COUNTERFEIT DRUGS VIA INTERNET

A growing hazard for the developing countries as well as for the industrialised countries

Exposé submitted for Ph.D. Dissertation under Supervision of Prof. Dr. H. G. Schweim at the department of Drug Regulatory Affairs, University of Bonn

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Abbreviations:

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<th>Abbreviation</th>
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<tr>
<td>ABDA</td>
<td>Bundesvereinigung Deutscher Apothekenverbände</td>
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<td>BPI</td>
<td>Bundesverband der Pharmazeutischen Industrie</td>
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<td>CFD</td>
<td>Counterfeit Drugs</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>US</td>
<td>United States</td>
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<td>WHO</td>
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1. Introduction

Examples of Counterfeit Drugs:

- **Nigeria 1990**: 100 children died because of cough syrup, which was mixed with solvent
- **Mexico 1991**: several burn ointments contain saw dust
- **China 1997**: investigations show that 10 percent of drugs were fakes or low grade
- **Cambodia 2000**: at least 30 people died due to fake malaria drugs
- **China 2001**: around 100,000 people died in 2001 due to counterfeit drugs

Counterfeit drugs turn out to be a global hazard throughout the world. This caused nearly 35 billion Euro of deficits for the world economy. Beside the economic loss the health of millions of people worldwide is endangered due to the spread of counterfeit drugs. Although the industrialised world has a good controlled regulatory system and authorities as well as efficient pharmaceutical laws, people can gain possession of counterfeit drugs easily in most cases via internet.

The reason for buying counterfeit drugs in the developing countries is the availability and the price of the expensive drugs due to the poor situation of the population and they are forced to buy counterfeit drugs even if they have low quality or are even toxic.

A different situation is the counterfeit drugs problem in the industrialised countries. In these countries CFD became a market in form of “life-style drugs” like Viagra®, doping pills, fat reducing pills or sleeping pills. Since these drugs need a prescription, many people ordered it via internet to avoid being embarrassed by going to the doctor asking for a prescription and also explaining why these drugs are needed.

Since any legal internet pharmacy also asks for a prescription, the market for these drugs via internet from illegal internet pharmacies or sellers from unknown sources especially from foreign countries is big. Furthermore, many people feel ashamed to order drugs like Viagra® or fat reducing pills. The huge danger is that the consumers appreciate the anonymity of that form of buying via internet.
CFD in general and CFD bought via internet in the industrialised countries will or even is a great danger and also big economic issue for the whole world in the future. A big hint for the increasing internet drug business is the mass of spam mails received by every internet-user each day. Also a fear of epidemics like bird flu could be a reason for many people buying antiviral drug (e.g. Tamiflu®) via internet, if it seems to be, that the drug is out of stock. Statistics show that every 10th of all drugs which were bought via internet are CFD. Therefore the reasons mentioned above and many other reasons lead to people deciding to buy drugs via internet and unfortunately most people are not aware of the risks caused by CFD for their health.

2. Aim of the Dissertation

The aim of this dissertation will be on the one hand to analyse the different situations in the industrialised countries (i.e. EU, US, Canada and Australia) and their tools to counteract the illegal sellers of CFD especially over the internet. On the other hand to discuss the situation of the developing countries, where the most counterfeit drugs are produced and to see how the authorities and the government have to change their policies to put an end to the illegal CFD business. In this context China plays a big role with regards to the production, sale and spreading of CFD and this will be exemplified in more detail. Beside the main focus on CFD via internet, the situation of CFD and how these disperse in all countries should also be discussed. A detailed analysis will be presented of how the current situation has developed. Furthermore the history of CFD will be deconstructed and as a result an estimation of the future in the developing countries as well as industrialised countries in terms of the market of CFD in general as well as the route via internet sellers will be pointed out. Also the position and the capacity to act of the different institutions (government, regulatory authorities, health organisations etc.) and the pharmaceutical companies should be drawn up in order to thwart the huge increase of the presence of CFD worldwide.
Finally an analysis of various internet pharmacies will be presented. Questions should be pointed out, like how safe it is to buy drugs over the internet and also how broad the spectrum of the different internet pharmacies is, from legal and controlled to illegal, where the source of the drugs is unknown and the customers are often in danger. In this context, examples of the different ways to buy drugs over the internet will be shown in detail.

2.1. General Situation

CFD are developing to be a global threat for the population all over the world as well as for the economies of all countries worldwide.

In the moment more than 7% of all drugs sold throughout the world are CFD. In the eighties till 1997 nearly 70% of these CFD were found in Africa. Due to the globalisation the current situation shows that about 30% of CFD now are discovered in the industrialised world. This fact shows very clearly that the CFD issues also become a problem to the “rich countries”, where it is easy to receive CFD purchased via internet.

2.2. Industrialised Countries

2.2.1. Europe

On the European level, EU as well as WHO, both emphasise the difficulties of the CFD worldwide. EU has already established a tool to hit the CFD. A task force team named IMPACT was implemented to raise all the problems concerning CFD in the world and also try to adopt regulations in order to make the business with CFD aggravating.

Furthermore, EU also cooperate closely with WHO, who has already started the battle against the CFD business around the world.

WHO tempt to put pressure on the several governments of countries, where the most CFD are produced in the developing world, so that the punishment for example becomes higher on CFD crimes.
2.2.1.1. Germany

In Germany the pharmaceutical law of 2004 changes the situation of buying drugs via internet. In the past the sale of drugs over the internet was forbidden. Since the European market put pressure on Germanys pharmaceutical laws, the government had to lighten the pharmaceutical law. Right now buying drugs via internet is allowed, although some drugs still need the prescription of a doctor. All legal internet pharmacies in Germany are licensed and controlled, therefore the danger of buying CFD is coming from foreign internet pharmacies or even small companies or distributor, where the source of the drugs is unknown.

In 2005, the BPI (Bundesverband der Pharmazeutischen Industrie) had already issued a warning of internet drug commerce and the danger of CFD. Beside the financial economic loss, also the people's trust in pharmaceuticals as well as the whole branch was damaged.

2.2.2. US/Canada

In the US, the number of drug-purchases via internet is also increasing. The FDA reports that several consumers need medical care due to the consumption of drugs, which were bought via internet. Although the FDA could identify the websites, there were no tools to bring those sellers to justice. Therefore, US, EU and other countries have to cooperate to uncover the companies and also bring the responsible persons to justice by the national government.

Additionally, the penalties for individuals who are involved in CFD-trafficking have to increase.

Furthermore intermediary companies selling CFD with foreign sources have to be punished stronger and these information have to be published to the population. The FDA also emphasises to do more to secure business practices and to issue warnings as to dealing with companies or people with unknown background.

Another way to hit the CFD business is one which is absolutely new in history: Pharmaceutical companies investigate together with the government to discover the selling-routes of CFD.

A good example is Pfizer, a company that has a special division to discover CFD of
their products especially for their bestseller Viagra®. They also work closely with governments of many countries.

Furthermore, also the situation of Canada will be discussed. Since the geographic closeness as well as similarities to the US in terms of regulations and regulatory environment also Canada generates tools (i.e. information on the health authority website) to make the population in Canada aware of the threat of CFD and especially those bought via internet.

2.3. **Developing Countries**

2.3.1. Asia

An overview will be given in this dissertation on several Asian countries that are affected by the CFD problem as well as the impact on the population in these countries and also on the population in the industrialised countries. A focus will be on China, where currently already the “big business” with CFD is made.

2.3.1.1. China

China plays an important role in CFD business and in the meantime the major source of CFD is China. Where other countries (e.g. India, Africa) the fakes are produced in small backyard labs, officers in China detect big facilities with all manufacturing equipment similar to a pharmaceutical company manufacturing CFD. China has a history in producing fakes for example watches, DVD, labels products etc. Since these fakes are in the most cases only an economic damage, the increasing of CFD is also a very high risk to the public health.

A figurative example is the Pfizer’s product Viagra®, which is one of the most copied drugs in the world.

There is a good example in China to investigate globally, where a cooperation of Chinese investigators and American investigators has uncovered five facilities in China, where fakes of Viagra® and other fake medicines were founded. These fake drugs were intended to put on market online in US, Great Britain and Israel. This example shows exactly, how big the business of CFD is present and the time is running away to tackle against this huge increasing problem.
In this dissertation the situation of China concerning CFD will be analysed in detail. Furthermore tools of the government, health authorities also in cooperation with foreign countries (e.g. actions with US government) will be analysed, summarised and presented.

2.3.1.2. India
Beside the “big player” China, India in recent years also developed to an important centre of the international CFD business. An overview of the developing of India’s CFD history will be summarised and also this dissertation should try to do a foresight how the progression in terms of regulatory bands and/or governmental structure will be displayed.

2.3.2. Africa
Africa is also strongly affected by the CFD problem. As mentioned in the examples in the beginning of the Exposé, Africa has many cases of accidents or even deaths with CFD. Compared to the other countries, Africa is among the poor countries and a health system is almost non-existent. Even the hospitals in some areas of Africa especially in sub-Saharan Africa are not able to buy drugs from the origin companies due to price reasons or the quantities they need. Therefore the hospitals have to order drugs through distributors and some of them are even unlicensed.

The situation of the population is even worse. Most of them are not able to pay for hospital costs or doctor’s fees, and they have to buy drugs on the street market. There are no pharmacies like in Europe or US and thus the people are forced to buy drugs on street markets, where the sources are absolutely unknown.

How this situation can be improved and also how the governments of the African countries act should be discussed in detail. Finally the cooperation of the WHO with the industrialised countries also tries to find solutions to advance the drug supply situation in Africa (e.g. reduce prices for several drugs (HIV drugs)).
3. Conclusion

Many task forces have been building up to fight against the illegal sale of CFD and also specified sales via internet. Government, authorities as well as pharmaceutical companies are collaborating to uncover the illegal commerce of CFD and also a special task force team was built to search the several internet pages, where CFD are offered.

Unfortunately there are still not enough tools to end the illegal commerce with CFD via internet, since the sellers are often situated in developing countries (i.e. China, India, Africa etc.). And there is no control function possible, if private persons order drugs via internet.

Therefore, it is extremely important to inform people about the dangers of CFD especially ordered via internet from unclear websites in foreign countries.

In all websites of the authorities e.g. FDA or other national authorities, there are many warnings to private people to be careful when buying drugs over unsecured websites. Although there are a number of warnings, the internet commerce with drugs is increasing exponentially and the resulting problems for everyone cannot be estimated. It is quite sure, that the problem with CFD via internet is not solved in the next future.

But as mentioned above, many efforts from the governments, world organisations (i.e. WHO), health authorities and finally the pharmaceutical companies are made to hit the illegal business of CFD. Furthermore the steady increase of globalisation makes the business of CFD easier. How all the efforts fighting against CFD can succeed, nobody can estimate, but the consequent actions of the different sides (government, authorities, etc.) and the most important is to bring the information to the public, which may avoid that the CFD become a normal situation around the world.
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