



School of Business,
Economics and Law
GÖTEBORG UNIVERSITY

**Counterfeiting and Parallel Trade of
Pharmaceuticals
- Free movement of goods versus consumer
protection**

Elisabeth Norling and Paulina Rautio

Graduate Business School

Intellectual Capital Management
Master Thesis No. 2006:18
Supervisor: Tomas Faxheden

Abstract

The occurrence of counterfeit medicines is a constantly growing problem, which poses a serious threat to human lives. It could also potentially lead to extensive economic implications for affected companies and countries in Europe. The purpose of the present study is to examine whether there is a connection between the free movement of goods and the occurrence of counterfeit medicines. Safety is crucial when it comes to pharmaceuticals; there must be an adequate balance between consumer protection and free trade. For the purpose of the study we have gone through the relevant legislation, case law and doctrine. We have also interviewed persons with knowledge of the area. The results indicate that there is no direct connection between parallel trade and counterfeiting of pharmaceuticals. In order to decrease the occurrence of counterfeiting intensified international cooperation in the fields of legislation and technical measures is necessary. The public must be made more aware of the problems with counterfeit drugs, and the risks associated with buying them. The control system must be improved in order to protect consumers.

Acknowledgements

We want to thank Raul Wannerholt, AstraZeneca, Göran Heintz, Föreningen för Paralleldistributörer av Läkemedel/Paranova, Inger Näsman, Läkemedelsindustriföreningen, Erika Haglund and Kerstin Hjalmarsson, Swedish Medicines Products Agency, and Hans Flodeer, Pfizer for contributing to this thesis by giving us their precious time and knowledge. The interviews provided us with valuable insight in the pharmaceutical industry and the different aspects of it.

We also want to thank Tomas Faxheden for his tutoring.

Index

ABSTRACT	2
ACKNOWLEDGEMENTS	3
INDEX.....	4
ABBREVIATIONS	6
1. INTRODUCTION.....	7
1.1 BACKGROUND.....	7
1.2 PURPOSE.....	9
1.3 METHOD.....	10
1.4 OUTLINE.....	10
2. INTERNAL MARKET	11
2.1 THE FREE MOVEMENT OF GOODS	11
2.2 THE IMPORTANCE OF COMPETITION	11
2.3 CONSUMERS AND INTERNAL MARKET	12
2.4 PARALLEL TRADE OF PHARMACEUTICALS.....	13
2.5 EXCEPTIONS TO THE FREE MOVEMENT OF GOODS.....	13
2.6 REASONS FOR PARALLEL TRADE	14
2.7 PRICE CONTROLS	16
2.8 PARALLEL TRADE IN PRACTICE	17
2.9 EXHAUSTION OF RIGHTS.....	19
2.9.1 <i>The purpose of trademarks.....</i>	<i>19</i>
2.9.2 <i>Legal ground for exhaustion of rights.....</i>	<i>21</i>
2.9.3 <i>Regional exhaustion.....</i>	<i>22</i>
2.10 REPACKAGING/RELABELLING	23
2.10.1 <i>Case law development.....</i>	<i>24</i>
2.10.1.1 <i>Essential function of trademarks and division of the market.....</i>	<i>24</i>
2.10.1.2 <i>Intention to divide the market.....</i>	<i>26</i>
2.10.1.3 <i>Level of invasiveness.....</i>	<i>26</i>
2.10.1.4 <i>Effect of dividing the market.....</i>	<i>27</i>
2.10.1.5 <i>The necessity of relabelling.....</i>	<i>28</i>
2.10.1.6 <i>Objective necessity.....</i>	<i>29</i>
2.10.2 <i>Dangers associated with repackaging/relabelling pharmaceuticals.....</i>	<i>30</i>
3. COUNTERFEITING OF PHARMACEUTICALS.....	31
3.1 COUNTERFEIT MEDICINES	31
3.2 THE EXTENT OF COUNTERFEITING	32
3.3 DISTRIBUTION OF COUNTERFEIT DRUGS.....	34
3.4 TYPES OF PRODUCTS AFFECTED	34
3.5 TYPES OF COUNTERFEIT PRACTICES.....	36
3.5.1 <i>Finished medicinal products.....</i>	<i>36</i>
3.5.2 <i>API.....</i>	<i>37</i>
3.6 FACTORS FACILITATING COUNTERFEITING.....	38
3.7 TECHNOLOGICAL ANTI-COUNTERFEITING MEASURES.....	40
3.8 CONSUMER PROTECTION AND HEALTH	42
3.9 ECONOMIC CONSEQUENCES	43
3.10 WORKING TOGETHER NATIONALLY, REGIONALLY AND INTERNATIONALLY	46
4. THE PHARMACEUTICAL INDUSTRY.....	46
4.1 THE CHARACTERISTICS OF THE PHARMACEUTICAL SECTOR	46
4.1.1 <i>High costs and uncertain return on investments.....</i>	<i>47</i>
4.1.2 <i>The importance of a strong pharmaceutical industry.....</i>	<i>48</i>
4.2 THE ISSUE OF PARALLEL TRADE IN PHARMACEUTICALS	49
4.3 PHARMACEUTICAL LEGISLATION	52
4.3.1 <i>Manufacturing authorization.....</i>	<i>53</i>

4.3.2 Wholesale/distribution authorization	54
4.3.3 Marketing authorization.....	55
4.3.4 Supervision and measures in case of breaches of legal provisions.....	57
5. CONCLUSIONS	57
5.1 THE RESEARCH QUESTION	57
5.2 PROBLEMS WITH LEGISLATION.....	58
5.3 ANTI-COUNTERFEIT MEASURES	59
5.4 REPACKAGING	60
5.5 AUTHORITIES	61
5.6 CRIMINAL LEGISLATION	61
5.7 DISTRIBUTION CHAIN	62
5.8 CONCLUDING REMARKS	63
6. REFERENCES	64
6.1 LITTERATURE.....	64
6.2 REPORTS AND ARTICLES	64
6.3 MISCELLANEOUS	67
6.4 CASE LAW	67
6.5 TREATIES.....	69
6.6 REGULATIONS	69
6.7 DIRECTIVES.....	70
6.8 COMMUNICATIONS	70
6.9 INTERVIEWS	71
APPENDICES	72
APPENDIX 1	72
APPENDIX 2	73
APPENDIX 3	74

Abbreviations

ACG	Anti-Counterfeiting Group
API	Active pharmaceutical ingredient
EAEP	European Association of Euro-Pharmaceutical Companies
EC	European Community
ECJ	European Court of Justice
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FPL	Föreningen för Paralleldistributörer av Läkemedel (Swedish Association of Parallel Distributors of Pharmaceuticals (authors' translation))
GDP	Good distribution practice
GMP	Good manufacturing practice
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
IPR	Intellectual Property Right
LIF	Läkemedelsindustriföreningen (The Swedish Association of the Pharmaceutical Industry)
OSCE	Organization for Security and Co-operation in Europe
RFID	Radio-frequency identification
R&D	Research and development
WHO	The World Health Organization

1. Introduction

1.1 Background

Medication has a vital role for a lot of people, enabling them to survive serious diseases or simply to live a normal life. Most persons occasionally use different kinds of pharmaceuticals. When they go to the pharmacy to pick up their medication, not many persons are considering that their medication could be counterfeited and thus might lack effect, have too low a dosage, or in the worst cases even be directly toxic.

Previously, numbers from the World Health Organization (WHO) estimated that 10 % of the medicines in the world trade were counterfeit drugs¹. Recently those numbers have been updated, and now WHO states that it is preferable not to refer to one number for the entire world, but rather to see to the specific circumstances in the different parts of the world. However, generally speaking, WHO has said that it can be estimated that less than 1% of all medicines in developed countries are counterfeited, compared to over 10% in developing countries. To note is that these numbers vary widely when one looks more closely at different geographical areas; in some countries the percentage of counterfeit medicines may amount to quite a lot more than 10%.² Sales of counterfeit medicines are predicted to increase, according to the Centre for Medicines in the Public Interest, with more than 90 % between 2005 and 2010. Sales would reach 75 billion USD globally.³

Counterfeit medicines have been perceived mainly as a problem for developing countries, but throughout the recent years counterfeit drugs have been found in ordinary distribution chains within developed countries as well. Counterfeiting of pharmaceuticals is increasingly becoming a bigger and bigger problem in developed countries.⁴

Between 2001 and 2005 there were 27 cases of counterfeit medicines found in the legitimate supply chain and 170 cases in the illegitimate supply chain within the European Union (EU).⁵ The problem has been given more and more attention all around the world

¹ WHO defines counterfeit drugs as “a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”

² <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf> Visited: December 12, 2006.

³ WHO, Counterfeit medicines, Fact sheet N°275, <http://www.who.int/mediacentre/factsheets/fs275/en/>. Visited October 1, 2006.

⁴ Counterfeit medicines, Survey report, p. 13.

⁵ Behrndt, WHO conference speech, Combating counterfeit medicines – Views from a regional organisation (EU).

lately, with reports concerning the subject being published by large organizations such as WHO, EU, Council of Europe and Food and Drug Administration (FDA). Nevertheless, the public often perceives counterfeiting as a victimless crime, as focus in media has mostly been on counterfeiting of luxury products, CDs and DVDs. The companies selling these products, that are victims of counterfeiting, seem to be perceived as multinationals that make huge profits on excessive prices and therefore can take the revenue loss. Counterfeiting of drugs presents a more complex problem due to the safety related risks though; the economic losses it could involve for the affected companies and countries should not be overlooked, however, the main issue is that counterfeited drugs are in fact potentially lethal. Traditionally, counterfeited drugs have often been expensive drugs, either so-called life style drugs like Viagra⁶ etc, or for diseases like cancer, HIV and AIDS. However, the current development seems to be that all types of drugs are targets for counterfeiting, without discrimination. The situation differs some though, for instance when comparing developed and developing countries.⁷

The circumstances in EU due to the efforts made to form a single market in pharmaceuticals present a different market structure in comparison with the other national markets. One of the contributing factors to the development of a single market of pharmaceuticals in Europe is the principle of free movement of goods. The purpose of a single market in Europe is to enhance competition in and between the member states. The price differences in pharmaceuticals among the EU member states have resulted in parallel trade with pharmaceuticals from low cost countries to high cost countries. It is sometimes argued that the regulation regarding free trade within EU/European Economic Area (EEA) facilitates the occurrence of counterfeit drugs as it allows parallel trade of drugs. One of the specific aspects of the parallel trade that is said to make it more vulnerable to counterfeit drugs is the right for the parallel importers to repackage the imported drugs; a unique restriction in the trade mark holder's rights. Counterfeiting poses challenges to custom unions like EU, due to lack of or reduced border controls within a region and the free movement of goods, including parallel trade.⁸

⁶ Trademark registered by Pfizer Inc.

⁷ Counterfeit medicines, Survey report, p. 133

⁸ Behrndt, WHO conference speech, Combating counterfeit medicines – Views from a regional organisation (EU).

1.2 Purpose

The purpose of this essay is to examine if there is any connection between parallel trade and counterfeiting of medicines. We aim to investigate if there is a connection between the parallel import of drugs and the occurrence of counterfeit drugs. If we find that there is such a connection, we also aim to look into what the main cause(s) of that connection is. The study will be conducted with a consumer safety perspective to see if the consumer safety interests are taken to consideration or if the free movement of goods is prevailing. The intention is to find out if there is a balance between the two aspects. Based on our conclusions, we will also make some suggestions of improvements.

In order to limit the extent of the study, we have made some delimitations to the subject. To notice is that the focus mainly lies on the trademark rights related to pharmaceuticals. Patents and other intellectual property rights (IPR) are somewhat disregarded in the discussion due to the fact that the WHO definition of counterfeiting focuses primarily on trademarks, and that we have found it necessary to look deeper into the issue of repackaging and relabelling of pharmaceuticals; a practice that mainly affects trademark rights. Further on, we have principally limited the study to EU and European Community (EC) law. However, in some cases we have referred to examples that involve national legislation and authorities, but the basis is EU/EC law. As we have focused on trade within the single market, we have consequently not looked deeper into customs regulations and trade with countries outside of the EU. Furthermore, we have focused on counterfeiting of, and trade with, pharmaceuticals within the legal, ordinary distribution chain. As the main objective of this thesis is to look at the legal distribution chain of pharmaceuticals and counterfeiting existing there within, the illegal trade on Internet has not been considered in itself. However, we have not been able to completely disregard the subject, as by totally excluding illegal Internet trade we would not be able to present a complete picture of the problems with counterfeiting. To notice is, though, that illegal sales of pharmaceuticals over the Internet presents specific circumstances compared to legal trade, as well as other types of illegal trade, with pharmaceuticals. For instance, there are problems with jurisdiction due to the difficulties with locating websites and managing to close them down. This is why we have chosen to only mention illegal Internet trade when it has been deemed necessary for the general understanding.

1.3 Method

For the purpose of this study we have gone through the relevant legislation, case law and doctrine. We have read books and articles, reviewed Internet homepages of relevant organizations, and authorities etc. We have also looked into reports and statistics from such authorities and organizations. We have looked at EU preparatory work, treaties, regulations, directives, communications and case law.

We have also interviewed persons with knowledge in the area. Our aim was to talk actors with different perspectives of the situation, to better see the whole picture. Therefore, we chose to interview representatives from AstraZeneca, Swedish Association of Parallel Distributors of Pharmaceuticals (FPL)/Paranova, The Swedish Association of the Pharmaceutical Industry (LIF), Swedish Medicines Products Agency and Pfizer. By interviewing these persons, we got to hear opinions from parties involved in pharmaceutical research and development (R&D) and manufacturing as well as parties involved in parallel trade of pharmaceuticals. We also got information from an authority point of view. Due to the limited time given for the study, we only managed to interview a limited number of persons. Therefore, the opinions expressed in the interviews give a limited picture of the situation in Europe, especially as all of the interviewed persons represent companies and organisations located in Sweden.

1.4 Outline

Further on in this thesis we will elaborate on parallel trade and counterfeiting of pharmaceuticals. In chapters 2-4 we will present a more thorough exposition in the three different main areas that the thesis concern; parallel trade, counterfeiting and the specifics of the pharmaceutical industry and trade.

Chapter 2 handles the matter of parallel trade, a phenomenon based on the European Union's fundamental principle of the single market and its subsequent free movement of goods. We will elaborate on the reasons for allowing parallel trade, as well as the consequences of doing so. Allowing parallel trade of such a special kind of products as pharmaceuticals has a lot of repercussions that will not occur when other kinds of products are concerned. The difficulties with creating a true single market for pharmaceuticals, as well as the safety aspects, are discussed.

In chapter 3 we describe counterfeiting more in detail; what it means, the problems it results in and what measures can be taken to fight it, naturally with an emphasis on the special circumstances regarding pharmaceuticals.

Chapter 4 deals with the legislation concerning pharmaceuticals, with a focus on the parts of the legislation that concern the issue of parallel trade and consumer safety. It also discusses the characteristics of the pharmaceutical sector.

Finally, we will present the findings of our study in chapter 5. We will also discuss how the issue concerning counterfeiting and parallel trade of pharmaceuticals may be resolved in the future, with the purpose of finding a well-poised balance between consumer safety versus free movement of goods, keeping the parallel trade from promoting the occurrence of counterfeited pharmaceuticals.

2. Internal market

2.1 The free movement of goods

The free movement of goods constitutes one of the four freedoms guaranteed by the EC Treaty. The purpose of the four freedoms is to establish an internal market among the EU member states. The free movement of goods is based on article 28 EC Treaty, with exceptions in article 30 EC. The objective of articles 25 and 28-31 EC is to ensure that competition is not prevented or distorted between goods coming from different member states. The aim of the provisions is to ensure that government provisions in form of quotas, that restrict the imported amount, tariffs, which affect the price or charges with equivalent effect, will not distort or prevent competition. The consumers, depending on their preferences, should make the choice of goods.⁹

2.2 The importance of competition

The competition law of EU is closely related to the free movement of goods, as a way to ensure a functioning internal market. The competition policy in EU has several objectives. One of the objectives is to facilitate the creation of a single European market. The competition law will prevent single companies with market power from disturbing the creation of a single market by for example partitioning the market along national borders. Another objective is to

⁹ Craig & De Búrca, EU Law, p. 581.

promote efficiency, through maximizing consumer welfare and striving for an optimal allocation of resources. According to traditional economic theory, services and goods will be produced in the most efficient manner in cases of perfect competition. There is significant disagreement between economists when it comes to defining the optimal competition policy. The disagreement concerns among others which kind of behaviour will hinder or promote competition. A third objective is to protect consumers and smaller companies from large constellations of economic power through monopolistic dominance from one firm or from a number of companies dividing the market in a cartel.¹⁰

2.3 Consumers and internal market

Consumers and consumer confidence is essential to the functioning of the internal market. Therefore consumer protection was during a long time seen as a way to promote the internal market. Differences in consumer protection legislation could create barriers to trade and alter competition, which is not compatible with the internal market objectives. Consumer policies in EU were justified based on internal market grounds in article 95 EC. With the adoption of article 153 EC it was recognised as an independent Community policy that should be considered when defining and implementing other Community strategies and activities.¹¹ The EU has developed a common public health and consumer protection strategy for 2007-2012 to ensure a better EU policy work for the citizens. Health and consumer protection shares many objectives: promotion of health protection, safety and integration of consumers and health concerns in all policies and information and education of the customers. The strategy has three objectives. First, protect citizens from risks and threats that cannot effectively be tackled by member states alone and are beyond the control of individuals. The second objective is to improve the decision making of the citizens when it comes to their health and consumer interests. The third objective is to put health and consumer issues at the centre of Community policy making by mainstreaming the policy objectives in all Community strategies.¹²

¹⁰ Op.cit., p. 936-937.

¹¹ Nebbia & Askham, EU consumer law, p 11.

¹² COM/2005/115final.

2.4 Parallel trade of pharmaceuticals

Parallel trade of pharmaceuticals has its origin in the free movement of goods, as a legal form of trade based on article 28 EC. Parallel imports are defined as “goods produced genuinely under protection of a trademark, patent or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right”.¹³ The term parallel trade comes from the fact that the trade is taken place outside the normal distribution network construed by the manufacturers or retailers or in parallel with this distribution network.¹⁴ Although the functioning of the internal market and especially parallel trade is dependent on competition on the market, there is a built in conflict between the IPRs and competition law. The purpose of IPRs is to give a limited monopoly to the owner, while the competition law aims to uphold competition between companies based on same conditions and therefore works against monopoly of any kind. According to article 5 of the trademark directive¹⁵ the owner receives an exclusive right to the trademark and owner can therefore prevent others from using the trademark without her consent. There are similar rights associated to the other IPRs.

2.5 Exceptions to the free movement of goods

Article 30 EC excludes industrial and commercial ownership from the prohibition of quantitative restrictions and measures having equivalent effects in article 28 EC. The relation between EC competition law and national intellectual property law was clarified by the European Court of Justice (ECJ) in *Consten & Grundig*¹⁶, where the court stated that the existence of the national law could not be tried, but the application of it could. The court stated that an exclusive distribution agreement could not be used to implement absolute protection for some markets. Dividing markets would have an effect on the creation of the internal market and restrict the free movement of goods. The competition regulations of EU have precedence over the national intellectual property law, if the result or effect is to hinder the free movement of goods.¹⁷

¹³ Arfwedson, Parallel trade in pharmaceuticals, p. 7-8.

¹⁴ EAEPC, http://www.eaepc.org/parallel_trade/general.php?n=2, Visited December 10th 2006. (EAEPC represents the European parallel distributors)

¹⁵ Trademark directive 89/104/EEC.

¹⁶ Cases 56 & 58/64.

¹⁷ The issue is further elaborated in section 2.10 concerning repackaging.

Public health and consumer protection can also constitute exceptions to the free movement of goods according to article 30 EC. In absence of Community legislation in the area it is up to the member states to decide on the protection of human health and life and how to ensure that the goal is achieved. However, the measures cannot go beyond what is necessary to achieve the goal. The measures cannot constitute a disguised restriction on trade. The public health argument has been used when national pharmaceutical regulations have been in conflict with the free movement of goods.¹⁸ In *Peijper v Commission*¹⁹, the same drug was marketed in several member states with the authorization of the national drug regulatory authorities. The regulators in the target state for the imports of the pharmaceuticals approved the imported goods on the documentation that was identical to the documentation already supplied by the authorised importer. In this case the parallel importer could not produce the documentation as it was in the possession of the manufacturer, whose price the parallel importer was undercutting. The rule made it impossible for the parallel importers to meet the importation requirements. The court recognised the authority for member states to restrict the movement of goods to protect human life and health, but pointed out that national rules and practices are not allowed if the same goal can be accomplished through measures that restrict intra-community trade less. It was unnecessary for the protection of public health to require the parallel importer to produce identical or almost identical documentation that had already been submitted by the manufacturer. Even in cases where the information was required by the national authorities to be able to trace a specific batch of medicine, needed in case of a pharmaceutical recall, article 30 EC could not be used to justify the demand of documentation that the parallel importer does not have access to, if the information could be obtained in another way.²⁰

2.6 Reasons for parallel trade

The main reasons for price differences on the market, and therefore the reason for parallel trade in general, are the following:

- 1) Differences in the IPR protection from one country to another, meaning that the patent protection may vary from one jurisdiction to another. Competition from generic

¹⁸ Hays, *Parallel importation under European Union law*, p. 70-71.

¹⁹ Case 104/75.

²⁰ Hays, *Parallel importation under European Union law*, p. 71.

medicines may be pushing down the prices of a certain branded product in the other country.

- 2) Variations in per capita income, purchasing power, and preferences affect demand and therefore market size, which is reflected in price differentials.
- 3) The regulation of prices by governments.
- 4) Retail price variations due to differing inflation rates, which create differences in exchange rates, and different tax rates. In the Euro countries the differences due to different exchange rates do not pose a problem any more.
- 5) Different marketing and sales strategies created by the IPR owner depending on the market.²¹

Parallel trade in pharmaceuticals present some specific circumstances. First, price discrimination among the countries would normally be limited due to international trade. However, it does not work this way in the pharmaceutical market. Differences in prices of pharmaceuticals are a result of national regulations of pharmaceutical markets. The prices in the European Union are often set after negotiations between different kinds of national health systems and industry, rather than by the market.

Second, parallel trade in pharmaceuticals is a consequence from lack of barriers to parallel trade, such as lack of total vertical control in the distribution chain by the original right holder. Lack of control in the distribution chain results in wholesalers having the possibility to redirect part of their stock from low-price countries to high-price countries.²² Efforts to obtain a stronger control over the distribution chain could lead to problems with the competition authorities in the European Union.

Third, the benefits of parallel trade in general have been debated in several studies; some of them have found that parallel trade may be beneficial for high-price countries. Regarding pharmaceuticals, there seems to be a conflict between two competing objectives: on one hand, paying sufficiently for innovation and, on the other hand, meeting national short-term costs goals for health. The consumer benefits of parallel trade in pharmaceuticals are also debated, as some studies indicate the benefits for customers and states are minor or nonexistent, due to the costs associated with parallel trade. The benefits of parallel trade in pharmaceuticals prevail today as the European Commission endorses free movement of goods in all areas.

²¹ Arfwedson, Parallel trade in pharmaceuticals, p. 10.

²² Kanavos, et al. The economic impact of pharmaceutical parallel trade in European Union member states, p. 25.

To finish, the parallel trade can be argued to be a short-term result of the lack of integration on the pharmaceutical market in the EU. If there were a single market in pharmaceuticals in the EU there would also be a pan-European pricing for pharmaceuticals.²³

2.7 Price controls

Due to the specific circumstances with health regulations and price controls, there have been attempts to exclude pharmaceuticals from parallel trade. The states negotiate the price for pharmaceuticals, and decide if they are allowed to be included in so-called reimbursement schemes.²⁴ The ECJ has in several cases stated that pharmaceuticals will not be exempted from the internal market. The existence of national price controls cannot justify measures that are incompatible with the rules of free movement of goods. It is the task of the community authorities to ensure harmonization of national measures intended to control prices and other forms of measures that distort competition and are incompatible with the common market.²⁵ The safety aspects that are involved in particularly the pharmaceutical sector adds to the problems, with demands on packing sizes, languages etc, and further harmonization in this area is occasionally demanded. However, at this point no final solution has been agreed upon and the problems remain.²⁶

The issues of price control and weak competition due to it has been up for debate within EU. The duality, with both national and EU legislation to adhere to, creates problems for the free movement of goods. An initiative to harmonize pricing in the member states was found in recommendation six in the report submitted to the European Commission President in may 2002, by the High Level Group on Innovation and Provision of Medicines set up by EU Commissioners Liikanen and Byrne. The group recommends: *“That the Commission and Member States should secure the principle that a Member State’s authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets.”* The initiative is seen as an important step towards a

²³ Kanavos, et al. The economic impact of pharmaceutical parallel trade in European Union member states, p. 25-26.

²⁴ EAEPC, Understanding competition in the distribution of pharmaceutical products, page 9-10. Hunter, The pharmaceutical sector in the European Union, p. 10.

²⁵ Case 15/74 Centrafarm vs. Sterling.

²⁶ Arfwedson, Re-importation (Parallel Trade) in Pharmaceuticals, p. 11. EAEPC, Understanding competition in the distribution of pharmaceutical products, p. 9-10. Hunter, The pharmaceutical sector in the European Union, p. 5 and 68-70.

single market in pharmaceuticals, while preserving the right for governments to control national health expenditures.²⁷

The right for member states to regulate prices has been determined in the cases *Roussel Laboratoria*²⁸ and *Commission v. Belgium*²⁹. The use of direct or indirect pricing is allowed by member states through their national reimbursement policies to ensure that all citizens gain equal access to medicines and to preserve the economical stability of the social security system. Due to the lack of harmonization in the pricing systems of pharmaceuticals, the ECJ has concluded that the member states can use pricing to ensure such legitimate interests as long as such measure do not result in legal or objective discrimination between national or imported products.³⁰ One important problem with governmental price control in the EU is the fact that such rules are national, meaning that the market conditions differ in each state and therefore there can be no true single market for pharmaceuticals.³¹ Another major problem with price control is the fact that government policies affect the pharmaceutical industry's possibility to make a profit. Making a profit is necessary not only to be able to recover the money spent on R&D for the pharmaceutical in question, but also to be able to invest money in R&D for future pharmaceuticals. Depriving the pharmaceutical companies of the possibility to find and bring new drugs to the market will not benefit anyone in the long run; innovation must be supported.³² Pharmaceutical prices must be balanced in order to both give the pharmaceutical companies reasonable profits that can be used to promote further research, and to make sure that all states and their inhabitants can afford purchasing the needed pharmaceuticals.

2.8 Parallel trade in practice

More than 140 millions pharmaceutical packages are parallel traded in Europe.³³ In Sweden, the market share for parallel traded pharmaceuticals is 12 %. The parallel trade turnover in Sweden is about 3 billions.³⁴ But how does parallel trade work in practice? It begins with that the parallel importer chooses a source country, such as Spain, where the

²⁷ CNE White Paper, Saving the European Pharmaceutical Industry, 2002.

²⁸ Case 181/82.

²⁹ Case C-249/88.

³⁰ COM 2003/839.

³¹ EAEPC, Understanding competition in the distribution of pharmaceutical products, p. 9-10, COM(1998)588final.

³² IFPMA, The Pharmaceutical Innovation Platform, 2004, p. 8. (IFPMA represents research-based pharmaceutical companies and organisations from all around the world)

³³ Harper, et al. Coincidence or crisis, p. XV.

³⁴ Intervju Göran Heintz, FPL/Paranova.

product destined for parallel import has a low price in relation to the price demanded by the original manufacturer or licensee in the import country. In most cases the target product is a product with a large price differential and therefore with a high profit margin. The target product is in most cases a new, innovative medicine offering a high price differential and therefore a high profit margin in the importing country.³⁵ A minimum price differential seen as necessary by most of the parallel importers is 15 %, but a more common price differential is between 20-30% so that the parallel import is economically sound.³⁶ Other factors influencing the choice of product are the extent of repackaging needed, volume of demand in the market of import, cost and possibility to obtain the license to market the products, existence of generic competitors and the formulation.³⁷ The products often require repackaging, or replacement of labels and notices in the languages of the import country, which is done by the parallel importer or a separate actor. The parallel importer has to ensure that the product conforms to EU as well as national regulations. European Medicines Agency (EMA) or the relevant national government agency has to permit the sale of product subject to parallel trade. The pharmaceutical has to be identical to the medicine registered in the importing country. Contacts will be made between the competent national authorities in the import country with their counterpart in the export country to receive documentation that ensure that the quality of the pharmaceuticals is the equivalent of the import country. The latter must also be identical to the drug registered in the importing country.³⁸ Some countries also have national regulation of the price of pharmaceuticals. The retail vendors in other EU countries are the main source for parallel importers. The retailers obtain the pharmaceuticals from licensed resellers or directly from original manufacturers. The retailers are mainly regional.

The conditions for parallel trade vary among the member states due to other circumstances. The physicians may or may not choose parallel imported drugs on their prescriptions. In some countries pharmacist have incentives to promote parallel drugs over original. Consumers may also have their reasons to choose the products of the original manufacture before the parallel imported drug. Finally, governments and national insurance programs for prescription drugs

³⁵ Arfwedson, Parallel trade in pharmaceuticals, p. 14.

³⁶ REMIT Consultants, Impediments to parallel trade in pharmaceuticals within the European Community, p. 22.

³⁷ Op cit., p. 17.

³⁸ For a further review of this legislation, see section 4.3.

have an incentive to keep down the cost for health programmes in the country and therefore choose cheaper alternatives when possible.³⁹

2.9 Exhaustion of rights

The doctrine of exhaustion of trademark rights (as well as of other IPRs) is crucial for facilitating free movement of goods within the EU and the EEA. Basically, the doctrine means that once a product bearing a trademark has been put on the European market by the holder of the trademark right, or with his consent, the proprietor's possibility to control the product by invoking trademark rights is exhausted. This leads to the trademark proprietor not being able to prevent parallel trade of e.g. pharmaceuticals by claiming that the parallel distributors are infringing his trademark rights, thus enabling free trade of pharmaceutical products within the European market.

2.9.1 The purpose of trademarks

In order to understand why the principle of exhaustion of trademark rights is a complicated and somewhat problematic issue, as well as why the following concept of repackaging and relabelling can be seen as posing such an infringement to the trademark rights, it is important to understand the basic function, signification and purpose of trademarks.

One of the main functions of trademarks is to enable companies to distinguish themselves and their products from others by the use of distinctive marks. This also facilitates the consumers' process of choosing amongst different products and services.⁴⁰ Trademarks are used as a way of informing the customers, and are often even as a guarantee of a certain quality etc for the products bearing the trademark.

For many businesses, especially in today's economy, trademarks might very well be the most important assets. A lot of money is put into advertisement in order to make the trademark well-known and trusted; to create a certain reputation and brand image. It would obviously be unfair to allow other parties to freely profit from the goodwill that the trademark holder has managed to create in connection to his trademark, thus the main rule of the trademark holder's exclusive right to the trademark.⁴¹

³⁹ Arfwedson, Parallel trade in pharmaceuticals, p. 14.

⁴⁰ Koktvedgaard & Levin, Lärabok i immaterialrätt, p. 339.

⁴¹ Op. cit., p. 339 and 368. Craig & De Búrca, EU law, p. 1093.

As mentioned above, the trademark holder's exclusive right to the trademark is important not only for the proprietor, but also for the buyers of the marked products. When buying a marked product, the customers rely on the mark to assure a certain quality that they have come to associate with the mark, through previous experience as well as commercials etc. The customers might also believe that if any problem with the purchased product occurs, the mark tells them where to turn for compensation. The mark functions as an indication of origin; guaranteeing that the marked products do originate from the trademark holder and "have not been tampered without the holder's authorisation"^{42, 43}. The trademark informs the customers of the identity of the purchased goods, helping them avoid confusing the marked goods with goods not produced by the trademark holder⁴⁴. The important functions of trademarks mentioned above were discussed by the European Court of Justice in the Hag II⁴⁵ and Ideal Standard⁴⁶ cases.

The described purpose and functions of trademarks explain why the exhaustion of rights doctrine, and the occasional right for parallel importers to repackage and relabel products, is problematic. The established functions of trademarks also clarify why counterfeiting of trademarked products is such a serious thing; even though counterfeiting might not always in itself cause serious economic harm or endanger lives, it always compromises the very functions of trademarks.

When someone other than the trademark holder is allowed to freely trade with products bearing the mark, use the mark in advertisements and so on, customers might be confused as to what that actor's connection to the trademark holder is. Therefore, in the Dior⁴⁷ and BMW⁴⁸ cases, the ECJ established that when using the trademark in advertisements the parallel importer must be careful not to damage the reputation of the trademark or to imply that there is a commercial connection between him and the trademark proprietor. The parallel importer must be loyal to the trademark holder in the use of the trademark. To cadge on the trademark's reputation and take advantage of the goodwill connected to it is not allowed.⁴⁹ The condition that the parallel importer may not damage the reputation of the trademark is important in the case of repackaging of pharmaceuticals. The repackaging must be done in a

⁴² Korah, *An Introductory Guide to EC Competition Law and Practice*, p. 271.

⁴³ Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 23.

⁴⁴ Craig & De Búrca, *EU law*, p. 1093. Korah, *An Introductory Guide to EC Competition Law and Practice*, p. 271.

⁴⁵ Case C-10/89.

⁴⁶ Case C-9/93.

⁴⁷ Case C-337/95.

⁴⁸ Case C-63/97.

⁴⁹ Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 23.

professional way; the packing must look professional so that it does not harm the customers' trust in the trademark. Repackaging and relabelling of pharmaceuticals also jeopardize trademarks as an indication of origin. Hunter argues that the customers can no longer trust that actors not authorized by the trademark holder have not tampered with the goods; in fact repackaging ensures the opposite.⁵⁰

It is clear that any restrictions in the trademark proprietor's exclusive rights to the trademark must be made with uttermost caution in order not to compromise the very purpose of trademarks. Sometimes what would normally be seen as infringement of the rights may be justified (things such as repackaging and relabelling). However, the essence of the trademark rights should not be affected.

2.9.2 Legal ground for exhaustion of rights

The legislation that the existence of parallel trade, and thus the exhaustion of rights principle, is based upon is essentially article 28 EC.⁵¹

The doctrine of exhaustion of trademark rights was first laid down by the ECJ in the *Centrafarm vs Winthrop*⁵² ruling.⁵³ The ECJ stated that “[a]s regards trade marks, the specific object of commercial property is inter alia to ensure to the holder the exclusive right to utilize the mark for the first putting into circulation of a product, and to protect him thus against competitors who would take advantage of the position and reputation of the mark by selling goods improperly bearing that mark”⁵⁴. The court continued with declaring that national laws of the EU member states containing provisions saying that the trademark rights are not exhausted by the marketing in another member state of the product protected by the mark may constitute an obstacle to the free movement of goods. If the product has been lawfully put on the market, by the trademark holder or with his consent, such an obstacle is not justified according to the court. The ECJ therefore consequently established that trademark rights are exhausted within the entire EU once the goods bearing the mark have been lawfully put on the market within any of the member states.

⁵⁰ Hunter, *The pharmaceutical sector in the European Union*, p. 69.

⁵¹ *Op. cit.* p. 27.

⁵² Case 16/74.

⁵³ NERA, *The economic consequences of the choice of regime of exhaustion in the area of trademarks*, p. 17-18.

⁵⁴ Case 16/74, para. 8.

Later article 7.1⁵⁵ of the trademark directive 89/104/EEC confirmed the principle of exhaustion of trademark rights and the legal practice already established by the ECJ's case law. Nevertheless, it does not mean that the exhaustion of rights is necessarily total; exceptions to the principle of exhaustion may occur "where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market".⁵⁶ One of the more common situations where trademark holders have (sometimes) successfully argued that article 7.2 shall apply involves repackaging of pharmaceutical products⁵⁷.

To observe is, that the doctrine of exhaustion does not involve the right to generally exploit the concerned trademark; the exhaustion applies only to each individual product that has been put on the market in accordance with article 7.⁵⁸ Consent to put the product on the market must thus exist for each separate product that exhaustion of rights is claimed to apply for.⁵⁹

2.9.3 Regional exhaustion

For a while it was uncertain what type of exhaustion of rights that was to apply within the EU; national, regional or global.

National exhaustion means that the rights are only exhausted within the territory of the country where the product has been put on the market, regional exhaustion means that by putting the product on the market of one country the rights are exhausted within an entire region that said country "belongs to" (for instance a region such as the EU), and global exhaustion thus means that when placing the product on the market in one country the rights are exhausted worldwide.

Today it is clear that regional exhaustion of rights prevails within EU. This fact was established by the ECJ in the *Silhouette*⁶⁰ ruling in 1998.

In its judgement, the ECJ elucidates that article 7 of the trademark directive shall be interpreted as not allowing the member states to have rules providing for global exhaustion of

⁵⁵ "The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent".

⁵⁶ Article 7.2. Trademark directive 89/104/EEC

⁵⁷ NERA, The economic consequences of the choice of regime of exhaustion in the area of trademarks, p. 18.

⁵⁸ Wireus, Parallelimport och försäljning av läkemedel, p. 19. Swedish Competition Authority, Parallel imports – Effects of the *Silhouette* ruling, p. 12.

⁵⁹ *Koktvedgaard & Levin, Lärobok i immaterialrätt*, p. 404, AIM Position Paper, Parallel trade – Consumer benefit or consumer loss?, p. 3. Case C-173/98.

⁶⁰ Case C-355/96.

trademark rights. If a trademarked product is put on the market in a third country it does not mean that the trademark rights are exhausted in the EU, parallel import of such a product is thus not allowed. The ECJ's decision clarifies that the trademark directive completely harmonizes the trademark law in the member states; the principle of regional exhaustion should be seen as a minimum as well as a maximum rule⁶¹. The ECJ argues that this interpretation safeguards the proper functioning of the internal market, and is thus in line with the aim of the trademark directive⁶²; regional exhaustion of rights ensures that the community market cannot be divided.

EU wide exhaustion of trademark rights is thus the main rule according to the Silhouette judgement. However, in the ruling the court also states "the Community authorities could always extend the exhaustion provided for by article 7 to products put on the market in non-member countries by entering into international agreements in that sphere"⁶³. This is what was done in the case of the EEA Agreement. Consequently, trademark rights are exhausted not only within EU but also the entire EEA.

2.10 Repackaging/relabelling

As a result of the principle regarding exhaustion of trademark rights (as well as of other IPRs) parallel trade of pharmaceuticals is enabled within the EU and EEA.

Regulations concerning pharmaceuticals may, however, complicate parallel distribution of pharmaceuticals.⁶⁴ National authorities may have decided that pharmaceuticals can only be sold in packages of a certain size, and countries demand that the packaging be printed in the language spoken in the concerned country; for instance, in Sweden pharmaceuticals with packaging printed only in Spanish may not be sold. The reason behind such regulations is generally the aim of protecting the customers. The lack of harmonization on EU/EEA level concerning some aspects of pharmaceutical regulations poses a problem for the free movement of goods. Further on, not only regulations, but also the actual situation on the market (consumer reluctance etc.) may hinder pharmaceuticals from being sold in a country if the packaging is not printed in the native language of that country, or if the packaging is in a different size than what is normally the case. The mentioned problems could become aggravated due to the fact that producers of pharmaceuticals may wish to prevent parallel

⁶¹ Westman, Ompaketering och utnyttjande av annans varumärke, p. 39.

⁶² Swedish Competition Authority, Parallel imports - Effects of the Silhouette ruling, p. 14.

⁶³ Case C-355/96, para. 30.

⁶⁴ LIF, Förfälskade läkemedel, p. 9.

import of their products, taking advantage of the possibility to sell their products in different sized packages or under different trademarks in different countries in order to make it more difficult for the parallel distributors.⁶⁵

Because of the above discussed circumstances, repackaging and relabelling of pharmaceuticals is occasionally allowed.⁶⁶ The invasiveness of the level of repackaging could vary. Depending on the situation, parallel distributors might need to completely re-package and re-label the pharmaceuticals (including the interior as well as external packaging), print new directions for use, or perhaps simply re-label the product by adding a sticker to the existing packaging.⁶⁷

Allowing repackaging and relabelling of pharmaceuticals also constitutes a bit of problem. It signifies a significant and unique restriction in the trademark holder's exclusive right to mark products with his trademark. Normally a third party labelling products with a trademark holder's mark would constitute trademark infringement, but in the case of pharmaceuticals it has been seen as necessary to make an exception in order to promote the free movements of goods within EU.⁶⁸

2.10.1 Case law development

The fact that repackaging and relabelling is allowed to a certain extent is a result of case law developed by the ECJ. The development leading up to the current situation has been somewhat volatile, with the ECJ changing opinion on some of the matters involved from time to time.

2.10.1.1 Essential function of trademarks and division of the market

One of the first more important cases concerning repackaging was Hoffmann-La Roche.⁶⁹ It concerned the situation that Hoffman-La Roche had packed their pills in packages containing different quantities in different member states. Centrafarm bought pills in England and imported them to Germany, where the pills were repacked in order to follow the German

⁶⁵ Westman, Ompaketering ommärkning och utnyttjande av annans varumärke, p. 43.

⁶⁶ Satchwell, A sick business, p. 12.

⁶⁷ Whether repackaging and relabelling is allowed or not, and to what extent, will be further discussed below.

⁶⁸ Koktvedgaard & Levin, Lärobok i immaterialrätt, p. 394.

⁶⁹ Case 102/77

practice regarding package sizes. Then the Hoffmann-La Roche's original mark, as well as Centrafarm's name, were placed on the packaging. The Court emphasized that "regard must be had to the essential function of the trade mark, which is to guarantee the identity of the origin of the trade-marked product to the consumer or ultimate user, by enabling him without any possibility of confusion to distinguish that product from products which have another origin"⁷⁰. The ECJ also pointed out that this means that the consumer can be certain that the original condition of the trademarked product has not been affected by interference from any unauthorized third person. Further on, ECJ remarked that "[t]he right attributed to the proprietor of preventing any use of the trade mark which is likely to impair the guarantee of origin so understood is therefore part of the specific subject matter of the trade mark right"⁷¹. The ECJ stated that in such circumstances it was in accordance with article 28 EC for the trademark proprietor to use the German trademark rights to prevent the parallel importer from relabelling the package following repackaging. However, the Court said that it must be considered whether the exercise of such a right may constitute a disguised restriction on trade between member states within the meaning of article 28 EC, having the effect of dividing the market.⁷² The fact that the trademark holder had used a marketing system with different packaging in different member states for the same product and then tried to stop parallel importers by exercising his trademark rights even when the repackaging might had been "done in such a way that the identity of origin of the trade-marked product and its original condition could not be affected"⁷³ could indicate a disguised restriction. The important question in the case was therefore said to be whether the repackaging of the trademarked product was capable of affecting the original condition of the product. When answering this question, consideration must be taken to the circumstances in the case and in particular to the nature of the product and the method of repackaging. Depending on the nature of the product, for instance only removing the outer packing while leaving the inner packing untouched could be considered as not affecting the original condition of the product. For the repackaging to be lawful in such cases, the repackager must also give the trademark proprietor advance warning

⁷⁰ Op.cit., para. 7.

⁷¹ Ibid.

⁷² Case 102/77.

⁷³ Case 102/77, para. 9.

of the repackaging, and also clearly state on the packaging that the product has been repackaged by him.⁷⁴

2.10.1.2 Intention to divide the market

In *American Home Products*⁷⁵, a case with circumstances similar to *Hoffmann-La Roche*, also involving *Centrafarm*, the ECJ stated that relabelling would be allowed only if the trademark holder intended to divide the market by his actions; focus was put on the intention rather than the effect. The trademark holder had used different marks for identical products in different member states, but the ECJ stressed that this fact in itself was not illegitimate. Only if the use of varying marks had taken place with the purpose of restricting trade between member states may the parallel importer change the mark on the products. *Centrafarm* failed to show that the proprietor had acted with the intention of partitioning the market and therefore lost the case in the national court.⁷⁶ To observe is, however, that the legal practice regarding the use of varying marks and the subsequent question of whether the mark may be changed by the parallel importer has somewhat changed since the *American Home Products* case; for instance, see the discussion concerning the *Bristol-Myers-Squibb* and *Pharmacia & Upjohn* cases below.⁷⁷

2.10.1.3 Level of invasiveness

In the *Pfizer*⁷⁸ case the parallel importer had repackaged the product by giving it a new outer packing, but leaving the inner packing untouched. The outer packing was partly transparent, exposing *Pfizer*'s marks on the inside packing. The ECJ stated that under such circumstances "the proprietor of a trade-mark right may not rely on that right in order to prevent an importer from marketing a pharmaceutical product manufactured in another member state"⁷⁹ since the repackaging was fairly uninvasive and had not affected the products

⁷⁴ Korah, *An Introductory Guide to EC Competition Law and Practice*, p. 270-271. Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 45-46. Craig & De Búrca, *EU Law*, p. 1095-1096.

Arfwedson, *Re-importation (Parallel Trade) in Pharmaceuticals*, p. 20-21.

⁷⁵ Case 3/78.

⁷⁶ Craig & De Búrca, *EU Law*, p. 1097. Korah, *An Introductory Guide to EC Competition Law and Practice*, p. 271.

⁷⁷ Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke – en studie av parallellimport av läkemedel inom EU*, p. 53-54.

⁷⁸ Case 1/81.

⁷⁹ *Ibid.*, para. 13.

original condition, and the parallel importer had further on clearly indicated on the final packing that the product had been repackaged by him and was manufactured by the proprietor (or his subsidiary in this case).⁸⁰

2.10.1.4 Effect of dividing the market

Bristol-Myers-Squibb⁸¹ is a joint case that is somewhat more recent than the before mentioned ones. In this case the ECJ once again stated that the effect of dividing the market is what is important, instead of the intention as was argued in the American Home Products case. In this case producers had once again sold their identical products in different sized packages in different member states, while the parallel importer had repackaged the pharmaceuticals in new external packaging in its own uniform style, stating that the product had been repackaged by the parallel importer and also displaying the trademark of the respective manufacturer. In some of the cases the repackaging also involved a change in size of the package, and in some cases new labels had been attached to the content.

In the case, one of the questions touched upon whether the existence of article 7 of the trademark directive had changed the situation regarding exhaustion of rights and repackaging.⁸² The ECJ stated that, other than in the circumstances defined in article 7.2, article 7.1 does allow for exhaustion of rights, making parallel import legitimate “even if that importer repackaged the product and reattached the trade mark to it without the owner’s authorization”⁸³. Further on, the Court once again declared that to rely on trademark rights to hinder marketing of parallel imported and repackaged products could, especially when the proprietor has placed an identical pharmaceutical product on the market in several member states in various forms of packaging, contribute to the partitioning of markets. Therefore, the proprietor cannot oppose repackaging in cases where it is demanded due to size-requirements etc in the importing country. However, the repackaging must be necessary in order to market the product in the importing country or the proprietor may oppose it. As stated in earlier cases, the trademark holder may also oppose repackaging if it involves a risk of the products original condition being affected. Every hypothetical risk of this happening is not enough to give the proprietor the right to oppose the repackaging though. If the repackaging is not done

⁸⁰ Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 46.

⁸¹ Cases C-427/93, C-429/93, and C-436/93.

⁸² Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 47.

⁸³ Cases C-427/93, C-429/93 and C-436/93 paragraph 37.

in a satisfying way, risking that the reputation of the trademark and the trademark owner may be damaged, the proprietor also has a possibility of opposing the repackaging.⁸⁴ As previously established, the repackager as well as the producer must be mentioned on the final packaging, and the importer must notify the proprietor of the repackaging before marketing the products and also provide him with a sample of the repackaged product upon request.⁸⁵

In *Beiersdorf*⁸⁶ the ECJ once more stated that parallel import is allowed also when it comes to repackaged and relabelled products, under the circumstances previously mentioned in the *Bristol-Myers-Squibb* case and the earlier case law.

2.10.1.5 The necessity of relabelling

In the *Pharmacia & Upjohn*⁸⁷ case the ECJ further discussed what it means that the relabelling must be necessary in order to be allowed.

Pharmacia & Upjohn marketed the same pharmaceutical under different trademarks in different member states. The parallel importer bought the product in one member state where the product was marked with one name, and relabelled it with the name that the product was sold under in the importing country.

The importer argued that “there is no objective difference between reaffixing a trade mark after repackaging and replacing the original trade mark by another”⁸⁸ and that the different trademarks used were in fact the same one, and also claimed that the trademark holder’s marketing system constituted an obstacle to intra-community trade giving rise to artificial partitioning of the markets between member states whether or not the proprietor intended such partitioning. The trademark holder argued that there were legitimate reasons for using various trademarks in different countries within the EU, he also stressed that there was no legal obstacle for the parallel importer to market the product without relabelling it, and claimed that the only reason for the parallel importer to relabel the product was to secure a commercial advantage.⁸⁹

⁸⁴ Cases C-427/93, C-429/93 and C-436/93.

⁸⁵ Korah, *An Introductory Guide to EC Competition Law and Practice*, p. 271. *Koktvedgaard & Levin, Lärobok i immaterialrätt*, p. 395-398. *Westman, Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 47-50.

⁸⁶ Cases C-71/94, C-72/94 and C-73/94

⁸⁷ Cases C-379/97

⁸⁸ *Op. cit.* para. 37

⁸⁹ Cases C-379/97.

The Court established that the same rules regarding artificial partitioning of the market will apply in cases “where a parallel importer replaces the original trade mark by that used by the proprietor in the Member State of import”⁹⁰ as in other cases of repackaging and relabelling. As in those other cases, the replacement of the trademark must be objectively necessary. It is up to the national courts to determine whether or not this is the case. However, the condition is fulfilled if replacing the trademark is necessary in order to effectively access the market in the importing state; this could be the case if rules in that state prevent the product from being marketed there under the trademark it has in the exporting country. To notice is, though, that the demand for necessity is not satisfied if the mere reason for replacing the trademark is the parallel importer’s attempt to secure a commercial advantage.⁹¹

In the national court, the parallel importer lost the case due to the fact that it had not been able to demonstrate the necessity of replacing the trademark.⁹²

2.10.1.6 Objective necessity

In the *Merck*⁹³ and *Boehringer Ingelheim*⁹⁴ cases ECJ continues to discuss what the objective necessity means. As mentioned before, it is most likely objectively necessary to repackage or relabel the product if there are rules preventing it from being sold on the importing market in the shape it is in when acquired in the exporting state.⁹⁵ It is objectively necessary to repackage the product if that is needed in order to gain effective access to the market. The fact that there may be a certain resistance towards relabelled pharmaceutical products does not in itself mean that repackaging is seen as necessary. If the resistance is strong enough though, it might be held to hinder effective market access and it could in such a case be justifiable to repackage the product.⁹⁶

⁹⁰ Op. cit., para. 40.

⁹¹ Cases C-379/97.

⁹² Westman, *Ompaketering ommärkning och utnyttjande av annans varumärke*, p. 55-58.

⁹³ Cases C-443/99.

⁹⁴ Cases C-143/00.

⁹⁵ Cases C-443/99.

⁹⁶ Cases C-443/99.

2.10.2 Dangers associated with repackaging/relabelling pharmaceuticals

The moment of repackaging is argued to be a weak link in the pharmaceutical distribution chain.⁹⁷ Although the process of repackaging is as regulated and monitored as the original process of manufacturing the pharmaceuticals⁹⁸, the repackaging process might take place in several stages and thus lacks overall control by one actor.⁹⁹ The fact that the repackaging could take place in several stages also makes the possibility of monitoring the process more difficult for EMEA and other authorities. The repackaging and relabelling process might also involve destroying anti-counterfeiting measures as well as the removal of safety devices attached to the original packaging. Naturally, it might not be possible to transfer such devices to the new packaging, or at least it usually is not done since the current system does not require it. This opens up opportunities for less scrupulous actors wishing to take advantage of the vulnerabilities in the handling of pharmaceuticals; they could introduce counterfeit¹⁰⁰ or outdated pharmaceuticals into the distribution chain.¹⁰¹ The more complex distributions chain the bigger the risk for counterfeit medicines to enter the distribution chain.¹⁰² Flodeer says that Pfizer has found that the less intermediaries there is on a market, the bigger the chance is to keep the pharmaceutical intact when reaching the end-consumer, which is the reason that the company has started supplying the pharmacies directly in the United Kingdom.¹⁰³

Allowing repackaging and relabelling could also result in more unintentional errors due to the fact that the parallel importers (and/or repackagers) might lack familiarity with the product compared to the producer that have developed the pharmaceutical. For instance, patient information leaflets could be translated incorrectly or be out of date, the doses of the medicine inside the packs might differ from those stated on the outside, the expiry date and batch numbers on the packaging perhaps not match the ones on the medicine inside, the information regarding origin of the product might be faulty, etc.¹⁰⁴ But the repackaging might also constitute an extra quality control, according to Heintz, FPL/Paranova.

⁹⁷ Harper et al., *Coincidence or crisis?*, p. 17. Interviews with Inger Näsman, LIF och Erika Haglund, Swedish Medicines Products Agency.

⁹⁸ For a further review of the pharmaceutical legislation, see section 4.3.

⁹⁹ It is also argued that there is an “absence of adequate controls on repackaging and relabelling” that “can inadvertently facilitate entry of counterfeit medicines from one member state into another”, Harper, *Coincidence or crisis?*, p. 17.

¹⁰⁰ For more information regarding counterfeiting, see section 3.

¹⁰¹ FDA Counterfeit Drug Task Force Interim Report, 2003, p. 13. Satchwell, *A sick business*, p. 2. Harper et al., *Coincidence or crisis?*, p. 68.

¹⁰² Interviews with Göran Heintz, Paranova/FPL, Inger Näsman, LIF and Hans Flodeer, Pfizer.

¹⁰³ Interviews with Hans Flodeer, Pfizer.

¹⁰⁴ EFPIA Position Paper, *Pharmaceutical supply chain evolution*, p. 2. Satchwell, *A sick business*, p. 12-13. LIF, *Förfälskade läkemedel*, p. 9.

Further on, another problem with repackaging and relabelling is the fact that end users might be confused by the fact that they could be getting the same pharmaceutical in different types of packaging, with different patient information leaflets etc from time to time. Of course, this confusion might to a certain degree also occur in the case of generic substitution of pharmaceuticals, so it is not necessarily a unique problem for parallel distributed pharmaceuticals. However, since parallel distributed pharmaceuticals are said to be extra vulnerable to the occurrence of counterfeits, the above mentioned circumstances could make it more difficult to discover counterfeit pharmaceuticals; if the consumers are uncertain what the pharmaceutical and its packaging is “supposed” to look like it is hard to notice any divergences.¹⁰⁵

3. Counterfeiting of pharmaceuticals

3.1 Counterfeit medicines

The definition of counterfeit medicines varies among the member states of the EU, but the WHO definition for counterfeit medicines is widely accepted and used by the pharmaceutical industry and other stakeholders (hereinafter we will be referring to the WHO definition unless otherwise is stated). WHO defines counterfeit medicines as “a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”¹⁰⁶ The definition of counterfeit goods in the EU custom regulation includes goods, including packaging, any trademark symbol and packaging material having an identical or similar trademark to an already registered trademark in the same category of goods.¹⁰⁷

¹⁰⁵ LIF, Förfalskade läkemedel, p. 9.

¹⁰⁶ WHO Counterfeit medicines, Fact sheet N°275, <http://www.who.int/mediacentre/factsheets/fs275/en/>. Visited October 1, 2006.

¹⁰⁷ Regulation 1383/2003.

3.2 The extent of counterfeiting

There is currently no effective method for determining the level of counterfeiting of medicines, or for counterfeiting in general for that matter. Different professional organisations at national, European and international level give estimations of the scale of counterfeiting on a regular basis, but they can only give a general idea of the problem. Considerations should also be given to the agenda of the specific organisation and their interest in publishing estimations. Police and custom actions and seizures can, as well, only give a limited picture due to the amount of goods that is passing through the single market. There are only resources to control a fraction of the goods passing through customs.¹⁰⁸

Today, WHO discourages from using a single average figure for estimating the global level of counterfeit medicines, as it will not give an correct picture and can therefore be misleading to the public as well as imprecise and inaccurate. Instead WHO recommends giving the concerned countries a development status and a range to describe the relevance of counterfeiting. A reasonable estimate of the occurrence of counterfeit medicines varies from less than 1 percent of sales in developed countries, to over 10 % in developing countries, with variances between geographical areas. The estimation considers both regional differences and specific and global market value shares. EU-15, USA, Australia, Canada, New Zealand, and Japan are among the developed countries with an effective control and regulatory system that have a very low level of medicines counterfeiting, i.e. less than 1% of market value. Nevertheless, there are signs that indicate an increase of counterfeit medicines in the developed countries, thus it is not only for developing countries. A number of the developing countries of Africa, parts of Latin America, and parts of Asia have areas where counterfeit medicines constitutes of more than 30 % of the medicines on sale. However, there are markets with less then 10 %, so a realistic estimate is between 10 and 30%. Many of the former Soviet republics fall into the range of developing countries due to fact that 20% of the market value of medicines is counterfeit. Over 50 % of the medicines purchased over the Internet, on those sites that camouflage their genuine physical address, are counterfeit.¹⁰⁹ According to a WHO survey of counterfeit medicines reports covering 20 countries in the period from January 1999 to October 2000, 60 % of the counterfeit cases were in developing countries, while 40 % in

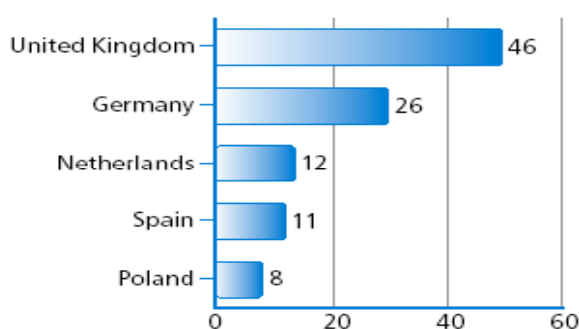
¹⁰⁸ COM(98)569final, p. 10.

¹⁰⁹ <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf> Visited December 12th, 2006.

industrialized countries.¹¹⁰

At the WHO International conference on combating counterfeit medicines in February 2006, Dr. Nils Behrndt, Deputy Head of Pharmaceuticals Unit, DG Enterprise and Industry stated that between 2001 and 2005, there have been 27 cases of counterfeits in the legitimate supply chain in EU. During the same period, 170 cases of counterfeit medicines in the illegitimate supply chain came to their knowledge.¹¹¹ EU has experienced a significant increase of reported incidents according to the Pharmaceutical Security Institutes' Counterfeit Incident System. Eighteen European countries were represented among the reported incidents. In 2004 there were 43 incidents, while the number had increased to 130 incidents in 2005 (see Table 1 below).¹¹² Highest number of reported incidents of counterfeit medicines is found in United Kingdom. The reason is said to be the large number of actors on the market, and lack of control of them.¹¹³ The seizures of counterfeit goods in general are increasing, especially after the new customs regulations have been introduced. Until 2005 the number of cases and pharmaceuticals seized by the custom authorities were placed in the category "others". Year 2005 was the first year when the statistics were published. There were 148 registered cases in EU and 560,598 articles seized that year. Pharmaceuticals constituted 1% of the goods seized. The majority of the cases of counterfeit medicines originated from India (75%), Egypt (7%), China (6%) and Thailand (4%).¹¹⁴

Table 1. Incidents in countries in Europe.



Source: Pfizer, <http://www.safemedicines.org/resources/documents/Pfizercftwo-pager.pdf>.

¹¹⁰ WHO Counterfeit medicines, Fact sheet N°275, <http://www.who.int/mediacentre/factsheets/fs275/en/>. Visited October 1st, 2006.

¹¹¹ Behrndt, WHO conference speech, Combating counterfeit medicines – Views from a regional organisation (EU).

¹¹² <http://www.safemedicines.org/resources/documents/Pfizercftwo-pager.pdf>. Visited November 16th 2006.

¹¹³ Satchwell, A sick business, p. 20-21.

¹¹⁴ http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2005_en.pdf. Visited November 16th, 2006

3.3 Distribution of counterfeit drugs

The distribution of counterfeit drugs is done via two main channels; the illegal and the legal one. The illegal way, consumers buy medicines of unknown quality through Internet, on the street or in different kinds of health and fitness clubs (hereinafter referred to as the illegal distribution chain). Dangerous drugs can also enter the ordinary distribution chain (hereinafter referred to as the legal distribution chain), ending up in pharmacies or hospitals.¹¹⁵

According to Flodeer, Pfizer, there is a significant black market for pharmaceuticals outside the legal distributions chains. Products such as Viagra® is sold in large quantities on Internet and on the streets, where there are no possibilities to control the quality. It is difficult to enforce the IPRs due to problems to determine the jurisdiction that the Internet page falls under. The differences in IPR protection varies among the countries and Internet legislation is not up to date.¹¹⁶ The strict regulation of the pharmaceutical industry should protect the consumers that buy their pharmaceuticals from the legal pharmacies, but that has not always been the case. The different actors in the pharmaceutical sector all agree that the problem lies in the complicated distribution chain that exists in Europe today. With the increasing number of actors involved in the distribution chain, there is also an increased risk for counterfeit medicines to slip into the legal distribution chain.¹¹⁷ A report from LIF (the Swedish trade association for the pharmaceutical industry) points out, that there is big risk that there are cases of counterfeit drugs that we are not aware of, as the problem is new in developed countries and there are currently few control systems in place.¹¹⁸

3.4 Types of products affected

In the Counterfeit medicines survey report conducted by the Council of Europe, the responses indicated that all types of medicines risk to be counterfeited, even though the risk is dependent on the characteristics of the products and market. High volume, high price, known brands especially blockbusters, lifestyle drugs and drugs in short supply are among the products reported likely to be counterfeited. In the developed world, especially targeted pharmaceuticals are so-called lifestyle and embarrassment drugs to treat weight gain, erectile

¹¹⁵ Counterfeit medicines Survey report, p. 41, LIF, Förfalskade läkemedel, p. 6.

¹¹⁶ Interview with Hans Flodeer, Pfizer.

¹¹⁷ Interviews with Göran Heintz, Paranova/FPL, Inger Näsman, LIF, Raul Wannerholt, AstraZeneca, Hans Flooder, Pfizer, and Kerstin Hjalmarsson, Swedish Medicines Products Agency.

¹¹⁸ LIF, Förfalskade läkemedel, p. 6.

dysfunction and high cholesterol. In EU, a case was discovered where the fake cardio-vascular medicine was made of a mixture of brick dust combined with yellow paint used to paint roads, to give it the same colour as the original medicine, and thereafter coated with furniture polish to give the right glossy appearance.¹¹⁹ In the developing world, antibiotics, anti-malarial, HIV drugs and vaccines are among the high-risk drugs. In the illegal Internet pharmacies, the only drugs offered for sale were ones for erectile dysfunction, anabolic steroids and slimming drugs.¹²⁰ Statistic from EU custom seizures, year 2005, shows that a wider range of products is now being counterfeited, including cancer cure medicines, antibiotics, anti-cholesterol tablets and common items such as paracetamol. Viagra® is still the favourite drug of counterfeiters, but condoms are also extensively counterfeited.¹²¹ In UK, the police exposed an illegal medicines laboratory with a daily producing capacity of more than half a million fake pills of diazepam, steroids and Viagra®. There have been cases of counterfeit medicines found in nearly all EU member states; at the wholesalers, over the Internet or at the retail pharmacies.¹²² In September 2004 four people were arrested in Spain and more than 4000 units of pharmaceuticals and €60,000 were seized, after a German citizen suffered from an overdose of pharmaceuticals bought on Internet via the illegal distribution chain. The criminal organization supplied the drugs to two distributors, which were shipping approximately 150 orders per week.¹²³

Manufacturing of counterfeit pharmaceuticals is largely found in Greece, Netherlands, Spain, Italy and Germany.¹²⁴ However, these days it can be suspected that the main production of counterfeit drugs might take place in the former Soviet states that have recently become EU members.¹²⁵ In connection to this, it can be mentioned that there is a so-called “specific mechanism” written into the Act of Accessions of some of the newer member states (the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia). This specific mechanism was agreed upon because of the sometimes lower levels of intellectual property protection found in the new member states, and it consists of a transitional period regarding the free movement of pharmaceuticals. During the transitional period, or the

¹¹⁹ MEMO/06/421.

¹²⁰ Counterfeit medicines, Survey report, p. 29.

¹²¹ MEMO/06/421.

¹²² EFPIA Position paper, Combating counterfeit medicines and protecting patients through a partnership approach, p. 6.

¹²³ Op. cit., p. 6.

¹²⁴ Report on responses to European Commission Green Paper on counterfeiting and piracy, p. 10, http://ec.europa.eu/internal_market/indprop/docs/piracy/piracy_en.pdf, visited December 12th 2006.

¹²⁵ Harper, Coincidence or crisis?, p. 27.

exception from the principle of exhaustion of rights as it really is, a patent holder will under certain circumstances be able to use those rights to prevent parallel imports from the new member states. If the rights were filed in a member state at a time when such protection could not be obtained in the acceding countries, the rights holder may rely on his rights to prevent the import and marketing of the product covered by the protection in the member state(s) where the products enjoys protection even if the product was put on the market in the acceding/exporting country for the first time by the rights holder or with his consent.¹²⁶ This was agreed upon in order to prevent possibly possible faulty copies originating from the new member states to freely enter the single market and thus the distribution chains in all other member states.

3.5 Types of counterfeit practices

Counterfeiting practices can be divided into two categories: finished products and active pharmaceutical ingredients (API). The pharmacological activity of the medicine is from the API. The different types of practices illustrate the variance of acts that are categorized as counterfeiting of medicines in Europe.¹²⁷

3.5.1 Finished medicinal products

- Identical copy with identical packaging and formulation.
- Pure counterfeits are products with altered ingredients and a similar packaging. They might lack API:s or contain the wrong dose of API.
- Re-use of components can constitute of refill of genuine vials, ampoules etc. with a substitute or no API.
- False/illegal labelling/packaging. Products are falsely labelled to appear as being from the original manufacturer. The counterfeiting activity may constitute of printing facilities that for example are involved in illegal labelling or packaging.
- Illegal relabelling and repackaging of medicines destined for one member state market.

¹²⁶ EMEA Post-Authorisation Guidance on Parallel Distribution, p. 34.

¹²⁷ Counterfeit medicines, Survey report, p. 33-35. Oldenhof, APIs: Why EU authority is vital,

<http://www.ptemag.com/pharmtecheurope/article/articleDetail.jsp?id=310781&pageID=4> , visited November 16th 2006.

- Illegal diversion and illicit trade of products through Internet or other channels. The largest factor is Internet sales requiring no prescription.
- Unpackaged medicinal products, for example medical products lacking primary packaging due to wholesale/retail.
- Placing a non-licensed medicinal product on the market.
- False documentation such as granting a certificate of suitability without auditing the company.
- Waste/expired product re-entering the market after repackaging the product with counterfeit labels.
- Combined counterfeiting, for example relabelling with wrong dosage, authentic product in counterfeit packaging to conceal expired date or counterfeit products in counterfeit packaging imitating the packaging of parallel imports.¹²⁸

3.5.2 API

Quality defects in API can result in the presence of dangerous quantities of toxic impurities. This can result in side effects that may span from minor inadequate physical effects that can slow down the action of the pharmaceutical, to lethal overdoses. If the API is not stable enough it can result in degradation of the API, resulting in that the patient receives a too low dose. The API production has been unregulated on EU level for a long time. The new EU regulation¹²⁹ from October 2005 demands that the production of API used in Europe is in compliance with the Good Manufacturing Practices (GMP) rules. During the last years there has been evidence that a large percentage of the older medicines in the EU market may contain noncompliant APIs from unknown and/or obscure sources. The directive giving legal ground for worldwide inspection of API producers is criticized, as inspections will not be carried out on a routine basis. A random factor and a high probability of inspection are necessary to ensure compliance from the API manufacturers. China and India are the main manufacturers and exporters of fake medicines in the world, mainly to Africa but also either directly or indirectly to Western markets. More than 70 % of the API in the medicines in EU originates from India and China. The increasing competition of commodity API results in that there is a need of regular inspection and enforcement of the GMP compliance.¹³⁰

¹²⁸ Counterfeit medicines, Survey report, p. 33-34.

¹²⁹ Regulation (EC) No 726/2004, Directive 2004/24/EC, Directive 2004/27/EC and Directive 2004/28/EC.

¹³⁰ Oldenhof, APIs: Why EU authority is vital,

The most common counterfeit practices are:

- Use of cheap API from non-GMP or uncontrolled origin.
- “Ghost plants”: the API is sold, but not manufactured by the “registered” producer and is as a result not produced according to the registered process. This is done both with and without the authorisation of the marketing authorisation holder.
- “Ghost suppliers” The marketing authorisation holder buys the API willingly and consciously from a manufacturer that is not covered by the marketing authorisation.
- “Paper curtain”, i.e. the API is not manufactured according to the registered process. The company maintains a double document system: one with the hidden process and another set with fake data complying with GMP for the inspectors to review.
- “Authorised facades” an authorised manufacturer/trader supplies API from a large number of unauthorised manufacturers. The labelling of the products shows only the name of the authorised manufacturer.
- Blended API containing authorised API as well as unauthorised.¹³¹

3.6 Factors facilitating counterfeiting

Often there are several areas that need improvement in the country or region to be able to effectively combat the presence of counterfeit medicines. WHO have identified the most common factors facilitating counterfeiting. One of those factors is lack of appropriate legislation. Countries need to have appropriate legislation covering control of the manufacturing and distribution process of drugs, otherwise counterfeiting might escape prosecution. To ensure proper application of the legislation there is a need of a competent Drug Regulatory Authority (DRA) with resources and a strong drug regulation to assess imported drugs and inspect local manufacturing facilities properly. It also discourages the development of illicit markets, and promotion and marketing of counterfeit drugs. An absent or a weak national DRA can contribute essentially to the presence of counterfeit medicines on the market. Corruption and conflicting interests may also affect the handling of counterfeiting cases at the DRA, leading to a failure to arrest, prosecute and convict the counterfeiters. The absence of legal mandate for the licensing/authorization of manufactured or imported drugs,

<http://www.ptemag.com/pharmtecheurope/article/articleDetail.jsp?id=310781&pageID=4> , visited November 16th 2006.

¹³¹ Counterfeit medicines Survey report, p. 34-35.

for inspections, and licensing systems to regulate production or importation of bulk API and finished dosage forms are contributing factors. Another factor facilitating counterfeiting is the lack of licensing systems to regulate the sale and distribution of drugs. Other such activities are distribution of products through unauthorized or unlicensed intermediaries or sales through unlicensed or unauthorized outlets. Lack of regulation by exporting countries and within free trade zones is contributing to export of the problem. Pharmaceuticals destined for export are not regulated to the same extent as those produced for the domestic market. Also, export through free trade zones, where repackaging and relabelling is allowed, can assist trade in counterfeit drugs.¹³²

It is not enough to have a good legislation or strong DRA if the existing legislation is not enforced. Lack of enforcement often results in that counterfeiters have little fear of arrest and prosecution, which aggravates the problem. Trademark infringement is currently not a prioritized crime and in many countries an infringement results in no or weak penal sanctions.¹³³ Absence of, or moderate, penal sanctions may encourage counterfeiting as criminals have possibilities to obtain licenses to trade with pharmaceuticals, as background checks are not common. The suitability of the licensees should be considered and checked before awarding licenses.¹³⁴ Few countries have a specific legislation for counterfeiting of drugs. The use of the trademark law for enforcement is often not in proportion with the danger caused by counterfeit medicines. A comparison should instead be made with the legislation prohibiting the sale of illegal drugs. Inefficient cooperation between stakeholders contributes to the problem.¹³⁵ According to Näsman, LIF, lobbying efforts are made by the pharmaceutical interest groups towards governments to achieve higher penal sanctions for counterfeiting of medicines. If the cooperation between national DRAs, custom services, police and the judiciary to combat counterfeiting is ineffective; counterfeiters will be able to avoid penal sanctions. There is a need for more cooperation between the different parties. The unwillingness of the actors in the pharmaceutical industry and the distributions chain to report counterfeiting to national authorities contributes to the problem.¹³⁶ The awareness of counterfeit medicines being on the market has resulted in a more cooperative climate among the different actors in the pharmaceutical sector, according to Hjalmarsson, Swedish Medical Products Agency. Today, the Swedish Medical Products Agency is cooperating with the

¹³² WHO/EDM/QSM/99.1 p.18-19.

¹³³ Ibid.

¹³⁴ Harper et al. Coincidence or crisis?, p. 97-98.

¹³⁵ Interview with Inger Näsman, LIF.

¹³⁶ WHO/EDM/QSM/99.1, p. 17-18.

pharmaceutical companies, the police, the customs, parallel traders and other actors in the industry.¹³⁷

When pharmaceuticals go through numerous intermediaries or paper transactions, the possibilities for counterfeit drugs to be introduced into the supply chain increases, especially in combination with bad control.¹³⁸ The European pharmaceutical supply chain is very complex to its nature, as pharmaceuticals may pass through 20-30 different intermediaries before reaching the patient.¹³⁹ Another contributing factor is when demand for pharmaceuticals exceeds the supply; counterfeiting of drugs is encouraged, as there are good opportunities to make large profits through the manufacturing and production of counterfeit products.¹⁴⁰ The demand of Tamiflu®¹⁴¹ is a recent example where the demand for the drug has exceeded the supply several times. Counterfeiters have taken the advantage of the situation and fake Tamiflu® drugs have been found on the market.¹⁴² High prices and large price differentials on the market creates a large incentive to supply less expensive counterfeit drugs. The technological advancement has led to a more sophisticated equipment for the manufacture and packaging of drugs which allows counterfeits to imitate the drugs almost flawlessly.¹⁴³ The detection of counterfeit drugs has been made more difficult and an analysis is often needed to determine if it is a counterfeit. High awareness of the problem and high level of knowledge of pharmaceuticals facilitate the detection of counterfeits.¹⁴⁴

3.7 Technological anti-counterfeiting measures

The existing anti-counterfeiting technologies can be divided into two types: authentication technologies and track and trace technologies. Authentication technologies are constituted of overt, covert, and forensic technologies. Holograms, colour shifting inks and certain watermarks that are visible for the eye, constitute overt technologies. Covert technologies, on the other hand, often require special equipment to authenticate, as it is not visible to the eye. It can be watermarks, certain dyes and inks that need ultraviolet light, and invisible bar codes. The most advanced authentication technology: forensic technology usually demands a

¹³⁷ Interview with Kerstin Hjalmarsson, Swedish Medicines Products Agency.

¹³⁸ WHO/EDM/QSM/99.1, p. 17-18.

¹³⁹ EFPIA Position paper – Pharmaceutical supply chain evolution, p. 1.

¹⁴⁰ WHO/EDM/QSM/99.1, p.18-19.

¹⁴¹ Trademark registered by F. Hoffman-La Roche AG.

¹⁴² Harper et al., *Coincidence or crisis?* p. 85.

¹⁴³ WHO/EDM/QSM/99.1, p. 18.

¹⁴⁴ Interviews with Hans Flodeer, Pfizer and Kerstin Hjalmarsson, Swedish Medicines Products Agency.

forensic chemistry lab to identify the chemical marks, and other matchless chemical properties of a material.

The track and trace technologies include radio-frequency identification (RFID) and barcodes. The former is a technology that requires tags/chips placed on products containing product specific information onto cartons, pallets, and individual products. The system requires the tags, an antennae attached to the tags, readers to receive the information in the tags and a database that is used to validate and track the pharmaceutical as it moves through the distribution chain.¹⁴⁵ Trials to use the RFID technology have been made by, for instance, Pfizer and GlaxoSmithKline.¹⁴⁶ To have a real effect it is necessary that the RFID technology is incorporated in each individual package, so that the trail of the pharmaceutical can be followed. Barcodes are numeric values printed on labels that are used to identify pharmaceutical products, after these are read by a scanner. Bar codes can be used in combination with covert technologies, such as security ink. Track/trace and authentications technologies can be used as complementary to other anti-counterfeiting technologies. According to FDA no single track/trace and authentication technology can constitute the whole solution to the prevention of counterfeiting medicines entering the legal distribution chain. Multiple technologies and measures must be used, as counterfeiters are normally able to circumvent the anti-counterfeiting measures within 18-24 months.

According to Näsman, LIF, the European Federation of Pharmaceutical Industries and Associations (EFPIA), that represents the research-based pharmaceutical industry, has decided to use barcodes to track pharmaceuticals as it is the easiest technology to start using immediately. It is important to get started as soon as possible; the technology can be changed later if necessary.¹⁴⁷

Wannerholt, AstraZeneca, says that the use of RDIF technology is debated in the pharmaceutical industry due to the fact that it requires a database, where information about the pharmaceutical routes in the distribution chain will be stored. A number of questions have to be resolved before the implementation, such as: Who will create the database? Who will have access to the data? Who will own the data? And, should the database be national, regional or international?¹⁴⁸

Depending on the pharmaceutical company and the products, there are today variances in the use of authentication technologies. Authentication technologies are today more commonly

¹⁴⁵ FDA Interim report, http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html

¹⁴⁶ Interview with Hans Flodeer, Pfizer. IBM spårar falska piller, Dagens Industri, November 10th 2006, p. 30.

¹⁴⁷ Interview with Inger Näsman, LIF.

¹⁴⁸ Interview with Raul Wannerholt, AstraZeneca.

used than track/trace technologies. In high-risk products, there is more likely several combinations or layers of authentication technologies. While, low-risk products have less anti-counterfeiting technologies incorporated in the packaging, manufacturing, or labelling.

The implementation of anti-counterfeiting technologies is associated with some cost as well as benefits. Included in the cost of implementation is the purchase of the technology and associated equipment (e.g., RFID receivers, barcode scanners, access to electronic databases) and services, integration of the technology into the manufacturing process, review by DRAs, if required, adopting constantly new anti-counterfeiting measures, and creation of infrastructure all through the distribution system. Apart from the social benefits due to better public health and economic benefits due to reduction of the number of counterfeit drugs, there are also other benefits for the companies employing the technologies. Improved inventory management and control, reduction in theft and products losses, reduced labour cost due to automation, reduction in the amount of diverted products, improved ability to recall the product, protection of pharmaceuticals from being used in terrorism and protection from intentional tampering of drugs due to track and trade technologies, are also beneficial for the pharmaceutical companies.¹⁴⁹

3.8 Consumer protection and health

The health effects of counterfeit drugs are in many cases difficult to estimate due to the fact that national databases registering adverse effects of medicine are not developed to detect adverse effects due to counterfeit medicines. To be able to assess the impact of counterfeits on public health, the reporting systems would need to include a category of drug ineffectiveness.¹⁵⁰ Counterfeit medicines may contain ingredients that are dangerous to health or may even have lethal consequences. In Haiti, 89 persons died after ingesting cough syrup containing a chemical normally used in antifreeze. When counterfeit drugs are providing inadequate doses of medicine, patients risk dying or getting far sicker than if they would have received the appropriate dose. The treatment period may be prolonged and may result in longer hospitalizations.¹⁵¹ Another effect of counterfeit drugs is drug resistance due to inadequate doses of active ingredients, which results in that not all of the viruses, parasites and bacterias are killed. This is especially a problem in countries with a high level of

¹⁴⁹ FDA Interim report, http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html

¹⁵⁰ Counterfeit medicines, Survey report, p. 134.

¹⁵¹ CEIPI, Impacts de la contrefaçon et de la piraterie en Europe, p. 39-40.

counterfeit drugs. It is a contributing factor to the doubling of malaria deaths over the last twenty years. HIV/AIDS is also facing the same problem in developing countries.¹⁵²

A consumer survey made by the Anti-Counterfeiting Group (ACG), representing brand-owner interests, to find out the consumer attitudes towards counterfeits in different sectors, shows that 59% of the public was aware that certain fake goods can result in injury or death of the purchaser. On the same time, only 13 % of the consumers were aware of that there existed counterfeits in pharmaceuticals.¹⁵³ Counterfeit products are bought for two reasons according to consumer behaviour studies. One category of consumers would consciously buy counterfeit goods, due to the higher social status they believe the item will give them. This category is unwilling or unable to buy the genuine product. Certain buyers choose goods where the quality is not affected by the fact that it is counterfeit, such as designer labels and digital format goods. The other category of consumers would buy counterfeit goods as they can not distinguish the counterfeit from the original.¹⁵⁴ Pharmaceuticals do not belong to the categories of counterfeit goods that consumers would knowingly purchase counterfeit goods in. Only 1 % of the respondents were prepared to buy counterfeit pharmaceuticals if the quality and price of the goods is acceptable.¹⁵⁵

3.9 Economic consequences

When considering future estimations of the level of counterfeiting as well as calculations of lost revenues to both state and companies, it is important to remain a bit sceptic to the estimations. Estimated numbers have, after a while, a tendency to be presented as common knowledge. When looking at the numbers in the calculations considerations should be given to who has made the calculations and for what purpose. Organisations that are lobbying for stronger counterfeit legislation and more money to the responsible authorities have a different agenda than WHO for example.

A survey made for ACG among city analysts in London demonstrate that, according to 46% of the respondent, brand security issues has an impact in the valuation of a company. The number rises to 60 % among specialists on pharmaceutical companies. A high profile counterfeiting story could, according to one quarter of the respondents, result in a fall of the share price with as much as 10%. Pharmaceutical companies were estimated to lose 5,8 % of

¹⁵² Harper et al. Coincidence or crisis?, p. 84.

¹⁵³ ACG, Why you should care about counterfeiting, p. 4-7.

¹⁵⁴ <http://assembly.coe.int/documents/WorkingDocs/doc04/EDOC10069.htm>, Visited July 4th 2006.

¹⁵⁵ ACG, Why you should care about counterfeiting, p. 4-7.

their annual revenue due to counterfeiting. Counterfeiting can also result in a loss in market shares. When discussing losses in market shares and revenues, there is a need to keep in mind that all consumers would not buy the original products.¹⁵⁶ In case of pharmaceuticals, the market surveys indicates that consumers are unwilling to buy pharmaceuticals that are counterfeits, but there is a certain group in the market in case of steroids and embarrassment drugs that probably would not buy it in the legal distribution chain. Sales of counterfeit drugs are estimated to reach sales of USD 75 billion worldwide in 2010 according to the Centre for Medicines in the Public Interest. It would be an increase of 90 % since 2005.¹⁵⁷ The loss for pharmaceutical companies is estimated to €292 millions per year.¹⁵⁸ Increasing counterfeiting sales and therefore a decrease in sales will eventually also reflect the amount of money invested in R&D, as it is necessary for the companies to be able to recoup their investments.¹⁵⁹ There is risk of loss of goodwill for the companies due to failure of the products to perform as promised. Due to the severe consequences that can be the result of the usage of counterfeit pharmaceuticals, it can also result in severe consequences for the goodwill of the company. Counterfeit products expose the manufacturer for liability claims due to recent changes in product liability laws in a number of countries. The original manufacturer has to prove that he has taken necessary actions to protect his product from being counterfeited. There are also considerable cost associated with the investigations and litigations in combating counterfeiters.¹⁶⁰

The impact of counterfeiting on the brand of the company was important to the analysts. A brand scare regarding counterfeits where perceived by 25 % of the respondents as much more harmful to a company than the resignation of the CEO or annual returns that where not meeting the expectations of the market. Approximately 20 % of the analysts said that the brands were not sufficiently protected. The main problem according to 83 % of the respondents constituted of the grey/parallel markets in their goods. There was also a need of increasing monitoring of overseas suppliers, the web and protection of patents/trademarks according to more than half of the respondents. 33 % saw the rise in counterfeiting as a problem.¹⁶¹ Pharmaceutical companies and governmental agencies have been criticized for their reluctance to reveal cases of counterfeit medicines. The reason given is that it would

¹⁵⁶ ACG, Why you should care about counterfeiting, p. 14.

¹⁵⁷ WHO, Counterfeit medicines, Fact sheet N°275, <http://www.who.int/mediacentre/factsheets/fs275/en/>.
Visited October 1, 2006.

¹⁵⁸ CEIPI, Impacts de la contrefaçon et de la piraterie en Europe, p. 43.

¹⁵⁹ Op. cit., p. 17.

¹⁶⁰ ICC, Countering counterfeiting, p. 9.

¹⁶¹ ACG, Why you should care about counterfeiting, p. 16-17.

damage customer confidence in pharmaceuticals and in the worst case lead to people not taking their medicine. Today, there are no reliable databases for health workers or the public, where updated information regarding the occurrence of counterfeit medicines in their region or country can be found. Strong competition is said to be one of the reasons why companies do not want to publish the discovery of counterfeit medicine. Competitors could use information about counterfeit drugs as an unfair commercial advantage.¹⁶²

It is not only companies that lose money on counterfeiting; states also lose significant amounts of money due to losses of value added taxes and custom duties as products distributed in the illegal distribution chain escape the tax authorities. Also in cases when counterfeits manage to enter the legal distribution chain a big proportion of the tax revenues are lost. However, products in the legal distribution chain will be imposed value added taxes at some point, but taxes that are supposed to be paid up until that point are avoided. As a result of the production of counterfeits escaping the public control, the workers are often badly paid and are not included in the social security system due to the illegal production of counterfeits. The estimated annual loss to states in Europe from counterfeit pharmaceuticals is €1554 millions.¹⁶³ The lost sales of the companies have a negative impact on the employment in the country and the trade balance, as missed sales often result in lower export. The lost sales will also affect the level of investments in R & D in the country, as companies cannot expect a full return on its investments. Today, many countries are also spending large amounts of money in combating counterfeiting and funding different enforcement operations to get the problem under control.¹⁶⁴ States that are known to have a large counterfeit production often also have difficulties to attract foreign investments as companies risk losing money to counterfeit production. According to the Organization for Security and Co-operation in Europe (OSCE) these countries also risk a loss in export due to the fact that products from counterfeit producing countries have gotten a reputation of producing products of bad quality. The bad quality of counterfeit products is also reflected on the original products.¹⁶⁵

¹⁶² Cockburn et al., The global threat of counterfeit drugs, <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020100> visited December 12th 2006.

¹⁶³ CEIPI, Impacts de la contrefaçon et de la piraterie en Europe, p. 18.

¹⁶⁴ ICC, Countering counterfeiting, p. 11.

¹⁶⁵ CEIPI, Impacts de la contrefaçon et de la piraterie en Europe, p. 18.

3.10 Working together nationally, regionally and internationally

For a long time it seemed like nothing happened in the work against counterfeiting. Neither governments nor different authorities took the threat seriously. Today, the situation is different, as most of the organisations have recognised the problem of counterfeit medicines in Europe. The interviews showed that there is a need of coordination and cooperation among the activities to achieve a secure supply chain. By working on several different levels, nationally, regionally and internationally, a coordination of resources can be achieved. As states, interests groups and companies coordinate their resources in the fight against counterfeit medicines resources can be spent more tactically and problem areas can be targeted. Nationally, Swedish Medical Products Agency has set up a working group that coordinates the anti-counterfeiting work in the different responsibility areas of the authority, among them pharmaceuticals. The work is conducted in small projects in specific areas. The work is done in collaboration with the pharmaceutical companies, police, Swedish National Institute of Public Health, Swedish consumer agency, prosecutors, the National board of health and welfare, the Ministry of health and social affairs among others. On European level, the European Commission, the Heads of Agencies and the Council of Europe are collaborating with national DRAs to ensure a safer supply chain. Internationally, WHO has started the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to help national authorities to keep out counterfeit drugs from their markets. The work is focused on five areas: enforcement, legal, technology, regulatory and communication, therefore international coordination is necessary.¹⁶⁶

4. The pharmaceutical industry

4.1 The characteristics of the pharmaceutical sector

The pharmaceutical sector has many peculiarities compared to other ones the main distinctive character being the strict regulation it is under.¹⁶⁷ Having proper rules in place is obviously crucial because of pharmaceuticals' immense influence on human lives; access to pharmaceuticals and protection from faulty and possibly dangerous drugs must be assured. The main purpose with the legislation is of course to promote safety for the end-consumers of pharmaceuticals, the patients. The safety aspect is the basis of everything from rules regarding

¹⁶⁶ Interview with Kerstin Hjalmarsson, Swedish Medicines Products Agency.

¹⁶⁷ Hunter, *The pharmaceutical sector in the European Union*, p. 1.

the manufacturing to the sale of pharmaceuticals. The regulations affect every aspect of the pharmaceutical industry and the use of pharmaceuticals. Of course, other sectors have regulations to comply with as well. However, in the case of the pharmaceutical sector the regulations have extremely far-reaching effects.

4.1.1 High costs and uncertain return on investments

The strict legislation results in extra costs for the pharmaceutical industry.¹⁶⁸ Procuring the right licenses to at all be allowed to manufacture and sell drugs and ensuring that factories etc comply with the rules is just the beginning. The uncertain nature of pharmaceutical R&D means that a lot of time and money must be put into finding and developing a particular drug without any guarantee that the drug will be a success or at all make it to the market.¹⁶⁹ The pharmaceutical industry is one of the most R&D intensive ones (see Appendix 1). The time length for developing and taking a new drug to market is said to be everything from 8-15 years¹⁷⁰, with 10-12 years¹⁷¹ being the most common time span. The success rate for a specific compound is as low as 1 % for drugs in the initial R&D and preclinical development phases¹⁷² (see Appendix 2) and a total chance of success between 0,02 and 0,03%.¹⁷³ The average cost of bringing a new drug to the market is said to be around €200 million.¹⁷⁴ Naturally, the number gets even higher if the post-marketing costs are included.¹⁷⁵

Once an effective and, as it seems, safe drug has been developed and tested in the clinical trials, the final step before introducing the drug to the market is getting approval from the regulatory authorities.¹⁷⁶ This can be a very lengthy process, not only costly in itself for the pharmaceutical companies, but also because the longer approval must be awaited, the more time of exclusivity on the market is lost.¹⁷⁷ The vast sums invested in R&D must somehow be covered, and most pharmaceutical companies plan to do this during the period of exclusivity granted to them by their patent rights. Once the patent protection has ceased to exist, copies of

¹⁶⁸ Arfwedson, Re-importation (Parallel Trade) in Pharmaceuticals, p. 6.

¹⁶⁹ Abrantes-Metz et al., Pharmaceutical Development Phases, p. 20. Hunter, The pharmaceutical sector in the European Union, p. 16.

¹⁷⁰ EFPIA, Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?, p. 13.

¹⁷¹ Hunter, The pharmaceutical sector in the European Union 2001, p. 7.

¹⁷² IFPMA, The Pharmaceutical Innovation Platform, 2004, p. 23.

¹⁷³ Hunter, The pharmaceutical sector in the European Union, p. 16.

¹⁷⁴ Op. cit., p. 7.

¹⁷⁵ IFPMA, The Pharmaceutical Innovation Platform, 2004, p. 22-23.

¹⁷⁶ Op. cit. p. 23.

¹⁷⁷ EFPIA, Article 82 EC: Can It Be Applied to Control Sales By Pharmaceutical Manufacturers to Wholesalers?, p. 12-13.

the drug will be introduced to the market; so-called generic drugs. Once the generics are introduced, losses in market shares for the original producer will naturally occur, and the price of the drug will be lowered. This is why having effective use of the patent rights (meaning having the drug on the market while enjoying exclusivity) for as long as possible is crucial for the pharmaceutical companies. Because the process of developing and getting a specific pharmaceutical approved could take a very long time, it is possible to apply for an extended period of patent protection for pharmaceuticals.¹⁷⁸ The short time of effective use of patent protection is also one of the reasons why it is so important for pharmaceutical companies to create a strong brand for the drug in question. Having a strong brand means that it is easier to keep market shares once there is no patent protection. The aim to create a well-known and respected brand is one of the reasons why many pharmaceutical companies do put a lot of money into advertising. The low success rate in the expensive pharmaceutical R&D, coupled with the long time to market and the following short effective use of patent rights means that not many drugs will actually cover their R&D costs, which is why it is important for pharmaceutical companies to repeatedly create so-called blockbuster drugs that bring in a lot of money.¹⁷⁹

4.1.2 The importance of a strong pharmaceutical industry

The Commission has emphasized the need to realize the single market for pharmaceuticals to as big an extent as is possible, as well as the importance of other ways to promote competition and keep the European pharmaceutical industry strong and productive.¹⁸⁰ A competitive market is one of EU's key objectives, and having a single market for pharmaceuticals, just like other products, will economically benefit both the consumers and the social security systems in the member states. It is crucial not only for the pharmaceutical sector as such to be healthy, but also for the domestic industry to be competitive. The significance of a strong European pharmaceutical industry lies in the fact that EU as a whole will benefit economically from it, due to things such as tax revenues, job opportunities and

¹⁷⁸ Regulation 1768/92.

¹⁷⁹ EFPIA, Article 82 EC: Can It Be Applied to Control Sales By Pharmaceutical Manufacturers to Wholesalers?, p. 13. Hunter, The pharmaceutical sector in the European Union, p. 7.

¹⁸⁰ COM(1998)588final, p. 4.

export possibilities.¹⁸¹ The industry is also essential for promoting health aims set by the Commission, ensuring the production of drugs.¹⁸²

Lately, the European industry has not seemed to be able to keep up with the competition coming mainly from the USA and Japan. The level of innovation is not as high in Europe, and the market has not grown as fast.¹⁸³ Hunter states that “the European market has increased in size by 125% in a decade compared to America’s 172% and Japan’s 177%. Furthermore, this has occurred despite the fact that over the period 1986-1995, R&D spending in the present EU-15 matched that of the USA, seeing an increase of 226% and 227% respectively, whereas Japanese investment increased by 252%”¹⁸⁴. Hunter further stresses the importance of an economically viable industry, dependant on a well functioning single market and the ability to generate revenues from existing products in order to ensure the development of new products, and goes as far as suggesting that “the competition rules must only apply in so far as they lead to economically positive results”¹⁸⁵.

4.2 The issue of parallel trade in pharmaceuticals

There is an ongoing discussion concerning whether parallel trade in pharmaceuticals is justified and beneficial generally speaking. This discussion is mainly based on the special aspects of the pharmaceutical sector; governmental price controls, high R&D costs etc. To no surprise, the pharmaceutical companies and the parallel traders usually disagree on whether parallel trade is favourable as a whole or not. One might say that the current regime is in favour of the parallel traders’ arguments, as parallel trade is allowed. Whether or not the present situation is the ultimate one continues to be discussed.

The pharmaceutical companies mainly refer to the situation as described above, stressing the problems with it: they are the weaker party when negotiating prices etc with the states, and they have high costs due to the pharmaceutical legislation with approval procedures and so on. They also have high costs due to the uncertain and intricate nature of pharmaceutical R&D, and unless the state or some other unidentified party wishes to finance pharmaceutical R&D to a much greater extent than is currently done, the pharmaceutical companies themselves must be able to generate enough revenues to cover their past as well as future

¹⁸¹ For instance, Hunter states that the pharmaceutical industry in the EU employs about 500 000 people, one in every 300 EU jobs (The pharmaceutical sector in the European Union, p. 2 and 6).

¹⁸² Hunter, The pharmaceutical sector in the European Union, p. 6.

¹⁸³ Op. cit., p. 6.

¹⁸⁴ Op. cit., p. 6.

¹⁸⁵ Op. cit., p. 7.

R&D costs. This is, however, claimed to be difficult for them at the present state, for instance with regard to poor effective use of patent rights and the need to put notable sums of money into advertising. The parallel importers, on the other hand, claim that the pharmaceutical companies' alleged weak position in agreeing on prices with states in connection to reimbursement schemes and other kinds of price control systems is exaggerated; there is always room for negotiation¹⁸⁶ and the pharmaceutical producers have high profits despite of the current regime. Also, the pharmaceutical companies do not solely bear the cost of R&D. They enjoy public financial support, and also benefit largely from research performed and funded by public researchers.¹⁸⁷ Furthermore, the pharmaceutical companies do have IPRs that protect their products for a certain time period, as deemed fair by the legislator.¹⁸⁸

To continue, the pharmaceutical producers state that they are in fact businesses with the aim of making money, and not charitable institutions as some might seem to think.¹⁸⁹ Therefore, the pharmaceutical companies claim that allowing parallel trade has too much of a negative effect on them. It is unfair that the parallel traders can take advantage of all costs paid by the pharmaceutical companies, and sort of jump in at the end without effort. Not only are the parallel traders taking advantage of the sums put into R&D, without contributing to further research, they are also taking advantage of the marketing efforts done by the pharmaceutical companies; in a lot of cases selling an already well-known product without having to advertise it.¹⁹⁰ The pharmaceutical companies often argue that the parallel traders cut in on their revenues at the expense of R&D; since the parallel traders do not put their money into R&D and the pharmaceutical companies' revenues decrease due to the parallel trade, the amount of money that will go into R&D is diminished.¹⁹¹ In response to this, the parallel importers claim that the argument regarding losses in R&D due to parallel trade is not viable.¹⁹² Moreover, the impression the pharmaceutical companies aim to give, that they put all their profits into new R&D, is incorrect. Supporting these statements are the facts that

¹⁸⁶ EAEPD, Understanding competition in the distribution of pharmaceutical products in Europe, p. vii.

¹⁸⁷ *Op. cit.*, p. vii and 28

¹⁸⁸ Hunter, The pharmaceutical sector in the European Union, p. 10. EAEPD, Understanding competition in the distribution of pharmaceutical products in Europe, p. vii.

¹⁸⁹ Hunter, The pharmaceutical sector in the European Union, p. 11.

¹⁹⁰ Kanavos et al., The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States, p. 37.

¹⁹¹ Hunter, The pharmaceutical sector in the European Union, p. 24. EAEPD, Understanding competition in the distribution of pharmaceutical products in Europe, p. 17. Arfwedson, Re-importation (Parallel Trade) in Pharmaceuticals, page i. AIM Position Paper, Parallel trade – Consumer benefit or consumer loss?, p. 8. Kanavos et al., The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States, p. 34-35.

¹⁹² EAEPD, Understanding competition in the distribution of pharmaceutical products in Europe, p. vii and 17-20.

more money is usually invested in marketing than in R&D, and that despite the occurrence of parallel trade R&D budgets have increased over time and the big pharmaceutical companies still show remarkable profits (see Appendix 3).¹⁹³

The pharmaceutical industry sees parallel trade as unfair competition¹⁹⁴, and embraces the concept of free pricing, or at least the ability to price discriminate (that is; set different prices in different countries according to purchasing power in each market segment).¹⁹⁵ Free pricing is, as mentioned above, not possible due to governmental price control, but without parallel trade price discrimination would be possible to a greater extent. It is argued that price discrimination ensures increased access to medicines even for poorer countries. Since a higher price can be charged in countries with an ability to pay that higher price, the pharmaceutical companies can afford to offer the medicines at lower prices in countries where it is necessary; ”price variations allow the burden of R&D costs to be spread across a larger consumer base. This contributes to minimizing the financial risk of R&D investment on one hand, and improves the diffusion of innovative pharmaceuticals among populations at different income levels”¹⁹⁶. It is argued that the so-called sunk costs should be shared in accordance with economic theories; charging higher prices in some markets where doing so is possible is the normal way to recover sunk costs.¹⁹⁷ Parallel trade is said to have the opposite effect compared to price discrimination; although it is often argued to be a tool for reducing prices, what parallel trade does is diverting products from low-price markets to higher priced ones, thus leading to product shortage hindering the poorer countries’ access to pharmaceuticals.¹⁹⁸ Also, the theory that parallel trade will lead to increased price competition and force prices to go down in the importing country, promoting overall price equalisation, is often rejected by the pharmaceutical producers.¹⁹⁹ Parallel trade is claimed to have a “lack of sizeable direct benefits to health insurance organisations”²⁰⁰ and it is argued that in the end it is not the state or the consumers who benefits from it, but solely the parallel trader.²⁰¹ The parallel importers, to the contrary, say that parallel trade is an important tool for market integration and that it

¹⁹³ Hunter, *The pharmaceutical sector in the European Union*, p. 10. EAEP, *Understanding competition in the distribution of pharmaceutical products in Europe*, p. 17 and 22.

¹⁹⁴ Hunter, *The pharmaceutical sector in the European Union*, p. 24 and 68.

¹⁹⁵ Arfwedson, *Re-importation (Parallel Trade) in Pharmaceuticals*, p. 10.

¹⁹⁶ IFPMA, *The Pharmaceutical Innovation Platform*, 2004, p. 38.

¹⁹⁷ AIM Position Paper, *Parallel trade – Consumer benefit or consumer loss?*, p. 8.

¹⁹⁸ The Pharmaceutical Innovation Platform, 2004, p. 41. Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States*, p. 16.

¹⁹⁹ Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States*, p. 15.

²⁰⁰ *Op. cit.*, p. 16.

²⁰¹ *Op. cit.*, p. 16.

lowers the prices by increasing the competition on the market, in the end saving money for the state and the consumers.²⁰²

Finally, as an argument against parallel trade, the pharmaceutical industry sometimes claims that it reduces safety and introduces a way into the distribution chain for counterfeit drugs etc.²⁰³ Parallel traders say that this is not the case since the parallel traders must comply with very strict regulations; as strict as the pharmaceutical companies themselves.²⁰⁴ It is even argued that the parallel traders act as an extra control function; since they, in order to comply with regulations, must check the pharmaceuticals they trade with, they would discover if faulty medicines have somehow entered the distribution chain.²⁰⁵

4.3 Pharmaceutical legislation

There is a huge amount of legislation concerning pharmaceuticals; it can be seen as quite complicated sometimes. There have been a number of attempts to harmonize pharmaceutical legislation within the EU. However, the legislation within the member states could be said to remain at a national level to a certain extent, mainly due to the fact that a lot of the EU legislation concerning pharmaceuticals has been made in the in the form of directives. Unlike regulations, that are directly applicable and binding upon all member states, directives are binding upon the member states only when it comes to the result to be achieved; they leave to the national authorities to decide the choice of form and method for achieving said result.²⁰⁶ This sometimes involves problems since the member states might choose very different ways of implementing the directives, meaning that the final national legislation could differ quite a bit. This opens up for discussions concerning the quality of the final rules, so to speak, in certain member states. One important EU move was the creation of EMEA in 1995. EMEA is the European Union's centralized medicines agency. EMEA continuously supervises and evaluates medicines within the EU. It also centrally authorises medicinal products, as well as provides a decentralised procedure where the member states mutually recognise each other's national authorisations.²⁰⁷

²⁰² Arfwedson, Re-importation (Parallel Trade) in Pharmaceuticals, p. i. Hunter, The pharmaceutical sector in the European Union, p. 24. EAEPC, Understanding competition in the distribution of pharmaceutical products in Europe, p. 22.

²⁰³ Arfwedson, Re-importation (Parallel Trade) in Pharmaceuticals, p. i.

²⁰⁴ EAEPC, Understanding competition in the distribution of pharmaceutical products in Europe, p. 22-23.

²⁰⁵ Interview with Göran Heintz, Paranova/FPL.

²⁰⁶ Article 249 EC.

²⁰⁷ http://europa.eu/agencies/community_agencies/emea/index_en.htm Visited October 16th 2006, and Tenth annual report of the European Medicines Agency 2004, p. 5.

4.3.1 Manufacturing authorization

In order to be allowed to produce pharmaceuticals, a manufacturing authorization is required. A manufacturing authorization is also required for repackaging of pharmaceuticals, meaning that parallel distributors (or the repackagers in cases where the parallel distributors themselves do not actually perform the repackaging) have to comply with exactly the same rules as the original producers.²⁰⁸ This fact somewhat disparages the validity of the argument that repackaging is one of the bigger problems with parallel trade because it could open up for the possibility of counterfeits entering the distribution chain. Since repackaging of pharmaceuticals is as carefully regulated and monitored as the original production, there is less reason to suspect that there might be dubious or simply illegal activities going on in connection to the repackaging process. Further on, a parallel distributor may only change the packaging of a centrally authorised product if the change is strictly necessary to market the product in the importing country (with respect to language etc).²⁰⁹ It must also be ensured that the repackaged version of the product is in conformity with latest version of the marketing authorisation for the concerned centrally authorised product.²¹⁰

In order to obtain a manufacturing authorization, the applicant must specify what products are to be produced or imported and the place where they are to be manufactured and/or controlled, have at his disposal suitable and sufficient premises, technical equipment, storage and control facilities that comply with the requirements laid down by the concerned member state, and have at his disposal at least one qualified person.²¹¹ The qualified person shall fulfil the minimum conditions of qualification set out in article 49 Directive 2001/83/EC. For instance, the qualified person shall as a main rule have completed four years of university studies in scientific disciplines such as pharmacy or medicine, with some exceptions, and must also have some previous practical experience. The qualified person is responsible for making sure that each batch complies with the national regulations and the concerned marketing authorisation. Samples of each batch should be retained for at least one year after the expiry date.²¹²

If the holder of the manufacturing authorization wishes to make any changes to the conditions mentioned above, the competent authority must be given prior notice of the

²⁰⁸ Directive 2001/83/EC, article 40.

²⁰⁹ EMEA Post-Authorisation Guidance on Parallel Distribution, 2006, p. 4.

²¹⁰ Ibid, p. 11-13 and 23.

²¹¹ Directive 2001/83/EC, article 41.

²¹² Directive 2003/94/EC, article 11.

planned changes. The holder of the manufacturing authorisation must comply with GMP²¹³ and make sure that the manufacturing operations are carried out in accordance with the manufacturing authorization and the marketing authorization for the concerned product²¹⁴, at all times allow the competent authority access to his premises²¹⁵ and have sufficient personnel at his disposal; sufficient both to number, qualifications and training.²¹⁶ The holder of the manufacturing authorization must also comply with the rules regarding packaging and information leaflets as set out in Title V of Directive 2001/83/EC.

4.3.2 Wholesale/distribution authorization

To be allowed to trade with pharmaceuticals, a wholesale authorization is necessary. If an actor already possesses a manufacturing authorization, he will automatically be allowed to trade with the products that are included in that authorization. However, it does not go the other way around; a holder of a wholesale authorization is not allowed to manufacture pharmaceuticals unless he also applies for a manufacturing authorization.

The holders of wholesale authorizations are subject to checks by the authority in the member state that has granted the authorization.²¹⁷

In order to obtain a wholesale authorization, the applicant must fulfil certain minimum requirements. He must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal product, and a responsible qualified person.²¹⁸ Further on, the holder of a distribution authorization must make the premises accessible at all times for the person inspecting them, the holder must obtain their supplies only from actors who are themselves authorised to distribute pharmaceuticals, the holder may only supply their products to other actors who also possess distribution authorisations or who are otherwise entitled to supply pharmaceuticals to the public in the concerned member state, the holder must have an emergency plan ensuring effective recall from market if necessary, records must be kept of purchased/sold products and those records

²¹³ ‘Good manufacturing practice’ means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use, Directive 2003/94/EC, article 2.6.

²¹⁴ Directive 2003/94/EC, articles 4 and 5.

²¹⁵ Directive 2001/83/EC, article 46.

²¹⁶ Directive 2003/94/EC, article 7.

²¹⁷ Directive 2001/83/EC, article 77.

²¹⁸ Op. cit., article 79.

must be kept available for inspection by the competent authorities for five years, GDP must also be complied with.²¹⁹

4.3.3 Marketing authorization

In addition to having a license allowing the actor as such to trade in pharmaceuticals, you have to have a marketing authorization for each separate product you trade with and place on the market.²²⁰ A marketing authorization may be obtained from the EMEA or a national authority.²²¹

To be allowed to obtain a marketing authorization, the applicant must be established in the Community.²²² The application must be accompanied by documents and information regarding for instance the contents of the pharmaceutical, a description of the manufacturing method, the results of clinical trials, the so-called product characteristics etc. After a marketing authorization has been granted, this information must be continuously updated.²²³ The marketing authorization application must also be accompanied by a copy of the proposed packaging for the product.²²⁴ If the packaging does not comply with the regulations, the marketing authorization could be suspended.²²⁵ The application for marketing authorization will be refused if the applicant has not properly and sufficiently demonstrated the quality, safety or efficacy of the medicinal product.²²⁶ The parallel importer must notify the original marketing authorization holder as well as the competent authority in the importing member state of his intent to parallel distribute a certain product.²²⁷

To observe is that it can be somewhat easier for a parallel importer to obtain a marketing authorization for the concerned product; the parallel importer does not need to provide the authority with as much information as the producer originally did when obtaining his authorization,²²⁸ but can obtain a so-called simplified marketing authorisation.²²⁹ As long as the parallel importer can demonstrate that the product he is seeking authorization for is essentially similar to a product that has already been authorised, he can partly refer to the

²¹⁹ Op. cit., article 80.

²²⁰ Regulation EEC 2309/93, article 3.1, and Regulation EC 726/2004, article 3.1.

²²¹ Directive 2001/83/EC, article 6.

²²² Regulation EC 726/2004, article 2.

²²³ Directive 2001/83/EC, article 8.

²²⁴ Op. cit., article 61.

²²⁵ Op. cit., article 64.

²²⁶ Regulation EC 726/2004, article 12.

²²⁷ Directive 27/2004/EC, article 76.

²²⁸ COM/2003/0839, p. 5.

²²⁹ EAEPG Good Parallel Distribution Practice Guidelines for Medicinal Products, 2005, p. 2.

information already given to the authority by the other party.²³⁰ When a pharmaceutical has been approved on community level²³¹ then the approval is valid in the EU. Parallel trade of identical pharmaceuticals approved centrally are comprised by one approval for sale. In cases where the national authority already has the pharmaceutical information needed to control the safety and the effect of the medicine, then the approval can be made through a simplified procedure. Then it is not necessary with reference to protection of human health and life to demand that another actor also submits the same information to the authorities as long as there is no therapeutic difference between the pharmaceuticals.²³² To use the simplified procedure it is necessary that the imported product have been approved for sale in the export member state and that the imported product is similar to products that have already been approved for sale in the member state of destination. The ECJ has defined what constitutes a similar product as products that have same composition, same active substance and therapeutic effect. It is not necessary that the products are identical in every aspect.²³³

The withdrawal of the original marketing authorization for other reasons than safety issues does not necessarily mean that the marketing authorization given to the parallel importer will automatically be withdrawn. The legal situation regarding this is somewhat uncertain though.²³⁴

The authority in the member state(s) that have granted the manufacturing authorization will mainly supervise the product concerned.²³⁵ Said authority will also ensure that the person responsible for placing the product on the market continuously complies with the regulation.²³⁶ If the person responsible for placing the product on the market suspects that the product may cause adverse reactions, the competent authorities must be informed.²³⁷ The holder of a marketing authorization must have an appropriately qualified person, responsible for pharmacovigilance (monitoring of possible side-effects etc), at hand. Further on, pharmacovigilance information reported to the concerned authorities will be forwarded to WHO.²³⁸ The marketing authorization is valid for 5 years, and can be renewed upon application. If the product for which the marketing authorization is valid is not actually put on

²³⁰ Directive 2001/83/EC, article 10.

²³¹ Council regulation (EEG) 2309/93, p.1.

²³² Case C-201/94, Smith & Nephew vs. Primecrown.

²³³ Ibid.

²³⁴ COM/2003/0839, p. 6-7. EAEPG Good Parallel Distribution Practice Guidelines for Medicinal Products, 2005, p. 6.

²³⁵ Regulation EEC 2309/93, article 16.

²³⁶ Op. cit., article 17.

²³⁷ Op. cit., article 20.

²³⁸ Op. cit., articles 21 and 25.

the market within three years after authorization, the authorization will cease to be valid, the same goes if the product was previously present on the market but is then removed for a period of three consecutive years.²³⁹

4.3.4 Supervision and measures in case of breaches of legal provisions

The competent authority in the member state concerned is required to see to that the provisions regarding medicinal products are complied with, by repeatedly performing inspections. The authority may, for instance, inspect manufacturing or commercial establishments and laboratories, take samples and examine concerned documents.²⁴⁰ GMP inspections of pharmaceutical manufacturers should be carried out at least every two years.²⁴¹ The authority shall suspend or revoke a marketing authorization if the product proves harmful, if the therapeutic effect is lacking, if the product's composition is not as declared, if the proper controls have not been performed, or if the holder has failed to notify the authority of changes as is demanded by the regulation.²⁴² The prohibition to supply to the market, or the withdrawal of the product, may be limited to certain batches that are under dispute.²⁴³

5. Conclusions

5.1 The research question

To answer the question whether there is a connection between the free movement of pharmaceuticals and the occurrence of counterfeit medicines; we have not found any evidence indicating that parallel trade as such promotes counterfeiting. Moreover, so far not that many cases of counterfeit medicines have been found within the legal distribution chains in the EU. The biggest number of counterfeit medicines is found in connection with illegal Internet trade. Therefore, if stopping at that conclusion, it seems that the balance between free trade and consumer protection (that is with the main focus being protecting consumers from counterfeit medicines) is fairly adequate. However, the opinions differ somewhat when comes to whether certain aspects of how parallel trade is actually conducted in practice might promote the

²³⁹ Directive 2001/83/EC, article 24, and Regulation EC 726/2004, article 14.

²⁴⁰ Directive 2001/83/EC, article 111.

²⁴¹ EMEA/Commission, Compilation of Community procedures on inspections and exchange of information, 2006, p. 33.

²⁴² Directive 2001/83/EC, article 116.

²⁴³ Directive 2001/83/EC, article 117.

occurrence of counterfeiting. Even though consumer safety aspects are considered in connection to parallel trade with pharmaceuticals, the free movement of goods prevails in most cases as it is considered that adequate consumer protection can be achieved with less invasive measures. The solution is not to exclude parallel trade of pharmaceuticals, but rather to improve the control of the supply chain. Lately the consumer aspect has been emphasized within EU by the development of the joint Health and Consumer Protection Strategy, but there is still a lack of information given to consumers regarding counterfeit medicines.

Generally the producers of pharmaceuticals tend to see parallel trade somewhat differently than the parallel distributors. Because of the underlying interests, it can be quite difficult to disclose which arguments are valid and which are not. It seems, though, that there are a number of things that can be identified as potential weak spots or problems with the current regime. As parallel trade is not in itself causing the occurrence of counterfeiting, the focus should not be on potential problems with parallel trade of pharmaceuticals, but rather on assessing the situation in an unbiased manner and finding better ways to seal the distribution chain to avoid counterfeits from entering.

5.2 Problems with legislation

The problems with how parallel trade is currently conducted mainly seem to be certain aspects of how the legislation is designed.

EU legislation governs the pharmaceutical industry as well as the trade with pharmaceuticals. This is positive in so far as it harmonizes the legislation, leaving no possibilities for loopholes. However, not all of the EU legislation is made in the form of regulations; a big part consists of directives that leave it up to each member state to decide how the legislation will be shaped more in detail. This is of course not necessarily a problem, the final national legislation might be excellent, but the opponents to parallel trade of pharmaceuticals sometimes argue that certain national legislation is faulty. For instance, it might allow persons convicted of narcotics crimes (or other crimes) to trade with pharmaceuticals. The opponents claim that the control of the persons given authorization is not sufficient, and that neither is the following control of the trade and production activities. This is said to give an opportunity for unscrupulous persons wishing to make easy money to partake in trade with pharmaceuticals, introducing faulty medicines that might harm the consumers into the distribution chain. Parallel traders have much lower costs than the pharmaceutical producers, not having to put money into R&D and lengthy approval

procedures, and acting as a parallel trader is therefore claimed to be highly lucrative, thus attracting persons wishing to make quick money by not only trading with real pharmaceuticals but also adding counterfeits and other defective products into the distribution chain to further increase the profit. One way to improve the situation in this regard would be to introduce more extensive background checks of persons involved in trade with pharmaceuticals. Perhaps the requirements that must be fulfilled in order to be given authorization to trade with pharmaceuticals should be harmonized. The demands on the qualified person, as well as other parties involved, might need to be strengthened; the demand that the qualified person must have certain academic and practical experiences seem to not be enough, extractions from police registers etc could be in order.

5.3 Anti-counterfeit measures

Previously it has been mentioned that there are several different technical anti-counterfeit measures that could help to prevent counterfeiting. It is necessary to develop the technical anti-counterfeit measures and to increase the use of these. It might not be enough to use them only in high-risk products due to the fact that almost every kind of pharmaceuticals are counterfeited today.

Today it is difficult to verify the route of the drug. The pharmaceuticals can be identified through batch numbers and the different actors in the distribution chain must have documentation showing where they bought the medicines. Due to the large batch quantities the pharmaceuticals can be spread all over Europe, which makes a recall more difficult. To be able to verify that the medicine is the same as the one sent from the factory, there is a need to develop an electronic track and trace system, either through individual packaging numbers or RFID. The different options are discussed in the industry. To be able to track the route of the pharmaceuticals there is a need of a database, where the different actors in the distribution chain can check the route of the drugs. To be an effective alternative the database has to be created through collaboration in the industry. Should it be a national, regional or international database? Having separate national databases in Europe would not be efficient due to the single market in pharmaceuticals in EU, so an EU or European level database would at least be necessary. Another option would be an international database through United Nations, maybe through the WHO Impact-collaboration. Before establishing databases, there are a number of issues to be solved. Who will have access to the database? Who will own the

information? How do we ensure that the information is not abused? The information will be valuable to many actors as it shows the whole distribution chain of the pharmaceuticals.

5.4 Repackaging

It is sometimes claimed that intensifying the control might not be enough. Perhaps certain parts of the current legislation and legal state should be changed. The fact that repackaging is allowed in connection with parallel trade of pharmaceuticals is often argued to be the biggest problem. This is so for instance because the repackaging moment could be the weak spot; when the counterfeit goods enters the distribution chain. To keep in mind though is that the repackaging process is as strictly regulated and monitored as the original production; repackaging and manufacturing of pharmaceuticals is governed by the same legislation. However, during the repackaging process anti-counterfeiting measures put on the original packaging are removed.

The issue of anti-counterfeit measures being removed during repackaging could be solved by joined efforts of the pharmaceutical producers and the parallel traders; agreeing on a uniform way of dealing with those technical devices, or by legislation concerning the matter. Repackaging could thus take place without interfering with anti-counterfeiting devices.

The right to repackage could be limited and further regulated in other aspects as well. Perhaps the current regime is too invasive when allowing complete repackaging; it could be stipulated that for instance the inner packaging may never be changed, or that it will only be allowed to cover the already existing packaging with labels. The necessity of repackaging pharmaceuticals could be diminished by EU legislation concerning the size of packages. Today one of the main incentives for repackaging (except for the issue of language) is the fact that the different member states have different customs and regulations regarding the package sizes. If this area is harmonized, total repackaging would not be required as often as it currently is. Instead, only new labels in the proper language could be placed on the package.

To note is that repackaging and relabelling is motivated by consumer protection; the consumers should get their pharmaceuticals in the packaging sizes they are used to and with directions of use etc in the proper language. However, at the same time it is argued that repackaging could lead to a higher number of faulty medicines reaching the consumers. So the question remains whether the appropriate balance between consumer protection and free movement of goods, or really the way free trade is performed, is adequate.

5.5 Authorities

The problem is moreover said to perhaps not be the legislation as such, but how it is put into practice. The authorities responsible for conducting the statutory controls and inspections are sometimes argued to be short-staffed and lacking financial funds, thus inspections are not carried out often enough. The persons coming into contact with counterfeit medicines in their line of work (such as medicines agencies, police, customs and other authority personnel) might not have adequate training for detecting the faulty products, nor be aware of the problem to a satisfactory level. The different authorities need to be informed about the serious consequences of counterfeit medicines and also about how and where they can discover these false drugs. Today, counterfeiters of medicine often escape punishment, as the prosecutor does not see counterfeiting as a prioritized crime. Education of the prosecutors could improve the current situation.

Also, the different involved authorities, both on national, regional and international level, might not communicate enough with each other regarding counterfeit issues. The majority of the counterfeit medicines seized by the customs originated from India and China, which shows the importance of international collaboration to combat counterfeit drugs. EU can, when it comes to third countries, put pressure as well as help foreign governments to act against counterfeiters in their country. Increased cooperation and communication would most likely be beneficial to minimize the occurrence of counterfeit medicines. The level of cooperation has been increased the last couple of years, but more work in this aspect is needed. An additional problem in this case is that there is no universal or even regional definition of counterfeit medicine.

5.6 Criminal legislation

The problem with counterfeiting might not only lay in the pharmaceutical legislation as such, but the criminal law-side of it. This aspect is often used as an argument for why persons involved in e.g. narcotics crimes would be interested in dealing with counterfeit drugs instead of narcotics. The fact remains that in most countries the penalty for dealing with counterfeit drugs is much lighter than the one for dealing with narcotics. There is no real harmonization of criminal law within the EU when it comes to counterfeit medicines crimes, or really any counterfeit crimes for that matter. It is a problem that counterfeiting of medicines fall under such varying criminal legislation in the different member states. Some countries have stricter

rules as well as laws governing crimes connected specifically to counterfeit medicines, and some do not. There is EU legislation governing minimum penalties for intellectual property crimes, but as it seems this might not be enough. Perhaps EU legislation specifically governing crimes connected to pharmaceuticals is needed. Counterfeit medicines has to be separated from the counterfeiting of sunglasses and handbags and there should be a separate crime for counterfeiting of medicines, with a common definition of counterfeiting of medicines, to ensure that counterfeiters do not escape prosecution due to more lax regulation in another country. The enforcement of existing criminal law should also be improved, which probably requires additional funding (as mentioned above, authorities might not have adequate resources).

5.7 Distribution chain

There is no single solution to stop counterfeit medicines in the distribution chains; rather it is a series of actions that could contribute to hinder the trade in counterfeit medicines. One problem is the fact that the distribution chain today can be very long. This increases the difficulties with properly controlling and inspecting each involved party as well as increases the risk that one of the links in the chain might not be acting lawfully, thus introducing counterfeit medicines into the distribution system.

Every time pharmaceuticals are sold, the transaction must be properly recorded. However, villainous actors might attempt to falsify such records and the more actors the goods pass by the harder it becomes to guarantee the quality and origin of said goods.

It is difficult to somehow limit the number of actors allowed to be involved in the distribution chain by regulations without restricting free movement of goods, but perhaps limiting the number of middlemen is what should be done. If not, it seems that a better way of monitoring the distribution chains and the pharmaceutical products they deal with might be necessary. One way of improving the possibility of tracking separate products is via the previously discussed “track and trace” devices. More thorough and comprehensive controls might also be achieved by increasing the EU aspect of the control; under the current regime the controls are mainly performed by the competent national authorities.

To notice is on this matter is that the parallel traders themselves say that they can be seen as an extra control system. Each time the pharmaceuticals are traded with, the distributor is required to check them and record the transaction and therefore it is argued that trade with

pharmaceuticals does not increase but decrease the risk of counterfeits or other faulty products reaching the consumers.

5.8 Concluding remarks

To conclude, there is a need for increased information regarding the existence of counterfeit medicines in Europe. To start with, a major information campaign of the dangers associated with buying counterfeit medicines over Internet from illegal pharmacies could be done. Such a campaign would introduce the thought of counterfeit medicines to the public in a more soft way, to avoid scaring patients about the safety in the legal distribution chain. Consumers need to be aware of what they are buying. The information to consumers should be made by the DRAs or consumer organisations to ensure that the information is balanced and does not cause panic among the consumers.

Further on, collaboration is necessary to achieve results in the work against counterfeiting of medicines, mainly in the area of anti-counterfeit measures. The problem has to be tackled on three different levels: regulation, information and control. The regulatory gaps have to be eliminated and there has to be control in place to ensure that the companies follow the regulation in the area.

6. References

6.1 Litterature

- Craig, Paul & De Burca, Gráinne, EU Law, text, cases and materials, third edition, Oxford University Press, 2003.
- Hays, Thomas, Parallel importation under European Union law, Sweet & Maxwell, 2004.
- Hunter, Russell Graeme, The pharmaceutical sector in the European Union – Intellectual property rights, parallel trade and community competition law, Institute for European Law at Stockholm University, 2001.
- ICC Counterfeiting Intelligence bureau, Countering counterfeiting, A guide to protecting and enforcing intellectual property rights, ICC publication No. 574, 1997.
- Koktvedgaard, Mogens & Levin, Marianne, Lärobok i Immaterialrätt, eighth edition, Norstedts juridik, 2004.
- Korah, Valentine, An Introductory Guide to EC Competition Law and Practice, seventh edition, Hart Publishing, 2000.
- Nebbia, Paolisa, Askham, Tony, EU consumer law, Richmond Law & Tax Ltd. 2004.
- Westman, Sophia, Ompaketering och utnyttjande av annans varumärke – en studie av parallellimport av läkemedel inom EU, Skrifter utgivna av Institutet för immaterialrätt och marknadsrätt vid Stockholms universitet, 2001.

6.2 Reports and Articles

- Abrantes-Metz, Rosa M, Adams, Christopher P, Metz, Albert D, Pharmaceutical Development Phases: A Duration Analysis, Journal of Pharmaceutical Finance, Economics & Policy, Volume 14(4) 2005.
- AIM Position Paper, Parallel trade – Consumer benefit or consumer loss?, 1999.
- Anti-Counterfeiting Group, Why you should care about counterfeiting – The Anti-Counterfeiting Group campaigning against the trade in fakes.
- Arfwedson, Jacob, Parallel trade in pharmaceuticals, 2003.
- Arfwedson, Jacob, Re-importation (Parallel Trade) in Pharmaceuticals, Institute for Policy Innovation, Policy Report 182, 2004.

Centre d'études internationaux de la propriété industrielle, Impacts de la contrefaçon et de la piraterie en Europe, Rapport final, 2004.

CNE White Paper, Saving the European Pharmaceutical Industry: Price Regulation and "Recommendation VI", 2002.

Cockburn, Robert, Newton, Paul N., Agayarko, E. Kyeremateng, Akunyili, Dora, White, Nicholas J.. The global threat of counterfeit drugs: why industry and governments must communicate the dangers, Public Library of Science Medicine, April 2005, Volume 2, Issue 4.

<http://medicine.plosjournals.org/perlserv/?request=getdocument&doi=10.1371/journal.pmed.0020100>

Community wide statistics 2005

http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2005_en.pdf. Visited November 16th, 2006.

Council of Europe, Counterfeit medicines – Survey report. Council of Europe Publishing, 2006.

Council of Europe, Counterfeiting: problems and solutions, Doc 10069,

<http://assembly.coe.int/documents/WorkingDocs/doc04/EDOC10069.htm>, Visited: July 4th 2006.

European Association of Euro-Pharmaceutical Companies, Good Parallel Distribution Practice Guidelines for Medicinal Products, 2005.

European Association of Euro-Pharmaceutical Companies, Understanding competition in the distribution of pharmaceutical products in Europe – An analysis of the application of Article 82 EC to supply-restrictions in the pharmaceutical sector, 2005.

European Commission, Report on responses to European Commission Green Paper on counterfeiting and piracy, p. 10,

http://ec.europa.eu/internal_market/indprop/docs/piracy/piracy_en.pdf, visited December 12th 2006.

European Federation of Pharmaceutical Industries and Associations, Article 82 EC: Can It Be Applied to Control Sales By Pharmaceutical Manufacturers to Wholesalers?, 2004

European Federation of Pharmaceutical Industries and Associations, Position paper, Combating counterfeit medicines and protecting patients through a partnership approach, 2005.

European Federation of Pharmaceutical Industries and Associations, Position Paper, Pharmaceutical supply chain evolution, 2005.

European Medicines Agency/European Commission, Compilation of Community procedures on inspections and exchange of information, 2006.

European Medicines Agency, Post-Authorisation Guidance on Parallel Distribution, 2006.

European Medicines Agency, Tenth annual report of the European Medicines Agency 2004.

Food and Drug Administration, Counterfeit drug task force interim report. Safe and secure, October 2003. http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html. Visited: November 23rd, 2006.

International Federation of Pharmaceutical Manufacturers and Associations, The Pharmaceutical Innovation Platform – Sustaining Better Health For Patients Worldwide, 2004.

Kanavos, Panos, Costa-i-Font, Joan, Merkur. Sherry, Gemmill, Marin. The economic impact of pharmaceutical parallel trade in European union member states: A stakeholders analysis. London School of Economics and Political science, Health and Social Care, 2004.

Läkemedelsindustriföreningen, Förfalskade läkemedel, Rapport 2005:5.

National Economic Research Associates, The economic consequences of the choice of regime of exhaustion in the area of trademarks, Final Report for DG XV of the European Commission, 1999.

Oldenhof, Chris, Pharmaceutical Technology Europe, 1 March 2006, APIs: Why EU authority is vital, Visited November 16th 2006, <http://www.ptemag.com/pharmtecheurope/article/articleDetail.jsp?id=310781&pageID=4>

Pfizer, Safeguarding the integrity of the medicines supply chain in Europe. <http://www.safemedicines.org/resources/documents/Pfizercftwo-pager.pdf>. Visited November 16th, 2006.

Remit Consultants, Impediments to parallel trade in pharmaceuticals within the European Community, Final report prepared for DGIV of the European Commission, London. EEC reference IV/90/06/01.

Satchwell, Graham, A sick business – Counterfeit medicines and organised crime, The Stockholm Network, 2004.

Swedish Competition Authority, Parallel imports – Effects of the Silhouette ruling, Report Series 1999:1.

WHO Counterfeit drugs, Guidelines for the development of measures to combat counterfeit drugs, WHO/EDM/QSM/99.1.

WHO, Counterfeit medicines, Fact sheet N°275,

<http://www.who.int/mediacentre/factsheets/fs275/en/>. Visited October 1st, 2006.

WHO, The new estimates on the prevalence of counterfeit medicine. Visited November 23rd, 2006.

<http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

Wiraeus, Frida, Parallellimport och försäljning av läkemedel – Fallet Losec, Examensarbete Lunds Universitet, 2000.

6.3 Miscellaneous

European Association of Euro-Pharmaceutical Companies,

http://www.eaepc.org/parallel_trade/general.php?n=2, Visited December 10th 2006.

European Medicines Agency,

http://europa.eu/agencies/community_agencies/emea/index_en.htm Visited October 16th 2006.

MEMO/06/421, 2005 custom seizures of counterfeit goods – Frequently Asked Questions

WHO conference, Rome 2006, Speech Combating counterfeit medicines – Views from a regional organisation (EU) held by Dr. Nils Behrndt, Deputy Head of Pharmaceuticals Unit, DG Enterprise and Industry.

6.4 Case law

Cases 56 & 58/64 Etablissements Consten SARL and Grundig-Verkaufs-GmbH v. Commission [1966] ECR 299.

Case 15/74 Centrafarm BV and Adriaan de Peijper v. Sterling Drug Inc. [1974] ECR 1147.

Case 16/74 Centrafarm BV v. Winthrop BV [1974] ECR 1183.

Case 104/75 *Officier van Justitie v. de Peijper* [1976] ECR 613.

Case 102/77 *Hoffmann-La Roche & Co. AG v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* [1978] ECR 1139.

Case 3/78 *Centrafarm BV v. American Home Products Corporation* [1978] ECR 1823.

Case 1/81 *Pfizer Inc. v. Euro-Pharm GmbH* [1981] ECR 2913.

Case 181/82 *Roussel Laboratoria BV v. The State of The Netherlands* [1983] ECR 3849.

Case C-249/88 *Commission v. Belgium* [1991] ECR I-1275.

Case C-10/89 *SA CNL-Sucal NV v. Hag GF AG (“Hag II”)* [1990] ECR I-3711.

Case C-9/93 *IHT Internationale Heiztechnik GmbH v. Ideal-Standard GmbH* [1994] ECR I-2789.

Cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers-Squibb v. Paranova A/S, and C H Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v. Paranova A/S, and Bayer Aktiengesellschaft and Bayer Danmark A/S v. Paranova A/S* [1996] ECR I-3457.

Cases C-71/94, C-72/94 and C-73/94 *Eurim-Pharm Arzneimittel GmbH v. Beiersdorf AG* [1996] ECR I-3603.

Case C-201/94, *Smith & Nephew vs. Primecrown* [1996] ECR I-5819.

Case C-355/96 *Silhouette International Schmied GmbH & Co. v. Hartlauer Handelsgesellschaft mbH* [1998] ECR I-4799.

Case C-337/95 *Parfums Christian Dior SA v. Evora BV* [1997] ECR I-6013.

Case C-63/97 *Bayerische Motorenwerke AG (BMW) and BMW Nederland BV v. Ronald Karel Deenik* [1999] ECR I-905.

Case C-379/97 *Pharmacia & Upjohn SA v. Paranova A/S* [1999] ECR I-6927.

Case C-173/98 *Sebago Inc., and Ancienne Maison Dubois et Fils v. G-B Unic SA* [1999] ECR I-4103.

Case C-443/99 *Merck, Sharp & Dohme GmbH v. Paranova Pharmazeutika Handels GmbH* [2002] ECR I-3703.

Case C-143/00 *Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG v Swingward Ltd, and between Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG and Dowelhurst Ltd, and between Glaxo Group Ltd and Swingward Ltd, and between Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG and Dowelhurst Ltd, and between Glaxo Group Ltd, The Wellcome Foundation Ltd and Dowelhurst Ltd, and between SmithKline Beecham plc, Beecham Group plc, SmithKline & French Laboratories*

Ltd and Dowelhurst Ltd and between Eli Lilly and Co. and Dowelhurst Ltd. [2002] ECR I-3759.

6.5 Treaties

European Community Treaty

6.6 Regulations

Council regulation (EC) No 1383/2003 of 22 July 2003 concerning custom actions against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

Council regulation (EEC) No 2309/93 of 22 July 1993 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.

Commission regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.

Commission regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93.

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

6.7 Directives

First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use.

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

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 use.

Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

6.8 Communications

EU greenpaper, Combating counterfeiting and piracy in the single market (COM(98)569final).

Communication from the Commission on the single market in pharmaceuticals, (COM(98)588final).

Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, (COM(2003)839final)

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions, Healthier, safer, more confident citizens: a Health and Consumer protection Strategy. Proposal for a decision of the European Parliament and the Council establishing a Programme of Community action in the field of Health and Consumer protection 2007-2013 (COM(2005)115final)

6.9 Interviews

Raul Wannerholt, AstraZeneca.

Göran Heintz, Föreningen för Paralleldistributörer av Läkemedel/Paranova.

Inger Näsman, Läkemedelsindustriföreningen.

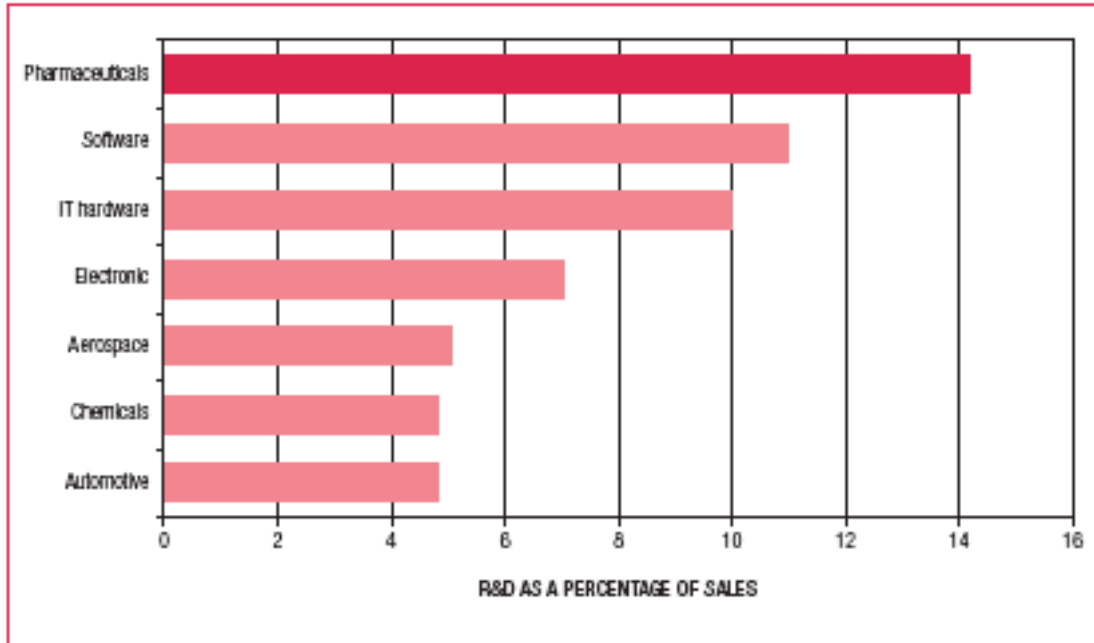
Erika Haglund and Kerstin Hjalmarsson, Swedish Medicines Products Agency.

Hans Flodeer, Pfizer.

Appendices

Appendix 1

R&D intensity as a proportion of total sales



Source: International Federation of Pharmaceutical Manufacturers Association. The Pharmaceutical Innovation Platform – Sustaining Better Health For Patients Worldwide, 2004, page 12.

Appendix 2

Process of pharmaceutical R&D

R&D Stage	Research & Discovery	Preclinical development	Phase I	Phase II	Phase III	Registration	Phase IV
Main Activities	Drawing on basic exploratory research to identify targets, initial research on new compounds is carried out in the laboratory (high throughput screening, lead identification and optimization) to select the most promising compounds.	Selected compounds are studied in animals under Good Laboratory Practice for toxicity and safety; in parallel, specific analytical methods are developed for further development.	Successful compounds are then tested in humans in 3 phases of clinical trials: <ul style="list-style-type: none"> • Phase I – safety 120 and tolerability in healthy volunteers • Phase II – safety, efficacy and bioequivalence studies in small groups of patients • Phase III – large trials with different populations to demonstrate proof of efficacy, safety and value 			If the results of clinical trials are satisfactory in terms of quality, efficacy and safety, a regulatory dossier is presented to the regulatory authorities for approval.	Post-marketing studies involving thousands of patients are initiated after the launch of the medicine, to identify any previously unforeseen side effects.
Success Rate*	Less than 1 %		70 %	50 %	50 %	90 %	N.A.
Time	4-6 years	1 year	1-1.5 years	1-2 years	2-3 years	1-2 years	Several years

* Success rates reflect the number of drug candidates that successfully pass through to the next R&D stage.

Source: International Federation of Pharmaceutical Manufacturers Association. The Pharmaceutical Innovation Platform – Sustaining Better Health For Patients Worldwide, 2004, page 23.

Appendix 3

Annual profit and annual expenses for R&D

	2001	2002	2003	2004
AstraZenca	4,156	4,356	4,111	4,770
GlaxoSmithKline	8,551 (4.697£)	10,308 (5.662 £)	11,850 (6.509 £)	11,196 (6.150 £)
MSD (net income)	7,282	7,149	6,831	5,813
Novartis	4,325	5,092	5,889	6,539
Pfizer (net income)	7,788	9,126	3,910	11,361
Roche Group	2,627 (3.247 CHF)	1,080 (1.335 CHF)	4,525 (5.592 CHF)	7,727 (8.979CHF)

Annual Profit in million \$ (source: annual reports of the pharmaceutical companies)

	2001	2002	2003	2004
Astra Zeneca	2,773	3,069	3,451	3,803
GlaxoSmithKline	4,869	5,206	5,279	5,410
MSD	2,456	2,677	3,280	4,010
Novartis	2,528	2,843	3,756	4,207
Pfizer	4,982	5,208	7,487	7,684
Roche				
only pharma			3,267	3,649
total R &D	3,262	3,567	3,993	4,267

Annual expenses for R&D in million \$ (source: annual reports of the pharmaceutical companies)

2003	Sales	Profits	Marketing expenses	R&D expenses
AstraZeneca	18,849	4,111	6,856	3,451
GSK	35,163	11,850	12,403	5,279
MSD	22,485	6,831	6,394	3,280
Novartis	24,864	5,889	7,854	3,756
Pfizer	45,200	3,910	15,242*)	7,684
Roche	22,650	4,525	6,553	3,649

Comparison for the year 2003 in mill \$ (source: annual reports of the pharmaceutical companies)

*) Pfizer: Selling, informational and administrative expenses.

Pharmaceutical promotional expenditures in Europe, 2003.

Country	spend (€ million)	% increase over 2002
Germany	1,914.93	24.6
Italy	1,041.71	20.3
France	890.57	12.7
Spain	515.78	26.1
UK	316.81	15.3

Source: Understanding competition in the distribution of pharmaceutical products in Europe – An analysis of the application of Article 82 EC to supply-restrictions in the pharmaceutical sector, European Association of Euro-Pharmaceutical Companies, 2005, pages 84-85.