

NURSING MATTERS

Nursing Matters fact sheets provide quick reference information and international perspectives from the nursing profession on current health and social issues.

Counterfeit Medical Devices

Introduction

A medical device is defined as any instrument, machine, material or related article that is used in preventing, diagnosing, monitoring, and treatment of illness or disability.^{1,2} It can be a simple tongue depressor or a sophisticated haemodialysis machine. A counterfeit medical device is a product which is imitatively made or copied without licensed owner approval and fraudulently mislabelled to appear authentic.³ The magnitude of counterfeit medical devices is increasing worldwide, presenting a serious public health threat, putting human lives at risk and compromising the credibility of health systems.⁴

According to the World Health Organization (WHO), 6% to 8% of the total medical device market is comprised of counterfeit products. Additionally, the number of incidents reported in 2007 increased by around 20% compared to 2006.⁵ Nurses and national nurses associations (NNAs) have an important role in detecting and reporting of counterfeit medical devices.

What medical devices are counterfeited?

Fake medical devices may be products with incorrect components or materials, or they may be made from cheaper, inferior quality or even toxic materials.^{6,7} Medical devices that are counterfeited include a wide range of products, such as microscopes, contact lenses, thermometers, gloves, condoms, surgical instruments, cardiac catheters, ventilators, wheelchairs and diagnostic test strips used by diabetic patients to monitor their blood glucose level.⁸ The adverse consequences of counterfeit devices can range from minor effects such as skin irritation to serious effects such as severe injury, disability or death.

The main reasons driving counterfeiting include: a high level of profit, inadequate legislation, regulations and enforcement, ineffective cooperation and exchange of information among stakeholders within and between countries, lack of awareness among health professionals and patients,⁹ and rapid expansion of the Internet and its widespread commercial use.^{10,11}

Why are we concerned about counterfeit medical devices?

The extent of counterfeit medical device is increasingly present worldwide. For instance, in 2006, counterfeit blood glucose test strips used by diabetic patients were discovered in Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia, Turkey and the USA;¹² in 2007, counterfeit condoms were reported in the UK;¹³ and in 2009, counterfeit insulin pen needles were reported in the UK. However, there is lack of detection and underreporting and the true magnitude of counterfeiting is difficult to determine.

Counterfeiting of medical devices has become a serious health care issue which can have direct health impacts such as a threat to patient safety, loss of life and suffering^{14, 15} and increasing infection rates.¹⁶ For example, possible consequences of counterfeit condoms could include inadequate protection against sexually transmitted infections (STI) or increase in unplanned pregnancy.¹⁷ The indirect health impact of counterfeits is to undermine public confidence in health systems and health professionals. Overall, counterfeit devices increase the burden of disease and disability with negative impact on the health care budget of countries and expenditure of individuals and families.^{18, 19}

How to combat counterfeiting

The anti-counterfeit strategies proposed by WHO and Medicines and Healthcare Products Regulatory Agency's (MHRA) used to minimise risk of counterfeit medicines can also be adopted as strategies to combat counterfeiting in medical devices. These strategies include:^{20, 21}

- Strengthening legislation infrastructure to recognise that counterfeiting in medical devices is a serious health issue. Ensuring that the penalty is commensurate to the negative consequences on individual lives and on the credibility of health care system;
- Strengthening regulatory supervision ensuring that manufacturers, importers, exporters, distributors, and retailers comply with the requirements to ensure quality products;
- Improving coordination and collaboration of governmental entities and private stakeholders, who are concerned and competent in addressing the problems; and
- Developing effective communication strategies to provide accurate, timely and specific information enabling increased awareness of the dangers related to counterfeit medical devices to health care professionals, the public, supply chain, industry, and other stakeholders.

In addition, technology can be used to combat counterfeiting. Technology involves the use of high-tech devices or auto-identification tools to track and monitor medical devices, by using a unique barcode, a radio-frequency identification or optical character recognition.²² However, to combat counterfeit medical devices requires concerted efforts and strategies and stakeholders acting at the same time.

What nurses and NNAs can do

Nurses and NNAs can play crucial roles in the fight against counterfeit medical devices. In daily practice nurses need to be constantly vigilant to changes in patient conditions, signs of toxicity, or unusual results²³ that may be due to counterfeit medical devices. Moreover, nurses should be aware of any minor changes of medical device packages such as colour and design, as well as the brand and manufactory of products.

To protect patients and the community from adverse effects of counterfeit medical devices, nurses can also create public awareness by providing appropriate information and education on signs and consequences of counterfeit devices as well as the risk of buying them from unknown and unauthorised sources.^{24, 25} This means nurses and patients have to work together in order to identify and report counterfeit medical devices to increase patient safety. It is important that health care systems provide continuous educational programmes and encourage the use of reporting systems so that nurses and other health professionals are able to mobilise against counterfeiting in medical devices.

At the same time, NNAs can lobby for strengthening legislation and regulation infrastructure for quality medical devices. NNAs can also work with manufacturers of medical devices to learn more about quality products and ways of detecting counterfeits. Finally, NNAs can provide continuing education for detecting and reporting counterfeits, and raising awareness among nurses and other health care professionals.

For further information, please contact: icn@icn.ch

The **International Council of Nurses (ICN)** is a federation of more than 130 national nurses associations representing the millions of nurses worldwide. Operated by nurses and leading nursing internationally, ICN works to ensure quality nursing care for all and sound health policies globally.

TG/September/2009

References

- ¹ GHTF: Global Harmonization Task Force (2002). Study Group 1 (SG1), Document No. N029R11, www.ghtf.org/
- ² Medicines and Healthcare Products Regulatory Agency MHRA. Anti-Counterfeiting Strategy 2007-2010. www.mhra.gov.uk
- ³ Counterfeit Medical Devices (2005, August). Medical Devices Newsletter
- ⁴ WHO (2008). Sixty-first World Health Assembly, A61/16, 7 April.
- ⁵ WHO (2008). Ibid.
- ⁶ Counterfeit Medical Devices (2005) Op. Cit.
- ⁷ International Medical Products Anti-Counterfeiting Taskforce (IMPACT) (2007). First ASEAN-China Conference on Combating Counterfeit Medical Products, Jakarta.
- ⁸ WHO (2008). Op. cit.
- ⁹ WHO/IMPACT (2008). Counterfeit drugs kill!

¹⁰ WHO (2008) Op. cit.

¹¹ Medical Device Network.com (2008). Phase out the fakes www.medicaldevice-network.com/features/feature1811/.

¹² Bruderlin-Nelson CS. (2007). *Chinese counterfeit devices elevate health concerns*. Medical Device Link. com. www.devicelink.com/ivdt/archive/07/11/004.html

¹³ WHO/IMPACT (2008). Op. cit.

¹⁴ WHO (2008). Op. cit.

¹⁵ Ness J (n.d.). *How Counterfeit Products Impact Innovation and Access to Advanced Medical Technologies*. Anti-Counterfeiting Health Products Seminar: Building International Cooperation to Protect Patients Seminar1/Ness.pdf

¹⁶ MHRA. Op. cit.

¹⁷ MHRA, Op. cit.

¹⁸ WHO (2008). Op. cit.

¹⁹ Ness J (n.d.) Op. cit.

²⁰ WHO/IMPACT (2008). Op. cit.

²¹ MHRA, Op. cit.

²² Medical Device Network.com (2008). Op. cit.

²³ ICN (2006) *Counterfeit Medicines : The Role of the Health Professional*, presentation by Judith Oulton International Conference on Combating Counterfeit Drugs: Building Effective International Collaboration, Rome, Italy, February 15, 2006

²⁴ ICN (2006). Ibid.

²⁵ World Health Professions Alliance (2008). *Be Aware : Helping to fight counterfeit medicines,. keeping patients safer*.

All rights, including translation into other languages, reserved. No part of this publication may be reproduced in print, by photostatic means or in any other manner, or stored in a retrieval system, or transmitted in any form, or sold without the express written permission of the International Council of Nurses. Short excerpts (under 300 words) may be reproduced without authorisation, on condition that the source is indicated.