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BUKO Pharma-Kampagne

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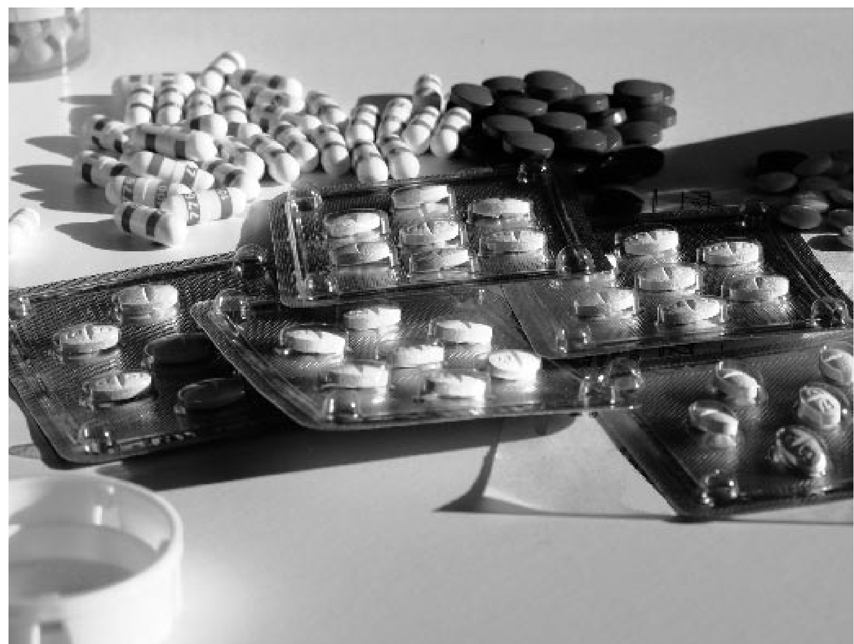
Counterfeit medicines – what are the problems?

Reports on counterfeit drugs are mushrooming. How frequent are fake drugs in reality and which health risks do they mean for people in developing and industrialized countries? What is at stake and what are sustainable solutions?

Reports on fake drugs are frequent: An adulterated fever syrup in Haiti which kills dozens of children, in the internet drugs against erectile dysfunction are for sale which contain only wheat flour. Recently World Health Organization (WHO) and big pharma jointly founded the *International Medical Products Anti-Counterfeiting Taskforce* (IMPACT).

Are fake drugs the most pressuring issue for world health? Certainly not, the biggest problem is that one third of the world population still has no regular access to essential drugs – not to talk about healthy living conditions. If one talks about drugs they must be the right ones and of good quality. Therefore it is important to know where, how often and why fake drugs emerge. Little is known about that.



It is not always easy to find out whether a medicine is safe, fake or of poor quality. Photo: ©Tom Oliveira /Fotolia

This Pharma-Brief Special gives an introduction (p 2) but also scrutinizes the rationale behind frequent arguments. In that context we take a closer look at the role of industry (p 7).

We present the results of a survey among German pharmaceutical companies and aid organisations, which Andrea Ungersbäck did as a master thesis (p 5). On page 10 we give an overview about data on counterfeit drugs and last but not least you will find a brief assessment of the new task force IMPACT (p 11). The bottom line: to really have an impact all measures against counterfeiting must actively involve actors from the countries most affected. And without securing access to essential drugs for everybody even the most ambitious strategies against counterfeits will have little impact.

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Drug counterfeits – A complex problem

The subject of drug counterfeits is quite a contemporary issue. This is not really surprising, since no one wants to receive an inefficient or hazardous drug. Many questions are connected with this problem: where do counterfeits appear, what are the risks involved, how frequent are they, who makes them, what are the reasons and what can be done against them?

On the international level, there is not even agreement on the definition of what a counterfeit is. A paper of the World Health Organization (WHO) admonishes that "a wider consensus on the definition of a counterfeit drug is needed".[1] According to WHO even collecting data would otherwise be difficult – let alone measures to combat such counterfeits.

What may sound banal at first glance is not that easy. Depending on the interests of the parties involved, counterfeits are defined in a different manner. The neo-liberal private *Center for Medicines in the Public Interest* (CMPI)[2], for instance, also counts the parallel imports of drugs – which is legal and well under control in the European Union – among counterfeits.[3] Such statements are usually influenced by big pharmaceutical companies, who – with an eye on their profit – sell their brands in each country at different prices (i.e. the maximum price which can be obtained on the local market). The manufacturers do not like at all if these price differences are used to import products from the cheapest EU country to another state, where the manufacturer sells the same product at a higher price. It is, however, alarming that the WHO continues to rely on the CMPI figures.[4] On the other hand, however, the WHO has recently advised against "using a single average figure for global proportion of counterfeit drugs", because, apart from being "inaccurate" it also "blurs the real picture and can mislead the public."[5]

What is a counterfeit?

As there is no satisfactory international definition of a drug counterfeit, the question must be approached from different angles. What counts for the patients is whether or not the drug actually contains the active substance indicated on the package and that it is of good quality. This definition does not include counterfeits where the drug does not originate from the manufacturer indicated on the package although its quality is alright.

The (preliminary) definition of the WHO reads "A counterfeit drug is a medicine, which is deliberately and fraudulently mislabelled with respect to identity and 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."[1]

The WHO definition thus excludes drugs with unintentional quality deficits resulting, for example, from production errors. However, these can have the same serious health consequences for the patients as intentional fakes. Nevertheless is a demarcation of counterfeits versus quality deficits important (even if the limits may be blurred). Lack of quality can best be remedied by improved supervision of manufacturers, this is not feasible in case of intentional fakes, since the true source is deliberately disguised.

The multinational pharmaceutical industry utilises the discussion about counterfeits not only to secure the sales of its expensive products but also to denigrate the unloved competition of low-cost generic drugs.

The term counterfeit is therefore quite frequently used by the industry in connection with the violation of intellectual property rights – i.e. with patent protection. This is, of course, a totally inappropriate connotation, which has nothing to do with a patent-oriented definition of counterfeits. (For more details on the role of the industry, please see page 7)

Where can counterfeits be found?

Drug counterfeits are probably more common in Third-World than in industrialized countries. However, there are no exact figures (see p 10). The German Pharma Health Fund (a non-profit association of the German pharmaceutical industry) commented on this: "Lack of control, the understandable reluctance of the manufacturers involved and the fact that drug counterfeits eventually fall under organized crime assume that the true scale of the problem is still in the dark."[6]

Specific problem areas are, however, obvious: non-regulated markets, especially in poorer countries, are an open gateway for counterfeit drugs. The few investigations which are known particularly point to problems involved in street sales of drugs. Wherever there is a lack of skilled pharmacists, private pharmacies are no absolutely safe source of supply. On the other hand, only sporadic counterfeits or quality deficits have been reported in connection with the public health sector. In

countries where the public health system only caters for a small proportion of the population or where it does not provide the medicines, a non-regulated market implies a considerable health risk for a great number of people.

Counterfeit medicines of drugs restricted to sale only under the supervision of a pharmacist are obviously extremely rare in industrialized countries. The German Federal Criminal Police Office reported as few as 28 suspicious cases between 1996 and February 2004, the majority of them package fakes.[7] A different picture presents itself for the internet trade, where counterfeits have been found more frequently, especially in connection with expensive, prescription-only lifestyle preparations.

Another grey area are "almost drugs", i.e. food additives and other miracle drugs assumed to have a therapeutic effect. Here especially the allegedly pure herbal products which stand out because of secretly added prescription-only substances. Such drugs are often offered on the internet.[8] Illegal preparations – mainly anabolic steroids – are traded in the field of bodybuilding, although most of the buyers should be aware that they are skating on thin ice here.

Poisonous paracetamol syrup in Haiti Who is responsible?

The case of toxic paracetamol syrup in Haiti which is often cited in literature shows how complex the discussion about counterfeits is. What are the facts? In 1996 at least 88 children died after taking paracetamol syrup which contained high amounts of diethylene glycol (used as automobile antifreeze). The drug was produced by the Haitian company Pharval using glycerine from the Dutch company Vos BV. Pharval trusted the labels certifying that the substance was "GLYCERINE 98 PCT USP". Vos BV is a 100% subsidiary of the German company Helm AG. Vos BV knew that the glycerine was highly impure and contained less than 54% of glycerine instead of 98% as stated on the label. The Dutch company received the results of the laboratory test before the shipment arrived in Haiti. But they did not warn the recipient Pharval at all.[1]

Further investigations by journalists uncovered that the contaminated glycerine was most likely produced by Sinochem in Peking. At that time Helm AG owned one third of Sinochem. Helm has not a very good reputation. E.g. the company faked quality certificates for drugs delivered to Botswana.[2]

Who is responsible for the death of the children? The Haitian producer of the syrup? Vos BV which mislabelled the raw material? The company which originally produced the substance? Helm AG which loves to label its products with "Made in Hamburg, Germany" and owns two of the actors? The authorities in China, Germany, The Netherlands and Haiti because they did not feel responsible or did not check the companies involved properly? (JS)

1 UN Commission on Human Rights. Fifty-fifth session. Item 10 IIIA. 20 January 1999 www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/50b343de843b83f28025672e004288ba?Opendocument

2 Fälscher unter uns. *Pharma-Brief* 5/1997, S. 1-3

Money counts

Especially expensive branded drugs are popular among counterfeiters, since they promise high profit margins.[9] Branded drugs with prices of 10, 20, 30 or even 50 US-dollars per package are a popular target of counterfeits. While the costs involved in copying an original preparation are usually very low, the achievable profit margins are correspondingly high. Only narcotics traffic offers such easy profit – and medicines have the decisive "advantage" of being more easily channelled into the market, since they are basically legal products.

However, the more expensive generics do not escape counterfeiting either, provided they are used frequently. A study carried out in Southeast Asia on the essential anti-malarial drug artesunate revealed that 38% of the samples bought in stores did not stem from the indicated manufacturer Guilin Pharma (China) and did not contain any active substance.[10] In Cambodia, a pack of artesunate costs 1.50 US-dollars, which may seem little to us, but is a huge amount of money in view of an average annual income of 300 US-dollars.[11] Cheap generics, on the other hand, are hardly at risk of being faked.

Are counterfeits the main health risk?

Paradoxical as it seems, counterfeits may at times have advantages. An older WHO data bank on counterfeits shows that the painkiller Novalgin® was among the most popular objects of counterfeiters and that the tablets contained no or a different active substance. Since the original drug contains the risky active substance dipyrone, which is banned in many industrialized countries, such counterfeits may even protect patients.

This example illustrates that the subject of drug counterfeits must be considered in a wider context. Medicines with too little or wrong active substances are only one of a multitude of problems preventing the rational use of drugs. Irrational medicines offered by multinational manufacturers on the markets of the Third World certainly are a higher health hazard. A study performed by BUKO Pharma-Kampagne shows that German manufacturers, for example, offer 39% of irrational, i.e. poorly efficient or even hazardous drugs in countries of the Third World.[12]

However, the best medicine makes no sense unless it is used appropriately. Limited lists of indispensable drugs and a continuous education independent of the industry are a prerequisite for the rational use of drugs. For about one-third of the world's population, high prices continue to pose an insuperable obstacle preventing them from getting the drugs they need.

What can be done?

As it would go beyond the scope of this publication to list all possible measures against counterfeits, we only indicate some major issues which are not exhaustive. A central issue are the high prices for pharmaceuticals and the fact, that patients in many countries have to pay for the drugs by themselves. Radical price cuts and the support of public health systems could abolish the major part of the counterfeit problem and, by the way, the quality problem as well. Low prices make counterfeiting unattractive. If patients do not need to pay for medicines, they will not try to buy them as cheap as possible from unreliable sources. A central supply would make quality control significantly easier. The limitation to a clear selection of essential drugs would reduce the confusing complexity, facilitate controls, storage and distribution and improve treatment.

Besides, control measures are of course indispensable. Import, manufacture and distribution of medicines need to be controlled and violations efficiently avenged. If counterfeits appear, the public must be warned without delay. (JS)

1 WHO. Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation. 27 January 2006
2 The CMPI does not act in the „public interest". In the contrary the majority of the advisory board consists of high rank people from neo-liberal think tanks which pledge for free markets and de-regulation and former members of the Reagan and Bush administrations.
3 21ST Century International Drug Terrorism. Testimony by CMPI Director, Peter J. Pitts, to the [US] Government Reform Committee Subcommittee on Criminal Justice, Drug Policy and Human Resources, November 1, 2005 www.pacificresearch.org/pub/sab/health/2005/21_Century_Counterfeiting_Testimony.pdf
4 WHO. Counterfeit medicines. Fact sheet N° 275. Revised February 2006 www.who.int/mediacentre/factsheets/fs275/en/ accessed 1.2.2007
5 WHO IMPACT. Counterfeit Medicines: an update on estimates 15 November 2006 www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf accessed 16.1.2007
We advise against using a single average figure for global proportion of counterfeit medicines because, besides being necessarily imprecise (i.e. not reproducible in subsequent studies) and inaccurate (i.e. not reflecting the actual value), a single global ratio blurs the real picture and can mislead the public.
6 GPHF. Arzneimittelfälschungen – Ein skrupelloses Geschäft. www.gphf.org/web/projekte/minilab/hintergrund_arzneimittelfaelschungen.htm accessed 1.2.2007
7 MSD. Mögliche Fälschungsformen. www.medikamentenqualitaet.de/gefahr/form_2200.html accessed 1.2.2007
8 Nahrungsergänzungsmittel aus dem Internet. *Gute Pillen – Schlechte Pillen* 6/2006, S. 8-9
9 SEARPharm Forum. A report on Database on Incidents of Counterfeit Medicines in the WHO-SEA Region. (South East Asian FIP-WHO Forum of Pharmaceutical Associations) New Delhi 28 December 2004 p 2
10 Paul Newton. Fake artesunate in southeast Asia *The Lancet*, Vol 357, 16 June 2001 p 1948-1950
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12 Jörg Schaaber et al. Data und Facts 2004: German drugs in the Third World. BUKO Pharma-Kampagne, Bielefeld 2004

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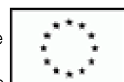

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What pharmaceutical companies say about counterfeits

In her thesis at the University of Applied Sciences, course of studies "Health management in the tourism industry" (FH Joanneum, Bad Gleichenberg, Austria), Andrea Ungersbäck investigated the subject of drug counterfeits.[1] She interviewed pharmaceutical companies and humanitarian relief organisations in Germany on the phone and by questionnaire. These are the most important results.

A comprehensive review of the bibliographic data bank MEDLINE preceded the interviews. Ungersbäck concludes, among others, that there is no worldwide standard definition of the term drug counterfeit and that it is particularly the demarcation of the terms "drug counterfeit" and "sub-standard product" (non-compliance with required guidelines such as Good Manufacturing Practice or Good Storage Practice) which are not clear. In most European countries there is not even a definition of drug counterfeits.

In the USA, Nigeria or Pakistan, drug counterfeits are defined by the legislator, however, different from the WHO, which distinguishes counterfeits from sub-standards and describes them as a deliberate and intentional action.

When is a fake a fake?

The US definition explicitly includes sub-standards.[2] The Nigerian law also summarises counterfeits and sub-standard products as "any product which is not what it pretends to be." The Pakistani Drugs Act, on the other hand, defines counterfeits exclusively as package fakes, which resemble or copy the label or packaging of a pharmaceutical manufacturer.[3]

Secretiveness harms

In the USA the industry made a voluntary commitment in 2003 to report all cases of counterfeits to the FDA within 5 days after taking note of them. However, there is no statutory obligation of pharmaceutical companies in any country of the world to report drug counterfeits. In Brazil, for example, information on fake contraceptives was withheld by Schering do Brasil, for 30 days.[4] In Ghana, Glaxo Smith Kline prevented a public warning concerning counterfeit halofantrine syrup.[5] Such secretiveness is not seldom, says Ungersbäck, because the companies want to prevent trust in their branded products from dwindling and resulting turnover losses.

Meagre data situation in the literature

No wonder that the data material is meagre where definitions of circumstances are unclear and information is kept secret. The Pharmaceutical Security Institute (PSI), an international association of pharmaceutical manufacturers to combat drug counterfeits, keeps a data bank on drug counterfeits. While it mainly contains reports of its member companies, PSI grants neither the WHO nor the health authorities, let alone the public, access to its data. Interpol collects cases, but does not disclose data without the consent of the member states. Governmental authorities like the FDA often have no data other than those of the WHO or PSI. While PSI reported 76 cases of drug counterfeits in 2004, the FDA speaks of 58 cases.

Methodology of the study

To investigate the status quo of degree, causes, consequences and promulgation of drug counterfeits all over the world, pharmaceutical companies and German relief organisations were interviewed within the scope of the above-mentioned thesis. The aim was to provide information on cases of drug counterfeits within the framework of internal drug supply and in the project environment in developing countries.

Half of the pharmaceutical companies included in the survey are member companies (total 39) of the German Association of Research-Based Pharmaceutical Companies (VFA) the other half were selcted from the drug study "Data and Facts 2004: German drugs in the Third World" of BUKO Pharma-Kampagne (total 33). Thirty-six companies, i.e. half of those available, were selected by random procedure from the two data banks. The contacts were identified on the phone and online questionnaires forwarded to them.

The 12 relief organisations interviewed were selected from the member data bank of VENRO, an association of German development NGO's, with the commitment in the health sector being the major criterion. The respective contact at the organisations was identified on the phone, and the interviews finally carried out in January 2006 with the help of a discussion guideline.

The industry stonewalls

The results of both polls must be described as limited. Eventually only 28 per cent, or as few as ten questionnaires, were returned. There were different reasons for this. Half of the interviewed companies said they were not affected by counterfeits of their products. Confidentiality and data protection prevented disclosure in many cases. When contacted on the

phone for the first time, already four companies refused to participate in the poll. Within the further course of the study, another 22 companies refused to participate. Ten companies claim scarceness of time as a reason, ten further companies said they had no experience with drug counterfeits, no contacts or no data available, three companies referred to data protection, one said they were not interested in the subject (partly multiple answers). Four companies did not give any reasons for not responding, not even after repeated contact. The experiences of Ms. Ungersbäck mirror those of a group of scientists which asked 21 international drug companies about counterfeits and yielded only four useful responses.[5]

German relief organisations are not aware of drug counterfeits within the scope or environment of their projects. The relief organisations interviewed are, however, frequently not active themselves in the developing countries but rather cooperate with local partner organisations. Interviews in the countries would most probably draw a different picture, says Ungersbäck.

Answers from companies

All companies which returned answers (10) had an officer responsible for drug counterfeits, 50 per cent even in their foreign subsidiaries. Half of the companies had been confronted with product fakes during the three years before, three companies had been affected by more than 20 cases, two companies by six to ten cases.

None of the companies revealed details on counterfeits of their products in the third world. All counterfeit cases – except one concerning an anti-retroviral drug – were about lifestyle drugs and typical high-priced products from industrialized countries.

Concerning their subjective assessment of measures against drug counterfeits, the companies primarily focused on new technologies. Investigating the source, method and degree of the counterfeits ranked second, followed by educational campaigns of the patients, tests in the distribution chain or raids in cooperation with governments. The participation in conferences and meetings was considered as little effective.

Expensive branded products faked

Among the faked medicines, drugs against AIDS, impotence, osteoporosis or loss of hair were mentioned. All five companies involved confirmed that the counterfeits concerned preparations for which there was no generic alternative and particularly more recent branded preparations. Two companies also confirmed that so far only package fakes had occurred. All cases had been reported by the companies to the local authorities. 80% of the companies had reported to the ministry of health of the country, the distribution chain and the media. None of the companies had reported to the World Health Organization (WHO).

In 80% of cases the counterfeiters could be identified. Only one company specified the financial damage: the turnover loss, they claimed, accounted for two million euros in Germany and additional cost of 500,000 euros for the information to the distribution channels. The total damage made up 10 per cent of the total turnover of the product involved.

Conclusion

Pharmaceutical companies seem to cooperate well with the national authorities and governments, concludes Ungersbäck. Cases of counterfeits were mutually communicated. This may contribute to the fact that most counterfeiters can be identified. Almost all companies said that they reported to the public and the media. It would be interesting to verify this statement, says the author.

Her conclusion: the companies' lack of readiness to provide detailed information on cases of counterfeits which occurred limits the results of her poll. The companies attach more importance to confidentiality of data than to educational campaigns to the public. In view of the potentially dramatic consequences which drug counterfeits may have on the health of the population it is astonishing that there are hardly any publications of high methodical quality on this explosive topic – the literature mainly offers case studies, media reports or letters. The health consequences and costs of drug counterfeits have not been systematically investigated either, says the author.

We conclude that a thorough data collection is therefore a task which the WHO should look into. Because it is only sound, publicly accessible and comprehensive data which allows for the right conclusions and the development of efficient solution strategies. (CJ)

1 Andrea Ungersbäck. Arzneimittelfälschungen. Befragung von Pharmafirmen und humanitären Hilfsorganisationen in Deutschland. Diplomarbeit (MA) eingereicht am 6.9.2006 Bad Gleichenberg (Austria)
2 FDA – Food and Drug Administration. (2003). FDA´s Counterfeit Drug Task Force Interim Report. accessed 16.9.2005 www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html
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4 Csillag, C. (1998). Epidemic of counterfeit drugs causes concern in Brazil. Lancet. Vol. 35 :p 553
5 Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ (2005) The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers. March 14, 2005 http://medicine.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pmed.0020100

Counterfeits as a marketing instrument?

The role of the industry

The pharmaceutical industry is somewhat ambivalent about counterfeits. For one thing, counterfeit medicines involve a turnover loss, for another, exposing such copies might reduce trust in the original product thereby even increasing the financial damage. Another problem is the instrumentalisation of counterfeits by the big pharmaceutical companies who suggest that they are the only ones who can produce high-quality drugs and that with generics you never know. At times, however, the fuss that the industry makes about counterfeits could be nothing but a red herring.

It is not surprising that especially companies with expensive products are concerned about counterfeits. What is indeed a problem is the selective perception – at least as regards the public image. The companies' very own interests cannot be denied with regard to the reasons quoted for counterfeits and the solutions suggested to combat them.

An indispensable step towards a reasonable problem analysis is the accurate knowledge of type and frequency of counterfeits. While companies tend to discuss the general topic excessively, they are rather elliptical when it comes to details. Chris Jenkins, founder-director of Pharmaceutical Security Institute (PSI; for details see below), comments this phenomenon as follows: "It is necessary to keep fake drug information confidential for commercial reasons […] to avoid media leaks and to prevent the possibility of rival drug companies taking unfair commercial advantage of a victim company. […] If a patient came to harm as a result of a counterfeit product, the company's good reputation is in danger of disappearing, together with a loss of confidence in the products […] the importance of meeting sales' targets is such that you can even find cut-throat competition between different operating divisions of the same company, let alone between two companies competing in the same market with similar drugs."[1]

The cases of fake halofantrine syrup (Halfan®) in West Africa illustrate the industry's attitude. The authority in Ghana discovered the faked children's syrup of this antimalarial, prepared a warning to the public and informed the manufacturer, GSK, who then even sent an officer from London, who took samples and urgently requested the authority to abstain from warning the public, as this would damage the company's reputation. – The parents of the little patients were left in the dark about the risks their children were confronted with.

Counterfeits of Halfan® Syrup also appeared in Sierra Leone and Nigeria and it is disputable whether the manufacturer informed the countries. The Nigerian Drug Authority NAFDAC discovered the counterfeits all by itself and immediately informed the public. Dora Akunyili, head of NAFDAC, gave the following reasons: "It is more dangerous not to alert the public. We will still issue a warning even if we find it in only one shop. If you find any fake drug product in only one shop you can be sure it is in many villages. We don't defend companies. We are defending the people"[2] The Schering company ran into problems with the Brazilian authorities in 1998, because it had kept secret that it had found oral contraceptives containing nothing but wheat flour.[3]

In view of the companies' (and at times also the authorities') secretiveness, it is not astonishing that a great number of reports on counterfeits are owed to investigative journalism. Although GSK knew about the Halfan® fakes in the three countries, the manufacturer did not inform the public anywhere. Its was a BBC radio programme which disclosed the affair.

Even the authorities are not necessarily informed about counterfeits, and this is not mandatory in many countries. In the USA, the industry did not make a voluntary commitment before 2003 to report all cases to the FDA within five days, and similar agreements are only known to exist in few other countries.[3] At the International Conference of Drug Regulatory Authorities in Madrid in February 2004, it was stated by the WHO that "the drugs industry had a great deal of data but was 'very reluctant to make them available'".[4]

Although the big companies collect information on counterfeits, they largely do so in secret. The *Pharmaceutical Security Institute* (PSI),[5] an institute specifically founded by the fourteen biggest companies to combat counterfeits, is particularly close-lipped when it comes to this topic. Its website does not even reveal which companies are among its meanwhile 21 members, let alone information on specific cases. Not only scientists are denied information from the allegedly largest data bank on drug counterfeits, the affected countries and the World

Health Organization (WHO) do not learn anything either. PSI only "encourages" its member companies to report to the authorities.[3] However, it is not possible to efficiently combat counterfeits without good information.

The lie about generics

At times, the threshold between generics, quality deficits and counterfeits appears to be blurred in the arguments of the industry. Under the headline "Counterfeit Q&A", the US company Pfizer, for instance, recommends that its patients join a patient organisation to "seek advice from them on […] the effects of switching to generic or different formulations" and on "your rights to refuse any medicine you are not confident in or are confused about."[6] It has to be emphasised in this context that generics in industrialised countries are generally of the same quality as the branded products since they are subject to the same strict quality controls. Quality problems do occur from time to time, however, also with branded products. The US company Warner-Lambart, a member of the Pfizer Group, for instance had to recall 33 product batches in the USA in 1994/95, nine of which concerned phenytoin, which is mainly used against epileptic seizures. In seven batches, the release of active substance was insufficient with potentially severe consequences for the patients.[7]

Patents and counterfeits

The industry causes additional confusion by their positioning of patent-protected medicines. According to the TRIPS Agreement of the World Trade Organization (WTO), poor countries are permitted to copy patent-protected medicines by means of compulsory licences. IFPMA director Harvey Bale has recently made the following comment on Thailand's announcement of producing affordable AIDS medicines themselves: "Compulsory licensing can be a route to commercial abuse and can put patients at risk."[9] It is thus not only Thailand's legitimate right to affordable medicines which is questioned, but also the quality of the products.

An isolated incident of 2002 shows that it is also the big companies who may become victim of their own price policy. A consignment of AIDS medicines of the British manufacturer GSK, which was meant to be supplied at reduced prices to Senegal, showed up in the Netherlands and Germany. A criminal Belgian wholesaler had rerouted and relabelled the products, hoping for extra profit. GSK had to admit that part of the drugs had probably never arrived in Africa and that the company had to look into their own channels of distribution. It seems they had not looked closely at where their drugs were supplied to.[10] Since the packaging was also identical, the drugs could only be identified by means of their batch number.

„Safety through quality! Only with the original drug". Suggestive logo on the German MSD website[8]

Are parallel imports illegal?

The subject of parallel imports – with the limits between legal trade and counterfeits being blurred – is quite a complex one. It describes the re-import of an original product, which is being offered at a lower price by the manufacturer in another country. The reason for such – at times considerable – price differences is the successful attempt of achieving as high as possible prices. Parallel imports, which are totally legal in the EU and many other countries, are a thorn in the manufacturers' flesh. In its information on drug counterfeits, the German Association of Researching Pharmaceutical Manufacturers (VFA), for instance, only refers to "[...] illegal re-imports – these are drugs which were designated for a country outside the EU but were illegally repacked there and channelled into the German market. Even if these drugs used to be original goods, they constitute a health risk due to mix-ups and reduced quality resulting from uncontrolled or improper storage and repackaging transactions as well as faked repackages and instructions for use."[11] This type of statement is meant to undermine the confidence in re-imports although there is no reason for this. It should not be forgotten, either, that the mere existence of re-imports is a consequence of the manufacturers' pricing policy.

Expensive technology is no solution

The introduction of radio frequency identification chips (RFID) on each packaging, which the industry requests for the sake of protection against counterfeits, can also be considered an expensive strategy to combat legitimate generic competition. Many manufacturers in the third world will be unable to afford the introduction of this technology. This would offer the manufacturers of expensive branded medicines a competitive advantage as they would be able to market their products as "safer".

It is just as dubious that the RFID chips would disproportionately increase the prices of low-cost drugs in particular. The technology would only be of benefit if authorities, pharmacies, hospitals and medical centres were equipped with scanners and computers with continuous online access and the correspondingly trained staff. All these conditions are non-exist-

ent in many places or would imply an enormous waste of the scarce resources.

Another problem of RFID chips is that they can be read with a standard scanner at a 2-metre distance, so that no data protection can be guaranteed. Even the German Association of Pharmaceutical Manufacturers points out that the US drug authority FDA has come to distance itself from its request to equip all medicines with RFID chips and considers bar codes adequate.[11]

The call for technical solutions distracts from the basic problem that it is especially high prices for drugs which make fakes lucrative. When it comes to prices, however, the big companies are unwilling to make essential concessions.

Red herrings

Counterfeits could also be a popular red herring. This became especially evident during the so-called dialogue programme which the churches in Germany have carried out with the pharmaceutical industry. When the criticism of the marketing of irrational drugs in third-world countries became unpleasant in the 1990, the industry successfully launched the counterfeit topic, thereby not only switching the emphasis of the discussion but even making a church-owned institute developing a small test laboratory to identify counterfeits – sponsored by the industry. The so-called "Minilab" is today part of the industry's successful public relations activities. A simple method to discover counterfeits is indeed a good thing and the support of the churches is good for the reputation of the industry. That the Minilab – apart from testing many essential drugs – is able to identify the analgesic dipyrone, which has been banned in many countries for its risks, is a different topic altogether.

A recent example for the attempt of placing the counterfeit subject from the industry's point of view, is a poll on the subject carried out at the beginning of the year be *Patient View* and *Together4Health* among patient organizations. Unlike the name suggests, *Patient View* is a marketing agency and *Together4Health* a service company founded by a former Pfizer manager and a former employee of an industry sponsored patient organisation. The aim of the Pfizer-sponsored poll among patient organisations is bluntly admitted: exerting influence on political circles.[12] It does indeed sound much better to say "the patient organizations request" rather than "the pharmaceutical industry requests".

What about IMPACT?

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) founded last year under the auspices of the WHO, also has a certain smack of diversion. Not only does the industry try to influence the orientation of IMPACT, the fact that this new alliance implies a considerable tie-up of attention and resources of the WHO is a side effect that should not be underestimated. There is reason for concern that IMPACT will eventually not be able to accomplish much because of the conflicting interests (for more information on IMPACT see page 11).

It is therefore worthwhile to have a closer look whenever the pharmaceutical industry talks about counterfeits: is this primarily about the securing of markets for high-priced medicines, a distraction from other problems or the real protection of patients from hazardous or inefficient preparations? (JS)

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10 Africa-bound AIDS drugs resold illegally. CMAJ 26 November 2003 Vol. 167 p 1281

11 VFA. Arzneimittelfälschungen. www.vfa.de/de/politik/positionen/arzneimittelfaelschungen.html accessed 13.2.2007

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Data on counterfeits

What is known and the role of hidden interests

Counterfeit drugs – there are few problems which are so hotly debated with such poor evidence. There is a number of reports on cases of counterfeit drugs but systematic overviews researching the extent and dimensions are missing. In the public discussion estimates are quoted often without giving reliable sources.

Global estimates on counterfeits vary grossly depending on the interests of the party publicising the data. Systematic research on the consequences of counterfeits on patients are missing completely.[1]

Nevertheless there is a worrying number of reports and small studies. Often these are the result of investigate journalism. Industry and drug control authorities tend to keep silent on cases of counterfeits they come across.[2] Most reports are not detailed enough to distinguish between criminal counterfeits and quality deficiencies in production or due to bad storage conditions.

Questionable data

Even WHO tends to quote data without a proper base. On WHO's website one still can find the following generalizing sentence: "An estimated 25% of the medicines consumed in developing countries are believed to be counterfeit. In some countries, the figure is thought to be as high as 50%."[3] In contrast to this figure a newer WHO-publication says that less than 10% up to more than 30% of the drugs in developing countries may be counterfeit.[4]

It is disconcerting that WHO gives the private *Center for Medicines in the Public Interest* (CMPI) as source for the amount of money earned by counterfeit drugs. Without any reservation the prediction of the CMPI "that counterfeit drug sales will reach US$ 75 billion globally in 2010, an increase of more than 90% from 2005" is quoted by WHO.

The CMPI does not act in the public interest as its name suggests. In the contrary the majority of members of the advisory board of CMPI are high level representatives of neo-liberal think tanks, which pledge for economic freedom and deregulation or former members of the Reagan and Bush administration.

If one takes it for granted that most counterfeits will be found in developing countries (there is little dispute about this assumption) the figure of counterfeits worth 40 billion US$ is unrealistic. Low and middle income countries together consume less than 10% of the world drug market[5] of 600 billion US$.[6] That would mean more than half of the drugs consumed in these countries would be counterfeit.

Reports

Besides the considerable amount of reports either on a single case of a counterfeit drug or without giving useful details about the drugs involved there are some studies which indicate problems of a larger scale. One example is the report of a group of scientists which analyzed 104 samples of artesunate, an essential anti-malarial, bought from shops, pharmacies, NGO health projects and hospitals in five southeast Asian countries.[7] 38% of the samples did not contain substantial amounts of the active substance. The highest amount of fakes was found in Vietnam (64%) the least in Thailand (11%). In many cases it could be proofed that the drug was not produced by the manufacturer stated on the label, even holograms were counterfeit.

Counterfeit or lack of quality?

Reports on problems with drugs often do not distinguish between counterfeits and bad quality. The latter seem to be more frequent (at least in developing countries). Long term observations from the Indian authorities showed that tests found 0.2% to 0.5% counterfeit drugs but approx. 10% of the samples did not have sufficient quality.[8] A WHO study on anti-malarials in seven sub-Saharan African countries yielded similar results.[9] There were no obvious counterfeits but deficiencies in the pharmaceutical quality were frequent (depending on the drug and country 0% to 60% of the samples were found to be substandard). Locally produced and imported drugs were equally affected. In most cases the content of the active ingredient was only a little below the accepted margin. That implies that not only problems at the production site but also bad storage may be a contributing factor.

Quality problems are also an issue for big companies in industrialized countries. The European fine chemical producers claim that 80% of the raw material used by the US-drug industry is imported, half of which stems from India and China. The US-FDA does inspect only a minority of these factories on the spot.[10] 80% of the antibiotic substances used in Europe are from China and India.[11]

For a successful fight it is essential to distinguish criminal counterfeits from substandard drugs – both may be fatal but the ways to tackle them are different. (JS)

1 Paul Newton et al. Counterfeit anti-infective drugs. The Lancet September 2006 p 602
2 Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ (2005) The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers.14 March 2005 http://medicine.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pmed.0020100
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11 Brigitte Gensthaler. Arzneimittelfälschungen: Wachsamkeit ist oberstes Gebot. *Pharmazeutische Zeitung* Nr. 39/2004

Quo vadis IMPACT?

WHO under industry influence

For many years, the World Health Organization (WHO) has been dealing with the problems resulting from faked and low-quality drugs. In 1988, the WHO passed its first resolution on the topic and comprehensive recommendations were finished in 1999.[1] However, besides some international meetings and working groups on the topic, nothing much has happened. The data situation was meagre, the most affected countries overburdened with other problems, the industry not overly ready to cooperate. This did not change until last year when the pharmaceutical industry organized a meeting in Rome together with the WHO, launching the *International Medical Products Anti-Counterfeiting Taskforce* (IMPACT) on the occasion. The strong influence which the industry had on foundation, goals and further procedure of IMPACT are, however, a reason for concern.

The conference "Counterfeit medicines: the quiet epidemic" was organized by WHO together with the international association of the pharmaceutical industry IFPMA and the Italian Ministry of Health in Rome from 16 to 18 February 2006.[2] The conference brought together representatives of different associations of the pharmaceutical industry, drug control authorities, the WTO, the World Intellectual Property Organization WIPO, customs authorities and Interpol. The representation of consumers and patients at the conference has to be considered but a mere fig leaf, especially as the latter group was represented by the *International Alliance of Patients' Organizations* (IAPO), an association founded and financed by the pharmaceutical industry.[3]

IMPACT is basically a "Public-Private Interaction",[4] i.e. a not really unproblematic cooperation between governmental authorities (in this case mainly the WHO and the national ministries of health) with the private sector, which is neither democratically legitimated nor publicly accountable. This cannot be belied by the mere fact that the IMPACT office is at the WHO.

Metamorphosis of goals

While the WHO had suggested quite a comprehensive package of measures at the beginning of the conference,[5] only part of the problem analysis and requests are found in the final document, the "Declaration of Rome". What is most striking is the total absence of any indication that high drug prices are an essential motivation for counterfeits and that a well regulated supply with essential medicines is a decisive step to combat the problem. Any mention of big price differences and lack of social insurance playing a major role has disappeared in the final document. The concept of adequate control mechanisms, which must not overburden the resources of the affected countries, is not mentioned in the final document, either. There is but a weak hint implying that the public has a right to be informed about any counterfeit and the risks involved in it. The Declaration of Rome clearly focuses on narrow technocratic solutions: stricter legislation, intensified prosecution, improved organisation and exchange of information between authorities, the industry and the health care staff.

During the first general assembly of IMPACT in Bonn in November 2006, five working groups continued the discussion along this setting. The pharmaceutical industry showed a massive pres-

ence at the meeting and readily volunteered to take over certain tasks. Harvey Bale, Director General of the International Federation of Pharmaceutical Manufacturers Associations IFPMA even chairs the technology working group, while "several representatives" from the industry are present in the other four working groups. WHO representative Howard Zucker welcomed Dr. Bale's election by saying that "technology will play a vital role in preventing and detecting counterfeit medicines." [6] As far as the financing is concerned, IMPACT will depend on the industry, since the WHO does not have a separate budget for IMPACT.

The extent to which the goals of IMPACT coincide with those of the International Federation of Pharmaceutical Manufacturers IFPMA[7] is reflected by a glance at the organisation's website. Under the keyword "Quality and counterfeits", IMPACT assumes the central position, the first nine links all indicate IMPACT.[8]

Better protection against counterfeits is of particular importance for the public supply with essential medicines for poor countries. No one there can afford sophisticated protection systems for lifestyle products sold on the private market. To achieve a real impact, the incorporation of players from the most affected countries has to be considerably improved on the one hand, and counterfeits be tackled as a problem in a wider context, on the other. Without improving the access to essential medicines, the situation will not change substancially. (JS)

Counterfeit drugs are a problem. But many people in the Third World do not have regular access to essential medicines. All measures against counterfeits therefore need to be tackled in the context of the universal access to essential medicines. Photo: Elisabeth Lipsewers

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2 WHO, AIFA & IFPMA Conference Seeks to Increase Cooperation in Combating Health Threat Posed by Counterfeit Medicines. IFPMA Rome, 2/16/2006 - IFPMA Director General, Dr. Harvey E. Bale Jr. said: "Counterfeit medicines are already a major health hazard in many developing countries and the problem is growing in developed countries. Today sees the start of the International Conference on Combating Counterfeit Drugs: Building Effective International Collaboration in Rome, organized by the World Health Organization (WHO), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Italian Ministry of Health's Medicines Agency (AIFA). www.ifpma.org/News/NewsReleaseDetail.aspx?nID=4331 accessed 7.2.2007
3 The IAPO receives about ten times as much money as the industry (at least 250,000 US-dollars) as from its member organisations (162 members at a contribution of 30 - 300 US-dollars) www.patientsorganizations.org/showarticle.pl?id=25&n=131
4 The term *Public-Private Partnership* is frequently used. We feel that this term is rather inaccurate, since the term „partnership" implies a cooperation with equal rights and interests. However, this is generally not the case, which is why we feel that the term *Public-Private Interaction* is more appropriate.
5 WHO. Combating Counterfeit Drugs: Building Effective International Collaboration. Speech by Howard Zucker, Assistant Director General for Health Technologies and Pharmaceuticals. Rom 16 February 2006 http://mednet3.who.int/cft/Combating-Counterfeit-Drugs2006_Speech-by-Dr-Howard-Zucker.pdf
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7 International Federation of Pharmaceutical Manufacturers Associations
8 www.ifpma.org/Issues/issues_quality_2.aspx accessed 8.2.2007

BUKO Pharma-Kampagne

BUKO Pharma-Kampagne is an independent non-profit NGO and part of the German Federal Coordination Internationalism (BUKO), a network of Third World solidarity groups. Since Germany is the world's largest exporter of drugs, BUKO Pharma-Kampagne monitors the marketing practices of the German pharmaceutical industry in developing countries. It tries to stop unethical practices of the companies such as the sale of dangerous, useless and irrational drugs, the distribution of misleading information, and unethical promotion. BUKO Pharma-Kampagne as a public awareness raising organisation has initiated campaigns against the marketing practices of Boehringer Ingelheim, Hoechst, Schering, and E. Merck and other companies, which resulted in the withdrawal of a number of hazardous drugs and changes in drug information. It successfully lobbied for a German export control law for pharmaceuticals and against the introduction of direct to consumer advertising for prescription drugs in Europe. BUKO Pharma-Kampagne is one of the co-founders of Health Action International (HAI) and continuously active in the network. Our bulletin Pharma-Brief is member of the International Society of Drug Bulletins (ISDB).

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