



## Substandard and Falsified Medical Products

The International Council of Nurses (ICN) is committed to action to address the ongoing problem of substandard and falsified (SF) medical products and their consequences. SF products cause significant threats to health, increased disease prevalence, loss of public confidence in healthcare professionals and health systems, and antimicrobial resistance. Working in all areas of patient care, nurses are most likely to identify SF medical products and must have the knowledge to identify and be empowered to report these products to robust national systems that are enabled to remove them from the healthcare landscape.

The World Health Organization (WHO) defines 'substandard' medical products as those which are authorised but fail to meet their quality standards or specifications and defines 'falsified' medical products as those that deliberately/fraudulently misrepresent their identity, composition or source<sup>1</sup>. Falsification includes substitutions and reproduction and/or manufacturing of an unauthorised medical product. It should be noted that the term 'counterfeit' is now associated with intellectual property rights infringements<sup>1</sup>. Falsified products can apply to both innovator and generic products and may include products without active ingredient, with insufficient active ingredient, with the wrong active ingredient and/or containing other toxic chemicals, impurities or bacteria<sup>2</sup>. SF medical products have been reported in all main therapeutic categories including medicines, vaccines and in vitro diagnostics. Anti-malarials and antibiotics are the most commonly reported SF medicines<sup>2</sup>. All countries are affected by SF medical products. However, low- and middle-income countries and countries affected by conflict, civil unrest, or with very weak health systems are disproportionately affected. Globalisation of the pharmaceutical supply chain and access to a global marketplace through a surge in internet connectivity has allowed for many entry points for SF medical products, with some countries identifying a substantial increase in reports in recent years<sup>3</sup>. In many countries, the sale of SF medical products is done openly at markets, through unregulated websites, clinics, pharmacies, hospitals and in illegal street markets<sup>2</sup>.

SF medical products have a substantial negative impact on public health. Although definite morbidity and mortality rates as a result of SF medical products are not available, with an estimated 10% of medical products in low- and middle-income countries being falsified or



substandard, the rates are projected to be extremely high<sup>4</sup>. SF medical products can lead to serious adverse reactions or no therapeutic response. As well, they severely challenge the progress and investment made in the prevention and treatment of communicable diseases. Antimicrobial resistance is considered one of the biggest threats to humanity and SF medicines are fueling this global problem and promoting the spread of drug-resistant infections. SF medical products also have significant socioeconomic and economic impacts including increased out-of-pocket spending, lost productivity, lost income and increased poverty<sup>4</sup>.

SF medical products are a symptom of a larger problem and one that is of utmost importance to ICN and the nursing profession: a lack of access to quality, safe and affordable healthcare. Much of the morbidity and mortality from SF medical products could be avoided if people were assured the availability of affordable, quality, authentic medical products<sup>5</sup>. Billions of people around the world do not have access to effective preventative, health promotive and life-saving healthcare. Inequities in access to healthcare, a lack of development of medical products for certain health conditions (vaccines, diagnostics and medicines), and high prices for both out-of-pocket payers and health systems are some of the factors that are fueling the proliferation of SF medical products<sup>6</sup>.

Healthcare professionals are an important component of a comprehensive pharmacovigilance system which is the activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem<sup>7</sup>. Working in all care settings, nurses administer, monitor and, in some countries, prescribe treatment and are therefore well-positioned to detect SF medical products which are often only detected when they do not have the intended therapeutic effect. Nurses play an important role in educating the public on safety concerns related to the use of SF medical products and can further prevent their use by promoting health literacy to support informed healthcare seeking behaviours and discourage a self-diagnosis and self-prescribing culture, which has perpetuated these products. The problem of SF medical products is further impacted by a poor reporting culture<sup>3</sup>. Nurses can foster a reporting culture within their multidisciplinary healthcare teams by committing to leadership in this area and empowering colleagues and through a dedication to ongoing vigilance.

ICN works with global stakeholders and partner organisations including the Fight the Fakes campaign which has built a global network of individuals and organisations who raise the profile of substandard and falsified medicines and raise awareness about their dangers and negative



impacts on individuals and health systems<sup>8</sup>. In collaboration with organisations representing dentists, pharmacists, physicians and physiotherapists, ICN and these other members work to combat SF medical products through various activities of the World Health Professions Alliance (WHPA)<sup>9</sup>.

## ICN Position & Recommendations

### As the global voice of nursing, ICN:

- Urges governments to recognise the risk that SF medical products pose to public health and develop national action plans that include comprehensive legal frameworks, multistakeholder engagement, robust reporting systems, and strong national regulatory mechanisms that are linked to the global regulatory network as well as increase pharmacovigilance capacity<sup>3,10</sup>.
- Asserts that nurses and other healthcare professionals must be involved in developing national action plans to prevent, detect and respond to SF medical products and are essential in implementing the related policies.
- Promotes the leadership of nurses and other health professionals in preventing the use of, detecting and reporting SF medical products.
- Encourages healthcare professionals, industry, supply chain, customs, law enforcement, procurers and nongovernmental organisations (NGOs) to report suspected SF medical products to their national or regional regulatory authority.
- Promotes a strong coordinated approach amongst multisectoral stakeholders to prevent the proliferation of SF medical products and to protect patients and public health. These stakeholders include, but are not limited to, the WHO, healthcare professionals, regulatory and enforcement agencies, NGOs, private organisations, patients, and medical product manufacturers, distributors, wholesalers and retailers<sup>11</sup>.
- Engages in multi-stakeholder collaboration to increase public awareness of SF medical products and inform consumers about the risks associated with their use in order to engage them in helping to reduce this risk.
- Encourages donors and philanthropic foundations to develop quality assurance policies that ensure that their funds go towards high quality, regulated medical products.



- Maintains that medicines and medical products should be prescribed, administered, and monitored only by qualified and competent healthcare professionals in the context of their professional scope of practice.

**ICN encourages national nurses' associations (NNAs), in collaboration with their respective government, to:**

- Participate in interprofessional committees aimed at combatting SF medical products.
- Collaborate with pharmacy associations, pharmacists, medical associations, physicians, law enforcement and others to disseminate accurate information on detection and elimination of SF medical products.
- Support nurses' engagement in research initiatives aimed at understanding the prevalence of SF medical products in their respective countries and the role that nurses play in detecting and reporting and the prevention of their use.
- Ensure nursing curriculums include pharmacovigilance and SF medical product education including the health risks associated with SF medical products and detection and response strategies.
- Develop or promote continuing professional development and training programmes for nurses and other healthcare providers in order to encourage reporting and help raise levels of reporting in countries with high rates of SF medical products and low rates of reporting.

**ICN calls on individual nurses in their role as clinicians, educators, researchers, policy influencers, or executives, to:**

- Increase vigilance and awareness of SF medical products in their own practice and amongst colleagues to increase detection and encourage reporting of suspected cases.
- Participate in the development of national and/or organisational plans for SF medical product prevention, detection, and response.
- When administering, dispensing, monitoring or prescribing medicines, always explain the desired therapeutic effect and known side effects.
- Educate patients, families and communities on choosing reliable sources for acquiring medical products and encourage them to only purchase from these sources; how to



identify SF medical products; and what course of action to take should they suspect a medical product to be substandard or falsified.

- Increase awareness amongst patients and the public of the risks of, and dangers related to, SF medical products and the important role they play in detecting and reporting these products.

Adopted in 2004

Reviewed and revised in 2010 and 2019

Formerly “Falsified/Counterfeit medicine”

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