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Counterfeit medicines – it will never happen to me

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There are two kinds of medicine: quick acting and long lasting, and we have to decide whether we want to feel better now or later. But there is another, counterfeit medicine, and this one is not funny at all. The risk is that, at best, it will never make you feel better. At worst, it will kill you.

According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source and may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients [1]. A counterfeit medical product is not a medical product. Counterfeiting medical products is a serious crime that threatens everybody's health.

Counterfeit medicines are unsafe and ineffective. They result in wasted resources spent on purchasing, inventory, transport and dispensing, with little or no effect or even cause harm to the patient. Counterfeit medicinal products threaten patient safety by, at best, causing no improvement or, worse, causing added burden of disease and even death. They endanger public health, for instance, by increasing the risk of antimicrobial resistance and by eroding patients' trust in health professionals and health systems, which are seen not to be able to provide an adequate treatment. Public health and patient safety are being put at risk and now is the time to act.

So what are the key factors which make counterfeiting possible?

- Inadequate legislation and enforcement
The main reason for counterfeiting medical products is the huge sums of money that can be made because of the low manufacturing costs. However, in many countries legislation or enforcement are

inadequate and counterfeiters face extremely low risks of being punished.

- Insufficient penal sanctions
This makes counterfeiting attractive for criminals, as production costs for many drugs are very low as compared to market value, particularly in the hospital sector.
- Transactions involving many intermediaries increase opportunities for counterfeiters to infiltrate the regulated distribution system.
- The expansion of trade and deregulation

and reporting, even when patients experience treatment failure. In hospital pharmacy, many very high value pharmaceuticals look like water!

The dangers brought about by counterfeit medicines are a public health risk. The cost for side effects from drug use has been estimated by IMS (a worldwide active pharmaceutical marketing company) to be as much as 60% of the drug cost for society (Figure 1). New packaging, mass-serialisation and authentication can significantly

Figure 1: Risk from a patient safety perspective

Public Risk	Manufacturer Risk
Contraindications and other drug related problems Compliance issues Administration errors Dispensing errors Recalls Expired medical products	The cost of a recall due to counterfeit can be as high as US\$100 million (Euros 64 million) for recall US\$ few billions for future earnings loss US\$ several billions for liability

(Source: IMS, 2007)

offers greater opportunities to introduce fake products into official channels.

- There is ineffective cooperation among stakeholders, so health authorities, customs, police, industry and trade need to establish successful collaboration and exchange of information in order to detect and stop counterfeiters.
- There is often a lack of political will, particularly in some countries where counterfeiters are not disturbed by authorities if their export capacity takes priority over the public health value of medical products.
- Lack of awareness among health professionals and consumers hinders detection

help to reduce the risk in dispensing errors, recalls, expired medical products and counterfeit products. But, the highest risk to public health safety lies in contraindications and other drug related problems, compliance issues and administration errors. These issues can seriously endanger a safe medicine use system.

All healthcare professionals, including pharmacists, need to realise that public health risks to patient safety can be very high if the quality assurance of the pharmacy service provision is not maintained. The foundations of pharmaceutical care, in ensuring positive patient outcomes that

will improve the quality of life of the patients they care for, are critical. WHO and the International Pharmaceutical Federation (FIP) advocate that [2]: “Pharmacists should move from behind the counter and start serving the public by providing care instead of pills only. There is no future in the mere act of dispensing. That activity can and will be taken over by the internet, machines, and/or hardly trained technicians. The fact that pharmacists have an academic training and act as healthcare professionals puts a burden upon them to better serve the community than they currently do.”

As pharmacists, we need to educate patients and the general public on what is a counterfeit medicine and among our colleagues in health care, the appropriate and efficient reporting systems available for suspected cases. Health professionals need to consider counterfeit medicines as a reason for non-response or unexpected response in pharmacotherapy in the patients they care for. The vigilance of healthcare professionals is paramount as often, in most primary care settings, the pharmacist is the most readily accessed healthcare provider and as such, needs to be able to pick up signs and symptoms from our patients and the people we interact with at the pharmacy and bedside.

The FIP provides a platform which reflects and communicates the objectives and actions of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and all its working groups. In attempting to provoke actions leading to policy change, we advocate key messages that promote appropriate measures to combat counterfeiting. These messages include:
 “Only get your medicines from known and reliable sources”
 “Counterfeit medicines are a threat to personal and public health worldwide”
 “When treatment fails, consider counterfeits as possible suspects.”

Together with the World Health Professions Alliance (WHPA), a Toolkit, “BE AWARE”, has been developed to

identify some key steps for health professionals to fight the criminal practices of counterfeiters and to be accountable for the safe treatment of patients in their use of medicines [3]. The WHPA Toolkit includes: an overview of the situation and suggestions as to what health professionals can do to help fight counterfeit medicines; a reporting form that can be copied and used to report any suspected counterfeit (this form serves as a model and does not replace any existing ones from the professionals’ own country); a visual inspection check list that can be used if a counterfeit medicine is suspected; an information leaflet that can be shared with colleagues; a patient information leaflet for distribution to patients or in community areas and finally a poster that can be put in waiting rooms.

Globally, according to the WHO IMPACT, it is reasonable to estimate that the prevalence of counterfeit medicines ranges from less than 1% of sales in developed countries, to between 10-30% in developing countries, depending on the geographical area [4]. Very often, we try to seek definite numbers of counterfeit cases and we know that it is very difficult to determine the prevalence or patient “kills” due to counterfeit medicines. The rhetorical question is do we need to know the exact figures to act now? Dr Valerio Reggi (WHO) said at the recent 67th FIP Congress in Beijing, 2007, a rough indication of different prevalence around the world is enough because even a single case is not accept-

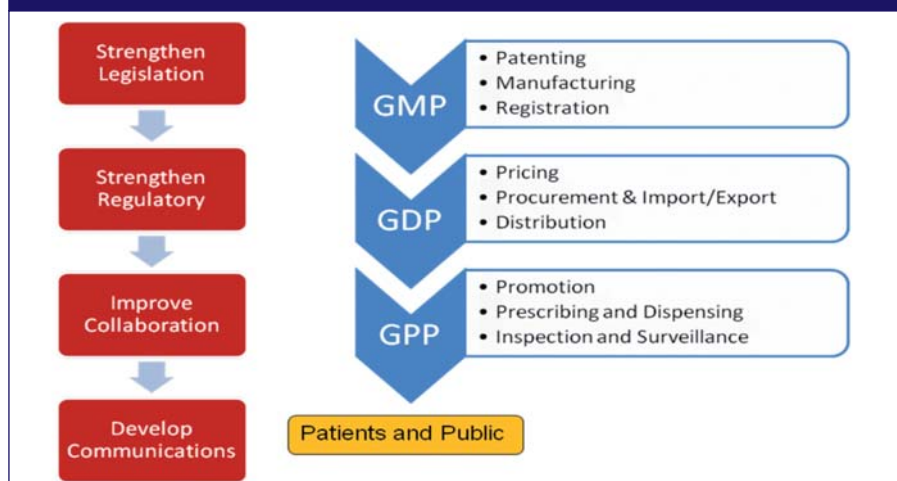
able [5]. There is also not a single average figure and a single figure blurs the picture and may mislead the public.

This is why each health professional has a role to play in helping to stop these counterfeit medicines reaching patients and endangering their health. The International Pharmaceutical Federation is leading the IMPACT Working Group on communications and more specifically, in risk communications related to counterfeit medical products. In this work, we define risk communications [6] to refer both to the content of any message concerning a hazard and the means of delivering that message. Risk communication can only be considered effective if it alerts the target audience as to what is hazardous, the extent of the danger and what should be done to protect oneself.

The work of IMPACT is carried out through its other four working groups: Legislative and Regulatory Infrastructure, Regulatory Implementation, Enforcement and Technology. A document on the principles and elements for national legislation against counterfeit medical products has been produced. The principles set out in the document focus on areas in legislation which needed to be appropriately addressed and are intended to complement or strengthen other legislation and not to replace it.

It is necessary to strengthen legislation to ensure that counterfeiting medical products is a crime and that punishment is

Figure 2: Priority action areas alongside the medicines supply chain



commensurate to the consequences that it has on personal health and on the credibility of national healthcare delivery systems.

And for legislation to be effective there is a need to strengthen regulatory oversight ensuring that all manufacturers, importers, exporters, distributors and retailers comply with the appropriate requirements, GMP and GDP that are necessary for a secure distribution chain for all medical products. Collaborations need to be improved among governmental entities, such as health, police, customs, local administrative units, and judiciary; that need to work together in order to effectively combat counterfeiters. Most importantly, a communications strategy needs to be developed to ensure that health professionals, the general public and the media are aware of the dangers associated with counterfeit medicines.

Conclusion

The rapid growth of counterfeit medicines will only be stopped through global cooperation among legislators, law enforcement units, health and industry representatives. But it is imperative that hospital pharmacists, as the key to the safe and effective use of medicines, also collaborate in the fight against counterfeit medical products in our daily practice. The misnomer of "it will never happen to me" is a dangerous one.

For more information about FIP's activities in combating counterfeit medical products, please contact impact@fip.org

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References

1. Available from: <http://www.who.int/medicines/services/counterfeit/faqs/05/en/index.html>. [cited 2008 April 25].
2. WHO/FIP Handbook developing pharmacy practice - a focus on patient care, can be accessed at: <http://www.who.int/mediacentre> [cited 2008 April 25].
3. Available from <http://www.whpa.org> [cited 2008 April 25].
4. Available from <http://www.who.int/impact/en/> [cited 2008 April 25].
5. Valerio Reggi IMPACT: A WHO initiative to combat counterfeit medical products: proceedings of the 67th FIP World Congress of pharmacy and pharmaceutical sciences held in Beijing, China, 2007.
6. Breakwell GM. Risk communication: factors affecting impact. Br Med Bull. 2000; 56(1):110-20.

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