authorization of the parallel import product, both the product in the member state of origin and the domestic reference product may be subject of variations.

Especially changes of product composition or changes in the patient information leaflet may have an influence on the similarity of parallel import product and reference product. These changes therefore may affect the validity of the marketing authorization for the parallel import product.

Also a change of the country of origin may affect the similarity of imported product and domestic reference product. As discussed above, the product imported from the proposed new member state of origin is not necessarily identical with the product imported from the current member state of origin. The similarity between the new parallel import product and the reference product has to be assessed again. Except in those cases where the marketing authorizations in the member states already have been harmonized by a mutual recognition procedure according to Directive 2001/83, the degree of similarity for the new imported product may be insufficient – even when it is marketed under the same trade name. Therefore the parallel trader is obliged to submit an application for variation when he intends to change the member state of origin.

Variations in the patient information leaflet of the reference product have to be implemented also in the patient information leaflet of the parallel import product. This is important especially for those changes, which concern the indications, contraindications, side effects, dosage, methods of administration and route of administration.

For Germany, a simplified procedure for updating the patient information leaflet of the parallel import product is described for the following situation[53]:

According to German Drug Law, an extension of the indication by including indications from another therapeutic field can only be achieved by an application for a new marketing authorization[54]. The holder of a marketing authorization for a parallel import product, however, is exempted from this obligation. Three months after the extended indication has been authorized for the reference product, the extended indication also can be included in the

[53] Bekanntmachung zur Verwaltungspraxis bei zugelassenen parallel importierten Arzneimitteln v. 22. Juli 2002
[54] §29 Par.3 Nr.3 of the German Drug Law (AMG)

patient information leaflet of the parallel import product - provided the authorities have filed no objections. Prerequisite for this procedure is that only the product information of the reference product has been changed, but not additionally the reference product itself.

Withdrawal of the Reference Marketing Authorization

Parallel trade is still possible even when the marketing authorization for the reference product has been withdrawn for non-safety reasons on application by the marketing authorization holder or when the reference authorization has expired because no renewal application has been submitted by the authorization holder.

In the judgement *Ferring*[55] the Court has stated that Article 28 EC of the EC Treaty *"precludes national legislation under which the withdrawal of the marketing authorisation of reference ... on application by the holder thereof means that the parallel import licence for that product automatically ceases to be valid."*

In the judgement *Paranova*[56] the Court has clarified that if the reference marketing authorization has been withdrawn for safety reasons however the EC Treaty does not *"...preclude restrictions on parallel imports ... if there is in fact a risk to the health of humans as a result of the continued existence of that medicinal product on the market of the importing Member State."*

The judgements in *Ferring* and *Paranova* do not cover a situation where the reference product has been withdrawn for non-safety reasons not by request of the marketing authorization holder but rather by the authorities. In such a situation the authorities may demand that both the reference product and the parallel import product are withdrawn from the market. Figure 1 gives an example for a recall of a parallel import product due to the German CFC-ban regulation[57]. This CFC-ban regulation is applicable both to reference products and to parallel import products - regardless whether the parallel import product is still on the market in the member state of origin or not.

Rückruf
Pulmicort „Kohlpharma" Dosieraerosol
Alle Chargen und Packungsgrößen
Die Firma Kohlpharma GmbH, 66663 Merzig, bittet um folgende Veröffentlichung:
"Gemäß BfArM Bekanntmachung vom 6. Dezember 2002 enden die Übergangsfristen für die Herstellung und das Inverkehrbringen von FCKW-haltigen Darreichungsformen inhalativer Steroide am 31. Dezember 2002. Pulmicort Dosieraerosol ist in allen Packungsgrößen deshalb ab diesem Zeitpunkt nicht mehr verkehrsfähig. Wir bitten Sie vorhandene Bestände an die oben genannte Firmenadresse zur Gutschrift zurückzusenden."
(Deutsche Apotheker Zeitung, 09.01.2003

Fig. 1

[55] Case C-172/00 Ferring
[56] Case 15-01 Paranova
[57] Verordnung zum Verbot von bestimmten die Ozonschicht abbauenden Halogenkohlenwasserstoffen (FCKW-Halon-Verbots-Verordnung)

### 3.3. The GXP Aspects in Parallel Trade

In order to safeguard public health a parallel import product is subject to product specific marketing authorization procedures, which have been described above.
But also inadequate handling of pharmaceuticals can cause risk to public health. Therefore parallel trade additionally is subject to process specific rules governing the activities of wholesalers and manufacturer.
According to Article 77 of Directive 2001/83[58] "*member states shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorization...*"
If the parallel-trader also performs the repackaging in his own facilities he needs a manufacturing authorization as Article 40 of Directive 2001/83 requests that "*the manufacturing of medicinal products ...is subject to...a manufacturing authorization. This authorization shall be required [also]… for the various processes of dividing up, packaging or presentation*". According to Article 77 of Directive 2001/83 the manufacturing authorization shall include the distribution authorization for all products covered by the manufacturing authorization.

The repackaging has to be performed in a member state of the EEA. Once the product has left the EEA it will be no longer subject of the regulations governing parallel trade within the EEA. The repacked product then will be subject of the rules governing the importation of products coming from third countries outside of the EEA.
Wholesaler licence and manufacturing licence are necessary to protect public health and they are required not only for the parallel-trader but for all participants in the pharmaceutical business. Both licences do not result in an unnecessary restriction to free trade nor are they specific obstacle just to hinder parallel trade.

#### 3.3.1. Good Distribution Practice – the Wholesaler Licence

The requirements, which have to be fulfilled for a distribution authorization, are described in Article 79 to Article 85 of Directive 2001/83. In the near future these requirements will be implemented into national German Drug Law by §52a AMG.

[58] Directive 2001/83 on the Community code relating to medicinal products for human use

The parallel trader must have adequate staff - in particular a designated person qualified to handle pharmaceuticals. He is obliged to work in adequate rooms and to use adequate equipment to ensure a proper storage and distribution of pharmaceutical products. To enable traceability of the product from the original manufacturer to the pharmacist the parallel trader is requested to obtain the pharmaceutical products only from persons who themselves possess a distribution authorization or a manufacturing authorization. Also the parallel trader itself is only allowed to sell the parallel import products to persons who themselves are authorized to deal with pharmaceuticals (e.g. other wholesalers or pharmacists). Additionally he is obliged to keep records enabling a batch tracking.

The parallel trader must install an emergency action plan, which ensures effective implementation of any recall from the market if ordered by the competent authorities.

In summary all pharmaceutical activities of the parallel trader have to comply with Good Distribution Practice and this compliance will be subject to inspections by the competent national authorities. In Germany the principle rules for wholesalers are presented in the ordinance on internal regulations for pharmaceutical wholesalers[59].

### 3.3.2. Good Manufacturing Practice – The Manufacturing Licence

The manufacturing licence certifies compliance with the principles of Good Manufacturing Practice (GMP) as laid down in the Community law. In Germany these principle rules for pharmaceutical manufacturing are presented in the ordinance on internal regulations for pharmaceutical entrepreneurs.[60]

If a parallel trader performs the repackaging by his own he has to comply with GMP. The details of GMP shall not be discussed here. A key issue relevant for repackaging of parallel traded products however is that the repackaging has to be performed under supervision of a qualified person[61] and that after repackaging the batch has to be released by a qualified person.

[59] Betriebsverordnung für Arzneimittelgroßhandelsbetriebe
[60] Betriebsverordnung für Pharmazeutische Unternehmer - PharmBetrV
[61] see Article 48 of Directive 2001/83, also §14(2) German Drug Law

### 3.3.3. Batch Release after Repackaging

Parallel traded pharmaceuticals have already been placed on the market in the member state of origin and therefore have already been released by the original manufacturer. By repackaging however these products will be changed and therefore after repackaging they need to be released again by a qualified person.
According to Article 51 of Directive 2001/83[62] the "*qualified person is responsible to ensure that the product has been manufactured and checked in accordance with the laws in force...and in accordance with the requirements of the marketing authorization*."

However batches which have already been tested and certified for quality in a member state shall be exempted from a repeated quality testing in another member state – but only if the batches are accompanied by the quality control records[63].
The parallel trader normally does not have access to these quality control records as the original manufacturer is obliged to keep these records at the disposal of the competent authorities but not at the disposal of the wholesaler who has purchased the batch to the parallel trader.

Acting in the spirit of the *DePeijper* judgement[64] the German authorities therefore have published the announcement concerning the demonstration of quality testing of parallel imported pharmaceutical products[65]. According to this announcement the parallel trader shall not be obliged to have the full quality control documentation in place. In case he has no access to these quality documents he can provide surrogate information to substantiate that the batch has already been tested for quality in the member state of origin. In case of doubt it is the obligation of the authorities to verify this e.g. by inspection or by contacting the authorities in the member state of origin. If also the authorities cannot provide evidence that the batch has already been checked for quality then of course the marketing of this particular batch can be prohibited in accordance with §69 of the German Drug Law.

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[62] Directive 2001/83 on the Community code relating to medicinal products for human use
[63] see also §13 (2) PharmBetrV
[64] Case 104/75 dePeijper
[65] Bekanntmachung über den Nachweis der Qualitätsprüfung bei parallelimportierten Arzneimitteln vom 23.Februar 1995

### 3.3.4. Official Control Authority Batch Release (OCABR)

According to Article 114 of Directive 2001/83[66] for certain pharmaceuticals (e.g. products derived from human blood and vaccines) a member state may require samples of each batch to be sent to an official state laboratory, a so-called Official Medicines Control Laboratory (OMCL). The OMCL examines the samples in order to ensure that the batch is in conformity with the approved specifications before it is released onto the market. When the results of testing are satisfactory, the competent authority issues an Official Control Authority Batch Release (OCABR) certificate. In Germany the OCABR-certificate is granted by the Paul-Ehrlich-Institut.

Parallel traded products are not exempted from this requirement. Also a parallel trader has to apply for an OCABR-certificate prior to marketing of a batch of the above-mentioned pharmaceuticals. This is in the interest of public health and therefore cannot be regarded as an unnecessary restriction to free trade. On the other hand according to Article 30 of the EC Treaty a procedure necessary to protect public health shall not be more restrictive to free trade than necessary. Therefore Article 114 of Directive 2001/83 requires mutual recognition of an OCABR-certificate granted by the authorities of another member state.

The parallel trader however normally will not have access to the OCABR-certificate granted to the original manufacturer and therefore will not be able to present any OCABR-certificates for recognition. Here again the authorities are requested to act in the spirit of the *DePeijper* judgement: In order to facilitate the free movement of goods the authorities are obliged to communicate with each other to verify if another authority already has officially released this particular batch. The Commission[67] has pointed out that this obligation arises directly from the EC Treaty. The authorities therefore "*should communicate with each other when necessary to verify if a batch of a parallel imported vaccine has been officially released by another authority, because the parallel importer will not necessarily have the relevant official batch release documentation."*

The Swedish authorities for example have described this procedure in a separate guideline[68] governing the examination of production batches of vaccines and blood products prior to release on the Swedish market. This guideline also provides detailed regulations concerning parallel imports of such products.

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[66] see also §32 German Drug Law

[67] European Commission - DG III E3: Pharmaceutical Committee - Information on the outcome of the 47th meeting, 15/16-Apr-1999.

[68] Medical Products Agency's provisions and guidelines on the examination of production batches of vaccines and blood products for human use prior to release on the Swedish market

### 3.3.5. Change of Batch Coding –Traceability of Batches

Batch codes are printed on the product to link the product with the manufacturing and quality test documents of a particular production batch. Batch codes are also necessary for identification in case adverse side effects or quality problems have been reported to the authorities.

Lack of traceability of parallel import products is an issue that is even addressed by the Commission in a paper on Rapid Alerts and product recalls: *"In case of parallel imports, where there is difficulty in establishing the traceability of batches, consideration should be given to notifying all member states by the Rapid Alert System*" [69].

Therefore the parallel trader shall not replace the original batch number by a new batch code. The original batch number however may be used together with a suffix that links the product with the repackaging documentation for that particular batch.[70]

The parallel trader has to consider that changing the batch number on the outer carton also makes it necessary to change the batch number on the blister packs and primary containers.

In parallel-distribution, which is as mentioned above parallel trade in centrally authorized products, the original manufacturer remains the marketing authorization holder and therefore remains responsible for pharmacovigilance actions and recalls. Changed batch numbers for repacked products however would make it impossible for him to do his duty. He would not be able to assign adverse side effects and quality defects to a particular original batch. Therefore especially in parallel-distribution the batch number shall not be changed in a repackaging. This is clearly stated by the EMEA[71]: "*The original batch number must always be retained*." The addition of an "*internal code to packaging material is considered by the EMEA as good practice and therefore acceptable… This includes the mentioning of a `re-pack batch´ or the addition of a prefix or suffix to the original batch number to reflect additional repackaging activities."*

[69] EMEA/INS/GMP/3351/03/Rev1/corr "Compilation of Community Procedures on Inspection and Exchange of Information - Revised Procedure for Handling Rapid Alerts and Recalls arising from Quality Defects"
[70] EMEA-PERF-Acq-1367-02 Reflection Paper on Parallel Imports
[71] EMEA/Ho/2368/04 EMEA Post Authorization Guidance on Parallel Distribution

## 4. Conflict between Free Movement of Goods and Protection of Commercial Property Rights

Exhaustion of commercial property rights is important in the context of parallel trade. Once the products are legally placed on the Common Market, the commercial property rights are exhausted in all member states and cannot be used to prevent further parallel trade.
The principle of exhaustion however does not apply if the patent owner is under legal obligation to market a product in a member state where no patent protection exists[72] or if patented goods have been made under a compulsory licence[73].
Limitations to the principle of exhaustion also have been agreed in Directive 89/104/EEC[74] under Article 7(2). In case "*the condition of the goods is changed or impaired after they have been put on the market"* the trademark owner has the right to oppose further commercialisation – provided however "*there exist legitimate reasons"*.

A legitimate reason does not exist when a trademark owner objects to repackaging which is necessary in order to market a product in a particular member state. A repackaging is necessary if it is required to enable the parallel trader to obtain effective access to the market.
On the other hand repackaging of a branded product is allowed only to such an extent that is strictly necessary to enable the marketing of the parallel traded product. This is also clearly stated by the EMEA[75]: "*…the only changes that parallel distributors may introduce to the packaging of a centrally authorized medicinal product are those which are strictly necessary to market the product in the Member State of destination"*.

### 4.1. Justifications for Repackaging

The parallel importer bears the burden of demonstrating that the repackaging he intends to perform is necessary to obtain effective access to the market.

Consumer Resistance to Over-labelled Boxes

In case of consumer resistance to over-labelled products it may be necessary to replace the outer carton completely as less intrusive methods of repackaging will not enable effective access to the market. This has been stated by the Court in the judgement *Merck Sharp & Dohme*[76] where it says: "*Replacement packaging of pharmaceutical products rather than*

[72] Case C-267/95 Merck vs Primecrown
[73] Case 19/84 Pharmon vs Hoechst
[74] Directive 89/104/EEC to approximate the laws of the member states relating to trade marks
[75] EMEA-Ho-2368-04-Rev 1 EMEA Post-Authorisation Guidance on Parallel Distribution
[76] Case C-443/99 Merck Sharp & Dohme vs Paranova

*simply sticking labels on those packages is objectively necessary if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products."*

Different Trademarks

Replacing trademarks normally is no issue in parallel-distribution as for centrally authorized products it is mandatory to market the product in all member states of the EEA under the same trade name[77].

Nationally authorized products however can be placed on the different national markets by using different trademarks. In such a case the parallel trader is allowed to replace the trademark used in the member state of origin by the trademark used in the member state of destination in order to have effective access to a national market.

The rights of the trademark owner are limited, as referring to trademark rights shall not result in artificial fragmentation of the Common Market. This has been stated by the Court in the judgement *Pharmacia&Upjohn*[78] where it says "*... to oppose the marketing of products ... where ... the original trade mark [has been] reaffixed or replaced with the trade mark used ... in the importing Member State - is regarded as justified ... unless it is established... that such opposition contributes to the artificial partitioning of the markets between Member States."*

Replacement of trademarks is only allowed to the extent that is necessary to have "effective access" to the market of a member state. The parallel trader is not allowed to replace a trademark only in order to gain a commercial advantage - for example by switching from a less successful trademark to a better known and more successful trademark. This is because the *"... condition of necessity ... will not be satisfied if replacement of the trade mark can be explained solely as an attempt by the parallel importer to secure a commercial advantage".*

Different Reimbursement Regulations – Change of Pack Size

Due to different reimbursement regulations issued by the national health insurance organisations the pharmaceutical products often are placed on the national markets in different pack sizes. This artificial fragmentation of the Common Market even is accepted for centrally authorized products and is addressed in Article 1 of Regulation 2309/93[79] where it

[77] 98/C 229/03 Commission communication on the Community marketing authorization procedures for medicinal products

[78] Case C-379/97 Pharmacia&Upjohn vs. Paranova

[79] Regulation 2309/93:Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the evaluation of medicinal products

says *"...the Member States may choose from the marketing authorization those ... pack sizes which will be covered by their social security organizations.*"

A parallel trader is allowed to generate the pack size necessary for the market in the member state of destination by repackaging. The trademark owner cannot oppose a change of the pack size if this change is necessary to market the product in the member state of destination and to overcome the artificial fragmentation of the Common Market. The pack size generated by repackaging however has to be covered by the marketing authorization in the member state of destination.

In case of centrally authorized products each pack size is authorized under a separate marketing authorization number, which has to be stated on the product. Therefore for centrally authorized products it also has to be considered that a change of the pack size always is accompanied by a change of the marketing authorization number[80]. According to the judgement *Aventis*[81] the "*Council Regulation (EEC) No 2309/93 ...precludes a medicinal product which is the subject of two separate central marketing authorisations, one for packs of five items and the other for packs of 10 items, from being marketed in a package consisting of two packs of five items which have been joined together and relabelled"*

Different "Blue-box-information"

Artificial fragmentation of the Common Market is also caused by differing national requirements[82] regarding the so-called "blue-box-information", which comprises any information like identification codes (e.g. German PZN-Nr.) or reimbursement levels (e.g. German N1, N2, N3 pack size coding). In order to have effective access to the market the parallel trader is forced to adapt the "blue-box-information" to the national requirements by repackaging of the product.

Different Languages

There is also a natural fragmentation of the European Common Market in areas with different languages. Article 63 of Directive 2001/83[83] requires that the relevant information on the packaging and on the patient information leaflet "*shall appear in the official language or languages of the member state where the product is placed on the market*."

In order to provide the relevant product information in the national language the parallel trader therefore is obliged to repack the product and to replace the patient information leaflet. This repackaging is necessary and justified due to the legal requirements.

[80] EMEA/Ho/2368/04 EMEA Post Authorization Guidance on Parallel Distribution
[81] Case C-433/00 Aventis vs. Kohlpharma , September 2002
[82] F2/BL D (2004) Notice to applicants: Guideline on the packaging information of medicinal products for human use authorized by the community; Annex "blue box"
[83] Directive 2001/83 on the Community code relating to medicinal products for human use

It sometimes can be difficult to replace product information provided on primary packaging materials e.g. information printed on the blister foil or information printed on glass ampoules. The Dutch Medicines Evaluation Board[84] has addressed this problem and for certain products it accepts non-compliance with the Dutch labelling requirements: "*If the MEB is of the opinion that relabelling of the primary packaging is technically impossible or undesirable, the MEB shall accept non-conformance with the Regulation in terms of the obligation to place a Dutch label directly on the primary packaging.*"

The Belgian authorities[85] however request that the primary container of the parallel import product and of the Belgian reference product shall bear the same information regarding the application of the product: "*Si l'emballage primaire du médicament de référence comporte des données relatives à l'utilisation du médicament, le médicament importé parallèlement doit également mentionner ces données au moins dans les trois langues nationales.*"

### 4.2. Legitimate Reasons to oppose Repackaging

As described above only those repackaging is allowed which is necessary to enable the parallel trader to have effective access to the market. The trademark owner therefore can oppose those repackaging which he regards to be unnecessary unless his opposition would contribute to an artificial partitioning of the Common Market

Article 7(2) of the Directive 89/104/EEC[86] gives the trademark owner the right to oppose further commercialisation of a product when the condition of the product is changed or impaired after it has been put on the market - provided a legitimate reason for the trademark owner exists. Every repackaging must be done in such a way that the legitimate interests of the trademark owner are respected. It is a legitimate interest of the trademark owner that:

- the repackaging does not adversely affect the condition of the product
- the repackaging does not damage the reputation of the trademark or of the trademark owner
- it is stated on the new packaging by whom the product has been repacked but also by whom it has been manufactured originally
- the person who repackages the product informs the trademark owner of the repackaging before the repackaged product is placed on the market[87]

[84] Dutch Medicines Evaluation Board in: MEB-14-1.0 Parallel Import Authorisations
[85] Arrete Royal relatif à l'importation parallèle des médicaments à usage humain et à la distribution parallèle des médicaments à usage humain et à usage vétérinaire
[86] Directive 89/104/EEC to approximate the laws of the member states relating to trade marks
[87] COM(2003) 839 final "Commission Communication on parallel import of proprietary medicinal products for which marketing authorization already has been granted"

Information of the Trademark Owner

To enable the trademark owner to check if one of these reasons is given, the parallel trader is obliged to inform him before the repackaged product is placed on the market.

The trademark owner also may request for a specimen of the repacked product in order to be able to decide whether the condition of the product is affected or the reputation of the trademark is damaged[88].

There is no deadline for information of the trademark owner given by law. Even case law just indicates that giving notice and sending a specimen to the trademark owner 15 working days before placing the parallel import on the market is regarded to be a reasonable time. But also shorter or longer periods may be acceptable according to the judgment *Boehringer*[88] where it says that "*...a period of 15 working days seems likely to constitute such a reasonable time where the parallel importer has chosen to give notice to the trade mark proprietor by supplying it simultaneously with a sample of the repackaged pharmaceutical product. That period being purely indicative, it remains open to the parallel importer to allow a shorter time and to the proprietor to ask for a longer time to react than that allowed by the parallel importer."*

It is not sufficient that the owner of the trademark is informed by a third party e.g. by the authorities. The parallel trader who intends to place a changed product again on the market is obliged to inform the trademark owner as stated by the Court in the case *Boehringer*: "*…it is incumbent on the parallel importer itself to give notice to the trade mark proprietor of the intended repackaging. It is not sufficient that the proprietor be notified by other sources, such as the authority which issues a parallel import licence to the importer."*

If the trademark owner has not been informed adequately he "*may oppose the marketing of the repackaged pharmaceutical product.*"

Repackaging Statement on the Product

Case law requires the parallel trader as well as the company responsible for repackaging and the original manufacturer to be identified on the pharmaceutical product. According to the judgment *Paranova*[89] the trademark owner can "*legitimately oppose the further marketing of a pharmaceutical product ... where the importer has repackaged the product ... unless the ...new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand. "*

[88] Case C-143/00 Boehringer

[89] Joined cases C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb and others vs Paranova

For parallel-distributed products the EMEA[90] recommends to mention a text like the following one on the outer carton (written in the national language of the member state of destination):

*"Parallel distributed and repackaged by.... (name and address)"*

*"Manufacturer: ....(name and address of the manufacturer)"*

For the inner labelling it is accepted to mention only the names but not the full addresses. German Drug Law (§10 AMG) even exempts the parallel trader from the requirement to add his name on each blister pack.

A parallel trader who adds or replaces articles (e.g. a graduated spoon) is requested by case law additionally to declare this change of the product in order to make clear that not the trademark owner but the parallel trader is responsible for this particular article. According to judgement *Paranova*[91] "*the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it.*"

The Condition of the Product

Leaving the primary packaging material (e.g. blister packs or ampoules) intact is a precondition for acceptance of repackaging. Each damage or change of the primary packaging would raise question on the stability of the product. Cutting of blister packs however is accepted[92] if it is "*carried out in such a manner as to exclude any real risk of affecting the original condition of the tablets inside.*"

Self-sticking labels on primary packaging can adversely affect the condition of the product inside the packaging – especially if they are fixed on a primary container made from plastic. Here it has to be considered that monomers and softeners from the adhesive layer of the label may migrate through the container material and so may contaminate the product. Therefore if primary packaging material is labelled the compatibility of label and primary packaging material has to be ensured[93].

[90] EMEA/Ho/2368/04 EMEA Post Authorization Guidance on Parallel Distribution

[91] Joined cases C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb and others vs Paranova

[92] Joined cases C-71/94, C-72/94 and C-73/94 Eurim-Pharm vs Beiersdorf and others

[93] Guideline 3AQ1A "Development Pharmaceutics and Process Validation"; Chapter 4.2 Leaching: "Data should be presented to show that there is no significant leaching of any pack component, including label adhesive, into liquid or finely divided solid preparations over the shelf life period, where relevant".

The condition of the product is not affected adversely by "*the removal of blister packs from their original external packaging and their insertion into new external packaging, or the addition to the packaging of new user instructions or information.*"[94]
Therefore a change of leaflets or a repackaging into other cartons has to be accepted by the trademark owner – provided it is performed in a manner that does not damage the reputation of the trademark owner.

Reputation of the Trademark

Defective, poor quality or untidy packaging could damage the reputation of the trademark - even when it is declared on the product that somebody else than the trademark owner has repacked it. In case of dispute on a possible damage of the reputation of the trademark it has to be considered whether the product is placed on the market in a pharmacy or is a hospital pack. The presentation of the product is of greater importance to the patient, who maybe is not familiar with parallel trade, than to a professional in a hospital[95]. This is stated in the judgement *Eurim-Pharm*[96] where it says "*However, the requirements to be met by the presentation of a repackaged pharmaceutical product vary according to whether the product is sold to hospitals or, through pharmacies, to consumers. In the former case, the products are administered to patients by professionals, for whom the presentation of the product is of little importance. In the latter case, the presentation of the product is of greater importance for the consumer….*"
Self-sticking labels on secondary packaging material like outer cartons are widely accepted and will normally not damage the reputation of the product. Nevertheless sometimes there is strong resistance from a significant portion of the consumers to products that have been adapted to national language by labels, fixed on the original carton. In such a case it may be necessary to replace the complete outer carton in order to protect the reputation of the trademark because *"even if the person who carried out the repackaging is indicated on ... the product, there remains the possibility that the reputation of the trade mark, and thus of its owner, may nevertheless suffer from an inappropriate presentation of the repackaged product."*

[94] Case C-232/94 MPA Pharma vs Rhone Poulenc
[95] COM(2003) 839 final "Commission Communication on parallel import of proprietary medicinal products for which marketing authorization already has been granted"
[96] C-71/94 Eurim-Pharm vs Beiersdorf

## 5. Parallel Trade and the EU Competition Law

The Commission believes that especially parallel trade would ultimately lead to the harmonization of the prices of pharmaceutical products. For example in the Commission Communication on the Single Market in Pharmaceuticals[97], published 1998, the Commission states that "*parallel trade acts as an important driving force for market integration where there are important differences in prices between Member States*." Furthermore the Commission notes that "*...it is reasonable to assume that parallel trade has a dynamic restraining effect, particularly on prices at the higher end of the European market; by contributing, therefore, to price competition for in-patent products…"*

In the *Bayer* case[98] the Court for the first time has questioned the appropriateness of the Commission's attempts to use parallel trade to create a Common Market and a harmonisation in prices for pharmaceuticals. The Court states "*Nor …can the Commission rely in support of its argument …that parallel imports will in the long term bring about the harmonisation of the price of medicinal products.*" This opinion of the Court has been confirmed in January 2004.[99]

The large disparities in the prices are mainly caused by different national governmental price regulations and reimbursement rules. The lack of homogeneity of pharmaceutical prices is not a result of deliberate decisions by the pharmaceutical companies or even a result of missing competition between pharmaceutical companies. Pharmaceutical prices often are determined by governmental regulations and are not freely set by pharmaceutical companies. Therefore the Court in the *Bayer* case rejects the Commission's argument that the EC Treaty imposes a general prohibition of the restriction of parallel trade by firms. In the pharmaceutical market, which has been artificially partitioned by the actions of the member states, it is the legitimate right of a pharmaceutical company to reduce the impact of this distortion of competitive conditions and to restrict parallel trade in a product whose price it does not control. The Court states that a manufacturer *"faced... with an event harmful to his interests"* has the right *"to adopt the solution which seems to him to be the best"* However in doing so he must not infringe Article 81 and Article 82 of the EC Treaty.
Article 82 of the EC Treaty prohibits "*any abuse ... of a dominant position within the common market…in so far as it may affect trade between member states*". Article 81 prohibits "*all*

[97] Commission Communication on the Single Market in Pharmaceuticals
[98] Case T-41/96 Bayer vs Commission concerning limited supply
[99] Case C-2/01 P & C-3/01 P Bundesverband der Arzneimittel-Importeure vs Bayer; Commission vs Bayer (the judgement rejecting the Commission´s appeal)

*agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market".*

Provided he does not infringe Article 81 and Article 82 of the EC Treaty "*a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim… to hinder parallel imports, the implementation of that policy may entail restrictions on competition and affect trade between Member States"*[100].

### 5.1. Measures to restrict Parallel Trade

Parallel traders cooperate with wholesalers in the member state of origin in order to obtain the pharmaceutical products at a low price level. Original manufacturers therefore sometimes try to restrict parallel trade by limiting the quantities available for the wholesalers in a particular member state or by installing a dual pricing system.

Limited Supply

Some pharmaceutical companies have tried to supply only limited amounts to those wholesalers who are known to cooperate with parallel traders. Due to the limited supply these wholesalers then have been short in products and therefore have not been able to offer large amounts to parallel traders.

Article 81 prohibits bilateral and multilateral agreements between companies but does not refer to unilateral measures of a company - except those measures where the unilateral character of the measure is merely apparent e.g. in case of a joint intention to hinder free trade. A continuation of the commercial relations between wholesaler and pharmaceutical company despite of limited supplies cannot be regarded as a "concurrence of wills" to restrict parallel trade – even not in case the intention of the supplier to restrict parallel trade is known[101].

However unilateral refusal to supply must not constitute an abuse of a dominant position in the Common Market. Such an abuse is prohibited by Article 82 of the EC Treaty. But even if a pharmaceutical company has a high market share in a therapeutic field, it is unlikely that this can be regarded as a dominant position in the Common Market. The pharmaceutical

[100] Case T-41/96 Bayer vs Commission concerning limited supply

[101] Case T-41/96 Bayer vs Commission concerning limited supply ; Case C-2/01 P & C-3/01 P Bundesverband der Arzneimittel-Importeure vs Bayer; Commission vs Bayer (the judgement rejecting the Commission´s appeal)

company is unable to act independently of the national price regulations and the company depends on the buying power of the national health insurance systems, which are the largest purchasers of prescription medicines[102].

Dual Pricing Systems

Pharmaceutical companies also have tried to restrict parallel trade by installing a dual pricing system. In the dual pricing system those wholesalers who export the products have to pay higher prices than those who only sell the product to pharmacists in the domestic market.

The commission has published a statement on the compatibility of Glaxo´s dual pricing system with Article 81 of the EC Treaty[103] where it says: "*Glaxo Wellcome has infringed Article 81(1) of the Treaty by entering into an agreement with Spanish wholesalers operating a distinction between prices charged to wholesalers in the case of domestic resale of reimbursable drugs to pharmacies or hospitals and higher prices charged in the case of exports to any other Member State."*

The Commission's decision to prohibit the dual pricing system however has been appealed. The appeal raises the question whether a pharmaceutical company is required by Article 81 to charge a wholesaler in a particular member state the price, which is set by national regulations of that member state even when it is known that the product is destined for sale in another member state where this national price regulation does not apply[104].

In a similar case the Court has to decide whether a pharmaceutical company is obliged to supply unlimited quantities of a product for the low price that has been set by a member state in order to contain public expenditure for the healthcare of its citizen – although neither the number of citizens nor their need for this particular product is unlimited.[105]

### 5.2. Measures to promote Parallel Trade

Member states often wish to reduce their health care budget. They can do so directly through price regulations or by measures to promote the sale of parallel traded products.

Regulations demanding the sale of parallel import products exist in several member states. In Germany for example §129 SGB V requires pharmacists to dispense those parallel import

[102] Spanish Competition Defence Tribunal ; Decision R 488/01
[103] Commission decision 2001/791/EC on compatibility of Glaxo´s dual pricing system in Spain with Article 81 of the EC Treaty
[104] Case T-168/01 GlaxoWellcome vs Commission
[105] Case C-53/03 Syfait vs GlaxoSmithKline

products where the minimum price difference between parallel import and reference product is 15 % or at least 15 Euro. [106]

Further details are defined in framework agreements between health insurance umbrella organisations and the pharmacists` organisations. In the current framework agreement the pharmacists have agreed to dispense at least 5% of the value of sold drugs as parallel traded product. In case a pharmacy does not meet this so-called "import quota" it is fined by the health insurance.

The idea behind these supply agreements is to ensure and safeguard the financial stability of the national social security systems

In the joined cases C-159/91 and C-160/91[107] the Court has ruled that the organizations of the public health security system fulfil a social function. Mainly they are non-profit organisations, which are not comparable to industrial companies. So Article 81 and 82 of the EC Treaty are not applicable to them. The agreements between health insurance organisations and pharmacists therefore are regarded as legitimate measures in order to protect the national solidarity system and as measures, which do not infringe the European competition law.

In another judgement[108] the Court has stated that health insurance organisations "*do not constitute undertakings or associations of undertakings within the meaning of Article 81 EC* " when they determine fixed maximum prices for pharmaceuticals products whose cost are borne by them. By determining the fixed maximum prices, the health insurance organisations "*perform a task for management of the German social security system which is imposed upon them by legislation …"*

However in case C-267/95[109] the Court also acknowledges that governmental price control can distort the trade between member states. But on the other hand "*although the imposition of price controls is indeed a factor which may…distort competition between Member States, that circumstance cannot justify a derogation from the principle of free movement of goods".*

[106] Sozialgesetzbuch Fünftes Buch (V)/ Drittes Kapitel: Leistungen der Krankenversicherungen/ Siebter Abschnitt: Beziehungen zu Apotheken und Pharmazeutischen Unternehmen/ §129 Rahmenvertrag über die Arzneimittelversorgung

[107] Case C-159/91 & Case C-160/91 Poucet

[108] Case C-264/01 AOK and other health insurance organisations vs Ichtyol-Gesellschaft and other companies

[109] Case C-267/95 Merck vs Primecrown

## 6. Products authorized under Previous Pharmaceutical Legislation

The principle of free movement of goods is only applicable to those products, which comply with EU-law. Article 76 of Directive 2001/83[110] requires that "*...the Member States take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory.*"

After accession of a country however often products are available in the "new" member state, which comply with previous national law but do not comply with the EU-law. And after harmonization of laws even in "old" member states temporary products are placed on the market, which are in compliance with previous national law but are not yet in compliance with the new EU-law.

Currently two major groups of pharmaceutical products do not comply with EU-law:

- Pharmaceuticals authorized in Germany prior to 1978 and which have not yet been reassessed (so-called products with fictitious approval). These products are legally on the German market according to an exemption based on §105 German Drug Law. This exemption is valid for a limited period of time and expires as soon as the reassessment of the dossier according to the principles laid down in Directive 2001/83 has been completed.
- Pharmaceuticals authorized in some of the new accession countries according to previous national law and which did not comply with the EU-law (also named *acquis communitaire*) by the date of accession (May 1st 2004). These products remain legally on the national markets for a limited period of time. This exemption has been agreed in the Accession Treaty and expires as soon as the reassessment of the dossier according to the principles laid down in Directive 2001/83 has been completed by the national authorities – at the latest however at the due date defined in the Accession Treaty separate for each of the concerned countries.

Within a defined timeframe these products have to be adapted to the current EU-law. For a transitional period the products, which do not comply with the Community law, are subject to specific regulations.

[110] Directive 2001/83 on the Community code relating to medicinal products for human use

### 6.1. Specific Regulations for Pharmaceuticals with Fictitious Approval in Germany

Although a German product with fictitious approval can be banned from import into another member state even this product may be subject of parallel trade activities. As Germany has a high pricing level for pharmaceuticals, a parallel trader maybe want to import a product for which he claims sufficient similarity to a German reference product with fictitious approval.
If the import product comes from another member state and complies with the community law, then the principles of free trade are applicable for this product - regardless whether the German reference product does not comply with the community law.
A licence for importation of a product that claims sufficient similarity to a reference product with fictitious approval however is not covered by the announcement on the authorization of parallel imported pharmaceutical products within the framework of a simplified procedure[111]. This announcement only refers to products for which a national marketing authorization has been granted according to the requirements given in Directive 2001/83.

In case the reference product is on the market based on a fictitious approval, the procedure according to the announcement concerning parallel imported medicinal products with reference to products with registrations according §105 German Drug Law[112] applies.
The legal construct implemented by this announcement is as follows:
The parallel trader has to submit a notification of co-distribution of an identical product. This notification is regarded as a variation according §29 German Drug Law concerning the fictitiously approved reference product. The parallel trader is allowed to submit this variation – although he is not holder of the fictitious marketing approval for the product.
The parallel trader however cannot receive an own marketing authorization for the parallel import product as he claims "sufficient similarity" to a reference product which itself is subject to a preliminary and fictitious approval. Therefore the parallel trader will be registered as co-distributor for this reference product.
As soon as the fictitious approval for the reference product is switched to a marketing authorization the exemption to market the parallel import product as co-distributor expires. In this case the parallel trader is required to apply for an own marketing authorization within two months after the marketing authorization of the reference product is published in the federal gazette. For this application the "simplified procedure" as described above applies.

[111] Bekanntmachung über die Zulassung von parallel importierten Arzneimitteln im Rahmen eines vereinfachten Verfahrens, November 1995
[112] Bekanntmachung über die Zulassung von parallelimportierten Arzneimitteln (Bezugnahme auf Zulassungen nach §105 AMG), April 1996

***Rückruf***

**Baycuten „Eurim-Pharm“ Creme**
**Alle Chargen und Packungsgrößen**

Die Firma Eurim-Pharm Arzneimittel GmbH, Am Gänsleben 4-6 83451 Piding, bittet um folgende Veröffentlichung:
“Wegen Erlöschens der fiktiven Zulassung ist das Präparat Baycuten Creme (PZN 7682072, 7682089, 7682095, 7682103) nicht mehr verkehrsfähig.
Aus diesem Grund bitten wir um Rücksendung sämtlicher Chargen und Packungsgrößen des Präparates zur Gutschrift an die oben genannte Firmenanschrift.“

(Deutsche Apotheker Zeitung 09.01.2003)

***Fig. 2***

In case the registration for the reference product is not upgraded and switched to a marketing authorization - regardless for which reasons - the fictitious approval for the reference product expires. Consequently also the allowance for co-distribution of the parallel import product expires. Both the reference product as well as the parallel import product has to be recalled from the market.

Figure 2 gives an example for a recall of a parallel traded product caused by expiration of the fictitious approval for the reference product.

These details on the legal consequences of the expiry of a fictitious approval are presented in the announcement concerning notification of fictitiously approved pharmaceuticals for which expiry has been declared[113].

## 6.2. Pharmaceuticals authorized under Previous Law in the EU-Accession Countries

All acceding countries have agreed to implement the current European pharmaceutical legislation from the date of accession.

Cyprus, Lithuania, Malta, Poland and Slovenia however have asked for an additional transition period to allow them an update of those previous marketing authorizations, which are not in compliance with the EU law. The transition period allows that the marketing authorizations issued under previous law remain valid even after May 1st 2004, the day of accession. The duration of the transitional period has been agreed[114] as follows:

Cyprus: until December 31st 2005

Malta: until December 31st 2006

Lithuania: until January 1st 2007

Poland and Slovenia: until December 31st 2008

So in these accession countries temporary a number of marketing authorizations exist that have been granted under previous legislation and have still not been re-assessed following the

[113] Bekanntmachung eines Hinweises auf die Mitteilung fiktiver Arzneimittelzulassungen nach §105 Abs.3 Satz 1 AMG, deren Erlöschen im Bundesanzeiger bekannt gemacht werden soll, sowie Rechtshinweise im Zusammenhang mit dem 10. AMG-Änderungsgesetz, b: Rechtsfolgen des Erlöschens fiktiver Arzneimittelzulassungen für die Verkehrsfähigkeit bezugnehmender Parallelimporte

[114] Report on the results of the negotiations on the accession of Cyprus, Malta, Hungary, Poland, the Slovak Republic, Latvia, Estonia, Lithuania, the Czech Republic and Slovenia to the European Union, prepared by the Commissions departments June 2003, Chapter 1: Free Movement of Goods

criteria of Directive 2001/83. Other Member States are allowed to restrict the free movement of goods in this particular case by prohibiting the import of these pharmaceuticals as long as their marketing authorizations have not been issued in compliance with the current European law. The duration of the country specific transition periods and even each concerned pharmaceutical product is listed in separate appendices of the Accession Treaty[115].

Since May 1st 2004 the European marketing authorizations granted according to Regulation 2309/93 automatically are valid in the new accession countries and those national marketing authorizations, which have been in conflict with centrally authorized products, became invalid. For a short transitional period however it is accepted by the EMEA that both the nationally authorized version and the centrally authorized version of the same product co-exist on the national markets.

Importation of a previously nationally authorized version of a centrally authorized product is not regarded as parallel distribution. The EMEA recommends[116] that the national authorities shall be competent for the approval of such importations: *"...there may be a transitional period during which both nationally authorised and centrally authorised products will co-exist on the national market. Any importation of a previously nationally authorised medicinal product, which has become centrally approved after the accession date of 1 May 2004, would qualify as parallel importation and not as parallel distribution. Such importations should be dealt with by national competent authorities."*

[115] *Poland* : Appendix A referred to in Annex XII; *Malta*: Appendix A referred to in Annex XI; *Cyprus*: Appendix referred to in Annex VII; *Slovenia*: Appendix A referred to in Annex XIII; *Lithuania*: Appendix A referred to in Annex IX of the Accession Treaty

[116] EMEA/Ho/2368/04 EMEA Post Authorization Guidance on Parallel Distribution

## 7. Previous Patent Law in the Accession Countries – the "Specific Mechanism"

In the past the accession countries - except Malta and Cyprus - have granted only process patents but no product patents. Product patents have been introduced 1991 in the Czech Republic and in the Slovak Republic, 1993 in Latvia, Poland, Slovenia and 1994 in Estonia, Hungary and Lithuania. In these eight accession countries therefore a number of those pharmaceutical products are unprotected by patents, which are protected by patents in the "old" member states.
And also after the accession date May 1st 2004 these pharmaceuticals remain unprotected by a patent. This is because in general a patent cannot be granted with retrospective effect as by nature a patent is issued to protect a new and innovative product but not a product that already is on the market since years.

The commercial right of exclusiveness granted by a patent however is limited to the first trade within the EEA. This applies whether or not the patent right exists in the member state where the product is placed on the market as stated by the Court in case *Merck* [117]: *"...to permit an inventor ... to invoke a patent held by him in one member state in order to prevent the importation of the product freely marketed by him in another member state where that product is not patentable would bring about a partitioning of the national markets which would be contrary to the aims of the treaty."*

For each batch the original manufacturer has sold in one of the eight accession countries, his patent right is exhausted in the whole EEA - although there was no benefit from patent exclusivity for this particular batch. Additionally, due to this EEA-wide exhaustion the patent owner cannot prohibit the import of this batch from the accession country into another member state of the EEA.

To overcome this situation a derogation of the principle of free trade has been introduced by the Annex IV of the Accession Treaty[118] in order to protect the patent rights. The purpose of this derogation is to limit the parallel trade between accession countries and other member states for those pharmaceuticals for which in the accession country the protection by a product

[117] Cases 187/80 Merck vs. Stephar, C-267/95 & C268/95 Merck vs. Primecrown
[118] Annex IV : List refered to in Article 22 of the Act of Accession

patent has not been possible in the past. This derogation is valid for the duration of the product patent plus the duration of the supplementary patent certificate[119].

A so-called "specific mechanism" requires the parallel trader to notify the patent holder of the intention to import from one of the eight accession countries. The patent holder then will have one month to decide whether to accept or not the importation. The full description of the "specific mechanism" in Annex IV is as follows:

*SPECIFIC MECHANISM*

*With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent. Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.*

This derogation from the principle of free trade however does not limit the importation of products from "old" member states with a low price level into one of the eight accession countries.

The German authorities recently have published a procedure[120], which links this "specific mechanism" with the "simplified procedure". In case the member state of origin is one of the eight accession countries mentioned above, the parallel trader is required to submit a separate statement[121] saying that he has already notified either the patent owner or the marketing authorization holder in writing. A copy of the letter of notification and a proof that either the patent owner or the marketing authorization holder has receipt this letter is to attach.

[119] A Supplementary Patent Certificate SPC is granted to compensate the time lost due to regulatory requirements The SPC prolongs exclusivity rights for up to 5 years from date of patent expiry but it extends exclusivity not longer than 15 years from date of first marketing authorization.

[120] „ Bekanntmachung des Bundesinstitutes für Arzneimittel, des Paul-Ehrlich-Institutes sowie des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit über die Bestimmungen des Besonderen Mechanismus nach Nummer 2 zu Anhang IV der Beitrittsakte des EU-Beitrittsvertrages vom 16. April 2003 betreffend den Parallelimport von Human- oder Tierarzneimitteln aus den Republiken Estland, Lettland, Litauen, Polen, Slowenien, Ungarn, der Slowakischen Republik oder der Tschechischen Republik in die Bundesrepublik Deutschland"

[121] „Erklärung zum Besonderen Mechanismus nach Ziffer 2 zu Anhang IV der Beitrittsakte des EU-Beitrittsvertrages vom 16. April 2003"

The EMEA also has updated the forms for notification of parallel distribution and for notification of a subsequent change by including the following declaration concerning the specific mechanism[122,123] which has to be signed by the parallel distributor: *"In order to comply with Annex IV (2) of the Act of Accession signed on the 16th of April 2003, I undertake to submit a "notification of a change" to the EMEA if the country of origin of the parallel distributed product changes. In accordance with the specific mechanism, I undertake to ensure that the patent holder or beneficiary will be notified in case the country of origin is changed to the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovak Republic or Slovenia, and the specific mechanism applies."*

In accordance with the specific mechanism as agreed in the Accession Treaty the German authorities and also the EMEA require the information of either the patent holder or the beneficiary of the patent (which normally is the marketing authorization holder). The Austrian authorities[124] however require the information of both the patent holder and the marketing authorization holder.

The requirement to inform the marketing authorization holder in all cases of parallel trade has recently been introduced by Directive 2004/27 where it says in Article 76 (3): "*Any distributor, not being the marketing authorization holder, who imports a product from another Member State shall notify the marketing authorization holder … in the Member State to which the product will be imported of his intention to import it."*[125,126]

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[122] Notification of a Change for Parallel Distribution of a Centrally Authorised Medicinal Product
[123] Notification of Parallel Distribution of a Centrally Authorised Medicinal Product
[124] Antrag auf Genehmigung für den Vertrieb im Parallelimport; May 2004
[125] Directive 2004/27/EC amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use
[126] Originally the following text was proposed: *"Any distributor, not being the marketing authorization holder, who imports a product from another Member State shall notify the marketing authorization holder of his intention to submit to a competent authority an application for a parallel import license"* (see *Amendment 94* in A5-0340/2002 Report on the proposal for a European Parliament and Council Directive amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use

## 8. Summary

Parallel trade within the European Economic Area is a form of trade whereby a wholesaler buys products in a member state with comparatively low prices, and then imports them into another member state with relatively high prices.

This master thesis gives an overview on the legal framework governing the parallel trade in pharmaceuticals for human use in the European Economic Area.

The harmonization of product related laws is a precondition for free movement of pharmaceutical goods. The free movement of goods has been agreed in the EC Treaty and forms the basis of parallel trade. But parallel trade in pharmaceuticals is also affected by competition law, commercial property law and pharmaceutical law.

In the field of pharmaceutical law all regulations affecting parallel trade have to balance the aim to safeguard public health and the need to obstruct as little as possible the free movement of goods. The competent authorities have elaborated a number of detailed measures designed to ensure this balance both for centrally authorized and for nationally authorized products.

In the field of commercial property law all measures concerning parallel trade have to balance the protection of trademark and patent rights and the need to hinder as little as possible the free movement of goods. In contrast to pharmaceutical law however there is a lack of clear regulations governing the commercial property aspects of parallel trade in pharmaceuticals. The current legal situation is mostly defined by case law, which provides details on the rights and obligations of the parties involved in the commercial property issues of parallel trade.

In the field of competition law all measures with regard to parallel trade have to comply with the competition rules as agreed in the EC Treaty. Also here the details of the current legal situation are mostly defined by case law, which for example provides guidance concerning supply agreements and price regulations.

The principle of free movement of goods is only applicable to those products, which comply with EU-law. Nevertheless specific regulations apply in case parallel trade affects those pharmaceuticals, which are not in compliance with current EU-law. An overview on the legal situation is presented for fictitiously approved products in Germany and for products authorized under previous law in the accession countries.

Finally reference is made to the “specific mechanism”. This “specific mechanism” has been agreed in the Accession Treaty and introduces a derogation of the principle of free trade for those products which remain unprotected by a patent in certain accession countries while they are patent protected in the “old “ member states of the EC.