

# **Anti-Counterfeiting in Global Pharmacovigilance**

## **A Question of Patient's safety**

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## 2. Introduction

### 2.1 Definition of Counterfeit Medicine

It is difficult to find a globally harmonized definition on counterfeit drugs, since each country has its own understanding what counterfeit drugs may be<sup>(1)</sup> with regard to the broad spectrum of possible drug product falsifications, e.g. patent infringement, fraudulent generics, smuggling and diversion of genuine products, as well as tampering of original product's packaging up to the complete imitation of licensed brands. For these various subtypes the potential risk on patient's safety and the stakeholders' interest in anti-counterfeiting activities may differ significantly. That is why the World Health Organization (WHO) developed the following definition:

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled 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."<sup>(1)</sup>

The opportunity to refer to a general definition eases the fight against counterfeit drugs and the harm they cause. This combat becomes more and more necessary because of the upstream of incidents with respect to counterfeit medicine on the market during the last 25 years, and with it, the increasing hazard on patient's safety.<sup>(2)</sup>

### 2.2 Definition of Pharmacovigilance

Medicinal products have to meet highest standards respecting quality, effectiveness and safety, as outlined in the medicinal drug regulations, to assure patient's safety.<sup>(2)</sup>

In addition to the accomplishment of clinical studies prior to the marketing authorization of a medicinal product, it is the marketing authorization holder's duty to implement a post marketing surveillance system to ensure that the product remains within the established risk-benefit balance.<sup>(3)</sup> Therefore, pharmacovigilance has been defined by the World Health Organization as "the science and activities relating to the detection, assessment,

understanding and prevention of adverse effects or any other medicine-related problem".<sup>(4)</sup>

### 2.3 Background of Pharmacovigilance

In 1968 the WHO promoted a pilot research project for International Drug Monitoring, that 134 countries were part of at the end of 2010. The initially reason why the WHO established the program for International Drug Monitoring was the thalidomide disaster detected in 1961.<sup>(5)</sup> The documentation of and investigation in adverse events concerning medicinal products, and corrective actions quickly provided by drug regulatory authorities based on the evaluated information could have saved thousands<sup>(6)</sup> of children of being malformed. For that reason, the need for an internationally applicable detection system for evaluation of information about adverse effects of medicines was reaffirmed on the Sixteenth World Health Assembly in 1963.<sup>(5)</sup> In reaction, the WHO pharmacovigilance program came into effect. In 1971 the WHO held a consultation meeting where it was decided to advocate the establishment of national centers for drug monitoring, to provide guidelines and to identify potential contribution by national centers to the international system.<sup>(5)</sup>

Today, the WHO Collaborating Center for International Drug Monitoring, set in Uppsala, Sweden, coordinates the membership of the WHO program for International Drug Monitoring and provides essential resources for regulatory agencies, health professionals, researchers and the pharmaceutical industry.<sup>(7)</sup> It is also known as the Uppsala Monitoring Center (UMC). Requirements on pharmaceutical systems have been included into drug regulations worldwide.

At present, every competent authority of the Member States as well as every marketing authorization holder for medicinal products have implemented systems<sup>(5)</sup> wherein data of adverse event reports concerning drug products is collected and evaluated so that national drug regulatory authorities are informed immediately if a report points to a serious case of adverse effect that demands rapid corrective actions to insure public health. Due to past occurrences, it is the aim of today's pharmacovigilance to enhance patient safety in relation to the use of medicines and to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit balance of medicines.<sup>(8)</sup>

## 2.4 Legal Framework of Pharmacovigilance in the EU

In the Directive 2001/83/EC, articles 101 to 108, the EU gives specific instructions how to handle the surveillance of authorized medicinal products. According to this Directive all Member States of the Community and marketing authorization holders of medicinal products have to establish a pharmacovigilance system in order to collect and to evaluate all information about potential risks regarding medicinal products, with particular reference to adverse reactions and interactions.<sup>(3)</sup> However, not only information about adverse drug reactions under normal conditions of use shall be in scope of the pharmacovigilance system, but also any data on misuse and abuse of the drugs that may have an impact on the risk-benefit balance of the products.<sup>(3)</sup> Such information is summarized in a risk management plan including the safety risk assessment and defined risk mitigation measures. The marketing authorization holders are expected to provide a succinct update of the worldwide safety experience of a medicinal product together with a critical evaluation of its risk-benefit balance considering new or changing information to the competent authorities at defined time points post-authorization. These reports are called periodic safety update reports (PSURs).<sup>(4)</sup>

Every marketing authorization holder is obliged to appoint a qualified person who is responsible for the permanently and continuously post authorization surveillance.<sup>(3)</sup>

The duties and responsibilities of the qualified person are clarified in the Directive 2001/83/EC in detail. Beyond the territory of the EU the Directive affects also all other countries with respect to single case and aggregate reporting requirements to competent authorities within the EU. The marketing authorization holder is required to record and report suspected serious adverse reactions promptly to the competent authority, latest within 15 calendar days, regardless whether the incident occurred within the territory of an EU Member State or in one of the third countries.<sup>(3)</sup> As one can see, national pharmacovigilance centers have become a significant influence on the drug regulatory authorities.<sup>(5)</sup>

In Germany the handling of pharmacovigilance is settled in the AMG, §§ 62-63c. The German competent authorities such as the BfArM, the PEI and the AMK collaborate closely and interact with the WHO, the FDA and the EMA, amongst others.<sup>(2)</sup>

Every health facility, e.g. pharmacies and medical practices, is obligated to report any adverse effect or unspecified adverse reaction of medicines, that is brought to their attention, pursuant to the graduated scheme which is given by governance as a guide so that everyone knows who the information has to be provided to.<sup>(2)</sup>

The law includes special regulations respective pharmaceutical companies. According to § 63a every company has got to implement and continuously run a pharmacovigilance system and name a graduated scheme responsible who has to account for the required qualification. This person's function is to ensure the pharmacovigilance system is managed according to the legislative regulations. Furthermore, the graduated scheme responsibility is the interface to the competent authorities.<sup>(2)</sup>

Because of the increasing case numbers with respect to counterfeit drugs, among other things, the EU initiated changes in the drug regulation and issued the so called "Pharmaceutical Package" containing three legislative proposals.

The first proposal focuses on strengthening the EU's system for the safety monitoring of medicines (pharmacovigilance). The Regulation and the Directive on Pharmacovigilance are already adopted. The transfer of the EU Directive into national law shall be realized within a grace period of 18 months after their release. Hence, both, the EU Pharmacovigilance-Regulation and the implementation of the Directive into national law will come into force in July, respective end of 2012.<sup>(9)</sup>

The second proposal of the "Pharmaceutical Package" specifically addresses the issue of counterfeit medicinal products and measures to combat counterfeits. In December of 2010 the European Parliament agreed on a draft according to the amendments of the new Directive on Counterfeit Medicine which were adopted on February 17, 2011. These amendments have to be transferred into national law within two years.<sup>(10)</sup>

The German BMG intends to connect all the adopted changes of the EU Directive 2001/83/EC with another amendment of the AMG. The third and last proposal aims to ensure that EU citizens have access on reliable information about medicines. For this proposal there has been no agreement achieved yet.<sup>(9)</sup>

### 3. Today's Situation

#### 3.1 Counterfeit Drugs

In the past 25 years the globalization and the explosion of free trade, as well as the ascending availability of medicines via internet, calls for a widening of the scope of pharmacovigilance. New hazards to public health emerged in connection with the changing situation regarding the drug market. Some examples for these alarming developments are increasing self-medication practices, illegal sale of medicines, including drugs of abuse, over the internet and, especially in the focus of this thesis, widespread manufacture and sale of counterfeit and substandard medicines.<sup>(5)</sup>

Reports about counterfeit drugs, received by the WHO, relate to the medicinal drug categories antibiotics, hormones, analgesics, steroids and antihistamines.<sup>(1)</sup>

Looking at past incidents of counterfeit medicines, the extent of the problem and its impact on public health becomes apparent. In 1990 more than 100 children died in Nigeria because of a cough mixture that was diluted with a poisonous solvent.<sup>(11)</sup> In 2002 the Nigerian National Agency for Food and Drug Control (NAFDAC) asserted that 60% of their medicines are falsified, substandard or with exhausted expiry date.<sup>(11)</sup> But counterfeit drugs are not only a problem of the developing countries anymore. The developed countries are concerned as well.<sup>(1)</sup> In 2003 there was a recall of almost 20 million doses of Lipitor® in the USA. Again, concerning counterfeit Lipitor® a whole batch had to be recalled in the UK in 2005.<sup>(12)</sup> Likewise in 2005 the illegal trading of counterfeit "lifestyle" drugs including the anti-obesity medicines Reductil® and Xenical®, the smoking cessation drug Zyban®, the hair restorer Propecia® and the erectile dysfunction medicines Cialis® and Viagra® via internet was uncovered and the responsible identified.<sup>(13)</sup> The patients may be lucky if the medicine itself is not falsified, but only the packaging. However, still not only the economical damage can be enormous but also the impact on the product quality of the tampered product remains uncertain, and thus, poses potential risk to the patient. The latest example for such a fraud is the illegal selling of HIV-medicines on the German market, revealed in 2009. The HIV-medicines, intended to be sold on the African market and therefore less priced by the pharmaceutical manufacturer, were repackaged and brought back to Germany

illegally. It is said that this is about more than 10,000 packages of the HIV drugs valued at about 6 Million Euro or more.<sup>(14)</sup>

As one can see, counterfeit medicines can not only result in economical mischief, but most importantly into treatment failure or even in death.<sup>(15)</sup> Although, the incidence of counterfeit drugs in the legal supply chain in the industrialized countries is less than 1% of market value<sup>(15)</sup>, it is estimated to reach an extent of around 50% in the illegal supply chain.<sup>(16)</sup> In the developing countries occurrence of falsified medicines is much higher. There are countries where 90% of the medicines on sale are considered to be counterfeit.<sup>(16)</sup> These percentages demonstrate the magnitude of the illegal trade of counterfeit drugs with an estimated turnover of 32 billion dollars a year, being the top ranking profitable business in the black market.<sup>(17)</sup> There is a variety of factors encouraging counterfeiters to infiltrate the medicine market. The demand for medicines is infinite. The costs for production are low, because one can use cheap substitutes or no active ingredient at all. Furthermore, expenses for manufacture are low when the production takes place in e.g. some kind of a dirty backyard or a small cottage industry. Since counterfeiters do not maintain cost intensive systems for quality assurance and Good Manufacturing Practices, their expenses are reduced additionally. All in all, considering the low costs for the manufacture of counterfeit medicines in comparison to their high value on the market, the profit to be made is huge. And while the profit in illegal trade of falsified medicines is extremely high, the risk to be apprehended and prosecuted is rather low. Moreover, the penalties are not of such scale to deter counterfeiters.<sup>(18)</sup>

If there is a competent national drug regulatory authority established in a country to control the manufacture, importation, distribution and sale of medicines, it is more difficult for counterfeiters to infiltrate the national distribution channels. But, at present, this is the case in only about 20% of the WHO member states. The remaining member states have a less developed drug regulation or none at all. For that reason, the amount of illegal or falsified medicinal products on the market is higher in these countries.<sup>(18)</sup> Other reasons for a greater amount of counterfeit medicines in the market, especially in the developing countries, could be a huge demand of medicines that already exceeds the available genuine product supply or the fact that many people are not able to afford expensive medicines and purchase less expensive drugs. In the developed countries

the reason for purchasing medicines from dubious sources may rather be driven to bypass prescription or intended misuse of medicines.<sup>(18)</sup>

### 3.2 The Internet and Mail-order sales

The Internet has become the criminal pusher's best friend with respect to falsified medicines. In over 50% of cases, medicines purchased over the Internet from illegal websites that conceal their physical address have been found to be counterfeit.<sup>(15)</sup> Moreover, they are available to everyone, even to teenagers and children, since these illegal websites have no mechanisms to block children to access or purchase prescription drugs as the CASA-Study "You've Got Drugs!" on the diversion and abuse of prescription drugs revealed. Even when the identification of the patient's age is required to access the website, it is just as easy to key in a fake age to the form.<sup>(19)</sup> Facts like that make it much more complicated e.g. for parents to comply to the warning "keep out of the reach of children", let alone the potential adverse effects in children caused by illegally sold and likely counterfeit or substandard medicines, or the abuse or misuse of genuine illegally sold prescription drugs.

In Germany the mail-order business concerning medicinal products was legalized in 2004 in accordance to the 12<sup>th</sup> amendment of the AMG. In the course of this the occurrence of counterfeit medicinal products increased swiftly.<sup>(20)</sup> The German customs seized 500.000 falsified tablets and capsules in 2005 and with about 5 million counterfeit drugs in 2009, already the ten fold.<sup>(21)</sup> The EU-Committee reports an amount of more than 11 million falsified medicinal products seized in the EU in 2009.<sup>(20)</sup> Furthermore, it has to be considered that there is a huge estimated number of unknown cases. The Internet is the main source of supply with regard to counterfeit medicinal products.<sup>(21)</sup> Round about 95 percent of the internet pharmacies are illegal as the BfArM reports.<sup>(22)</sup> Today, it is no longer difficult to create your own website, therefore persons or organizations with sufficient criminal incentive can easily set up a website undermining security features, and thus, pretending to be an authorized internet pharmacy.<sup>(23)</sup> Unfortunately, when the mail-order business was legalized, the German Government did not implement a specialized competent authority which constantly observes internet pharmacies and checks their legality.<sup>(24)</sup> At present, institutions such as the DIMDI, the

BKA and the ZL are involved in observing and checking internet pharmacies<sup>(21)</sup> but such efforts remain limited whereby the risk for patients to purchase counterfeit or substandard medicinal products from non-authorized internet pharmacies maintains rather high. On top of this, many patients are not aware enough of the risk concerning counterfeits.

Low prices and the anonymity given in the Internet keep many people stick to internet pharmacies to save money or to avoid the doctor's consultation on sensitive topics such as erectile dysfunction or incontinence, etc. Other reasons may be to reach out to drugs for misuse e.g. anabolics or narcotics. In these cases most of the patients most likely will not report the occurrence of an adverse drug effect or lack of drug effect after using the medicines.<sup>(21)</sup> Due to the lack of adverse event reporting related to suspect counterfeits, signal detection is hardly possible and appropriate actions, e.g. to warn other patients, cannot be initiated. For that reason, it is indispensable to raise people's awareness of the hazard to patient's welfare and public health caused by counterfeit medicines and purchase from illegal sources.<sup>(22)</sup>

### 3.3 Anti-counterfeiting measures and outlook

The WHO reacted to the enhancing hazard caused by counterfeit medicines by launching the IMPACT, the International Medical Products Anti-Counterfeiting Taskforce, in 2006, which is a partnership including e.g. international organizations, drug regulatory authorities and pharmaceutical manufacturer associations. It is the IMPACT's aim to combat the production and distribution of counterfeit medicinal products by building coordinated global networks between countries.<sup>(25)</sup> Together with Interpol and the WHO, the IMPACT was involved in the, at present, three international operations against the illegal trade of medicines over the Internet, called Pangea I, II and III.<sup>(26)</sup> The first operation, carried out in 2008, counted 8 countries that took part. In 2009 already 24 countries cooperated during the week of Pangea II<sup>(26)</sup> and in 2010 Pangea III counted more than 40 countries joining the combat against counterfeiting and the illegal trade of medicines.<sup>(27)</sup>

Each time, Interpol, the WHO and the IMPACT, as well as national drug regulatory authorities, customs and the police worked together for one week to inspect internet

pharmacies and their websites, Internet service providers and mail services. A huge amount of illegally distributed and falsified medicinal products could be seized, many non-authorized internet pharmacies identified and many website closed down.

In the scope of the Pangea operations additionally is to sensitize the public to the problem of counterfeit medicines and the extensive risk to patient's health that they constitute.<sup>(26)(27)</sup>

The AMG § 43<sup>(2)</sup>, combined with the ApoG § 11a<sup>(28)</sup>, stipulates that only community pharmacies, holding permission of the competent authority, are allowed to run an internet pharmacy which has to be reported to the DIMDI that lists all authorized internet pharmacies in Germany. Such an authorized pharmacy can implement a security symbol, licensed by the DIMDI, that identifies it as legal. Unfortunately, most of the people just know that licensed internet pharmacies have a security symbol to be identified as licensed, but they do not know how it looks like so that a falsified symbol can easily be used to deceive patients and to make them feel safe about the authenticity of the, in this case, non-authorized internet pharmacy.<sup>(20)</sup>

The problem of patients not being able to differentiate authorized internet pharmacies from non-authorized internet pharmacies remains unless the drug regulatory authorities, with the aid of physicians and pharmacists, will not enhance people's knowledge and awareness with respect to this issue. The hazard to patient's welfare is not to be underestimated. Mystery shopping, as the German ZL performs, shows that patients can purchase any prescription drugs via Internet without having a prescription, but none of the delivered products were genuine or with authorization for Germany. 50 to 60 percent of the lifestyle drugs were falsified or substandard.<sup>(21)</sup>

The new "Pharmaceutical Package", initiated by the European Parliament, is about to pose the next step in combating the distribution of counterfeit medicinal products in the legal and the illegal distribution chain. It comprises measures to improve the efficiency of pharmacovigilance systems in the EU by performing an international Union database, called "EudraVigilance", managed by the Agency. Hence, an international surveillance and exchange of information about adverse drug reactions will be available. All Member States are constrained to have a system in place to collect and handle all notifications of

suspected counterfeit medicines as well as suspected quality defects to prevent potential dangerous medicinal products from reaching the patient. The information about medicines under suspicion to present a serious risk to public health must be transmitted from the Member State of occurrence to all other Member States without any delay.

Furthermore, the opportunities to retrace medicinal products are extended by affixing identifying marks, called 2-D Matrix code, on the outer packaging which is readable by a scanner so that the hidden information about e.g. product's name and strength, country of origin, pharmaceutical manufacturer, batch number and expiry date, i.e. the authenticity of the product, can be verified and a double or adulterated package identified. To adhere to the cost-benefit ratio the 2-D Matrix code will not be applied to all medicines. Only prescription medicines, with a few exceptions, and some non-prescription medicines, assessed to be at risk of falsification, will be provided with this safety feature.

Concerning internet pharmacies offering medicinal products for sale at a distance the "Pharmaceutical Package" comprises new regulations as well. All pharmacies intend to offer medicines for sale at a distance need to have authorization according to national legislation where the pharmacy is established. The person or body running the pharmacy has to inform the Member State about certain indications, such as name and address of the place of activity, address of the website, starting date of activity. Moreover, every licensed website has to contain the common logo that shall be established and be recognizable throughout the EU. Therefore, the Member State authorities and the Agency will promote information campaigns on the function of the common logo and in general on the dangers of counterfeit medicines supplied illegally via Internet. These campaigns shall enhance consumer awareness of the hazard related to falsified medicinal products.

In addition, the Member States shall ensure that effective, proportionate and dissuasive penalties to punish counterfeiters are implemented.<sup>(29)</sup>

#### 4. Aim of the Thesis

The pharmacovigilance system is requested to insure patient's health by collecting and evaluating information concerning medicinal products after their marketing authorization, to monitor for potential signals and to define and implement risk mitigation measures. In this context, it is essential to uncover possible hazard to patient's welfare with regard to counterfeit medicines and to take appropriate actions so as to protect patient's safety and to sustain patient's trust in the quality of genuine medicinal products.

With regard to pharmacovigilance counterfeit drugs are able to create a bias of the safety profile of genuine products, since all received information about adverse events or lack of drug effects is accounted to be caused by the genuine product and is added to its risk-benefit profile regardless whether the event was caused by the genuine product itself or a counterfeit drug. It is the difficulty and a challenge, as well, to identify adverse event case reports related to counterfeit medicines in order to differentiate these reports from ones related to the genuine products.

Therefore, established methods for signal detection within pharmacovigilance and complaint management should be investigated for its options to utilize and improve the tools for signal detection of counterfeit drugs.

Information about the actual amount of case reports potentially related to counterfeit drugs in pharmacovigilance should be compiled and the consequent bias concerning the genuine product's risk-benefit profile assessed. Based on the available information from different sources an approach to estimate the potentially volume of counterfeit medicines of a given drug product on the market could be developed.

In this context, the company internal processes of case receipt and case processing should be evaluated for their capability and efficiency with regard to the identification of counterfeit related case reports.

Depending on the various types of falsification and manipulation of medicines, counterfeit drugs pose a big problem in our today's world but with a different threat to

patient's welfare. Therefore, the types of falsification should be characterized and their potential impact on patient's safety dependent on the risk profile should be explored.

By analyzing examples of past incidents referring to falsified medicinal products, the extent of damage counterfeit medicinal products already caused to patients and to economy should be outlined.

Moreover, available technologies which could be used to identify counterfeit medicinal products should be presented and evaluated for their suitability and usability in varying areas e.g. company headquarters, affiliates in the different countries, pharmacies or directly at the consumer level. This should be discussed by means of an evaluation of capabilities and limitations of the different technologies as well as the demands at the different user levels.

As public awareness plays a key role in anti-counterfeiting strategies, an analysis of the people's understanding, knowledge and attitude towards the counterfeit problem could be performed and used in the development of adequate communication measures which may also enhance counterfeit reporting by health care professionals and consumers.

If possible, a benchmark with other companies may be conducted on the handling of counterfeit issue and its signal detection within pharmacovigilance.

The thesis should comprise a comparison of the regulations according to pharmacovigilance systems in different countries. Moreover, an outlook on upcoming regulatory requirements should be developed with regard to counterfeit surveillance, reporting and corrective actions in collaboration with competent authorities.

In addition, actions already done by drug regulatory authorities, pharmaceutical companies and other stakeholders of the health care system could be presented and a variety of further actions discussed.

## 5. Methods

The information source for retrieval and subsequent analysis of data concerning adverse event and lack of drug effect reports will be the company's internal global pharmacovigilance and technical complaint data bases. The data evaluation should include the number of case reports per time period, country/region and product/product groups, and reporting rates of adverse events and complaints possibly related to counterfeit medicinal products. The confirmed counterfeit cases should be evaluated specifically with respect to the reporter country, the source of supply (e.g. the Internet, the legal distribution chain) and the events reported. In terms of signal detection algorithms such as e.g. PRR and Chi-square distribution can be used to sort out and evaluate data.

Existing local and global procedures and systems in place for case receipt and processing should be reviewed and analyzed e.g. by means of a process mapping. Cause-and-effect diagrams can be used to identify key success factors and improvement options of the current procedures e.g. collecting the necessary information to identify counterfeits. In order to include potential local differences in the analysis, a representative number of local procedures (SOPs) should be reviewed. In addition, an appropriate questionnaire could be developed and used to retrieve feedback from the affiliates and sales force units on relevant process and system factors in place.

Analysis of consumer behaviour could be conducted in collaboration with internal expert functions e.g. marketing, market access and by utilization of standard tools e.g. public interviews and surveys with respect to knowledge and awareness of counterfeit drug products, perceptiveness and sensitivity towards warnings and precautionary communication.

Thorough literature research on regulations and publications regarding established and upcoming requirements concerning counterfeit surveillance, as well as exchange of views with internal and external key opinion leaders in pharmaceutical industry, regulatory, or academia should be performed.

## 6. Abbreviations

<b>AMG</b>	Arzneimittelgesetz (German Medicinal Products Act)
<b>AMK</b>	Arzneimittelkommission (German Commission on Medicinal Products)
<b>ApoG</b>	Apothekengesetz (German legislation about the practice of pharmacies)
<b>BfArM</b>	Bundesinstitut für Arzneimittel und Medizinprodukte (German Federal Institute for Drugs and Medical Devices)
<b>BKA</b>	Bundeskriminalamt (German Federal Criminal Police Office)
<b>BMG</b>	Bundesministerium für Gesundheit (German Federal Ministry of Health)
<b>DIMDI</b>	Deutsches Instiut für Medizinische Dokumentation und Information (German Institute of Medical Documentation and Information)
<b>EMA</b>	European Medicines Agency (“the Agency”)
<b>EU</b>	European Union
<b>IMPACT</b>	International Medical Products Anti-Counterfeiting Taskforce
<b>PRR</b>	Proportional Reporting Ratio
<b>PSUR</b>	Periodic Safety Update Report
<b>SOP</b>	Standard Operating Procedures
<b>UMC</b>	Uppsala Monitoring Centre (The WHO Collaborating Centre for International Drug Monitoring)
<b>US</b>	United States
<b>WHO</b>	World Health Organization
<b>ZL</b>	Zentrallaboratorium Deutscher Apotheker e.V. (German Official Medicines Control Laboratory)

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