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**REPORT OF THE REGIONAL TASKFORCE ON PREVENTION AND CONTROL OF  
SUBSTANDARD/SPURIOUS/FALSELY LABELLED/FALSIFIED/COUNTERFEIT  
MEDICAL PRODUCTS IN THE WHO AFRICAN REGION**

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## BACKGROUND

1. Medical products<sup>1</sup> should meet the standards of quality, safety and efficacy. The quality of medical products is, however, a major public health concern to the World Health Organization and its Member States. Registered and unregistered medical products are often sold in most market<sup>2</sup> in the African Region. The illegitimate manufacture, distribution, widespread availability and indiscriminate use of substandard/spurious/falsely labelled/falsified/counterfeit medical products have serious consequences on public health.

2. According to WHO definition, counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to their identity and/or source. The definition is applicable to both branded and generic products. Counterfeit medicines may include products with correct ingredients, with wrong ingredients, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.<sup>3</sup> Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and are consequently ineffective and often dangerous to the patient. Substandard products may be the result of negligence, human error, insufficient human and financial resources or counterfeiting.<sup>4</sup> All these factors may lead to medical products being ineffective and harmful.

3. The use of ineffective, poor quality medicines can result in therapeutic failure, exacerbation of disease and resistance to antimicrobials. The use of counterfeit medical products is a global public health problem causing death, disability and injury to adults and children. Illegitimate distribution and rampant use of counterfeit medicines lead to loss of confidence in health systems, health professionals, pharmaceutical manufacturers and distributors.<sup>5</sup>

4. Considering the negative impact of substandard/spurious/falsely labelled/falsified/counterfeit medical products on public health, World Health Assembly Resolutions WHA41.16, 47.13, and 52.19 requested WHO to initiate programmes for the prevention and detection of the export, import and smuggling of such products. One of the core functions of WHO's Essential Medicines Programme is to provide support to medicine regulatory authorities to ensure quality and safety standards of medical products. Consequently, guidelines<sup>6</sup> to develop measures for combating counterfeit medicines were prepared. The guidelines provide an overview of the factors contributing to counterfeiting of medicines and include approaches to inspecting and testing suspected counterfeit medical products and providing staff training.

5. Furthermore, a global coalition of stakeholders, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), was established in 2006 with WHO as its Secretariat. The coalition has been active in forging international collaboration to seek solutions to this global challenge and in raising awareness of the dangers of counterfeit medical products.<sup>7</sup>

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<sup>1</sup> Medical products include medicines, vaccines, pharmaceutical ingredients, medical devices and diagnostics.

<sup>2</sup> Market in this context encompasses unauthorized outlets, shops, street peddlers, the open market, etc.

<sup>3</sup> Counterfeit medical products, Report by the Secretariat, A63/23, 22 April 2010.

<sup>4</sup> [http://www.who.int/mediacentre/factsheets/2003/fs275/en/](http://www.who.int/mediacentre/factsheets/fs275/en/), accessed 6 July 2010.

<sup>5</sup> Effective medicines regulation: ensuring safety, efficacy and quality, WHO Policy Perspectives on Medicines, November 2003, World Health Organization, Geneva.

<sup>6</sup> WHO/EDM/QSM/99.1.

<sup>7</sup> <http://www.who.int/impact/en/> accessed 16 June 2010.

6. The Sixty-third World Health Assembly, having considered the Secretariat's report on counterfeit medical products, decided to establish a time-limited and result-oriented working group on substandard/spurious/falsely labelled/falsified/counterfeit medical products comprised of and open to all Member States.<sup>8</sup> Following this decision of the Health Assembly, it is envisaged that a regional working group would be established to contribute to the global working group.

7. Meanwhile, the Regional Office has organized a consultative meeting involving medicines regulatory experts from Member States to review the current status, issues and challenges and propose actions to prevent and control substandard/spurious/falsely labelled, falsified/counterfeit medical products in the African Region.

8. This document presents the current status, issues and challenges related to substandard/spurious/falsely labelled/falsified/counterfeit medical products and proposes actions to prevent and control the manufacture, distribution and use of such products in the African Region.

## **CURRENT STATUS**

9. Member States with weak or no regulatory systems are fertile grounds for production and circulation of substandard/spurious/falsely labelled/falsified/counterfeit medical products. In 2004 WHO carried out a survey on the situation of medicine regulatory authorities in the African Region.<sup>9</sup> Only 4% of the Member States had developed national regulatory capacity, 33% had moderate regulatory capacity (i.e. carry out most functions to varying degrees) and 24% had basic regulatory capacity (i.e. carry out minimum functions). However, 39% of the Member States had limited regulatory capacity and the inspection of manufacturing premises, distribution outlets and ports of entries in these Member States was found to be weak or lacking.

10. Furthermore, over the last five years, 26 national medicines regulatory systems were assessed to identify gaps and were provided with need-based technical support. Apart from individual national regulatory authority assessments, two African medicines regulators' conferences were organized to exchange experiences, identify gaps and priority areas, and discuss the challenges of regulating pharmaceutical markets including combating the manufacture, distribution, sale and use of substandard/spurious/falsely labelled/falsified/counterfeit medical products in the Region.

11. In 2007, WHO undertook an assessment of national medicines quality control laboratories in the Region<sup>10</sup> and 20 countries responded to the assessment. The assessment report revealed that out of the 22 laboratories in 20 countries, 11 had the capacity to perform comprehensive tests. Five laboratories had moderate capacities and another five had limited capacities to perform relevant tests. The findings of this assessment showed the varying capacity of quality control laboratories in the Region. Some of the Member States with limited or no quality control laboratory occasionally send samples of medical products to neighbouring countries with better laboratory facilities. Furthermore, the WHO Collaborating Centres for quality of medical products in South Africa and Algeria provide support to Member States to test samples for quality as well as develop the capacities of the staff of National Medicines Regulatory Authorities (NMRA).

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<sup>8</sup> WHA63 (10) Decision.

<sup>9</sup> WHO/AFRO/EDP/04.5: Availability of Drug Regulatory and Quality Assurance Elements in Member States of the WHO African Region, 2004, Brazzaville.

<sup>10</sup> Assessment of Medicines Quality Control Laboratories, WHO/AFRO, 2007, unpublished.

12. A study was carried out in Kenya in 2006 on the status of antimalarial medicines prior to nationwide deployment of ACTs. The study found 187 different antimalarial products in the market, 42% of which were not registered in the country. Furthermore, out of 43 samples tested in the laboratory, 12% failed to meet quality specifications.<sup>11</sup>

13. A study carried out in Nigeria in 2005 revealed that 19% of medicine samples collected were not registered.<sup>12</sup> In 2008, a similar survey was carried out to assess the quality of antimalarial medicines distributed through public and private health care providers. The study found that 37% of the antimalarials that were tested for quality did not meet the United States Pharmacopoeia (USP) standards. A total of 78% of the suspect medicine samples were from private facilities, mostly low-level providers such as medicine vendors.<sup>13</sup>

14. Similarly, in 2009, WHO in collaboration with USP Convention carried out a study on artemisinin-based combination antimalarial products and sulphadoxine-pyrimethamine in nine<sup>14</sup> countries of sub-Saharan Africa. Samples of medicines collected from public, private and informal sectors went through full quality control. The results from Madagascar, Senegal and Uganda revealed that a high percentage of medicines (as high as approximately 44% in Senegal, 30 % in Madagascar and 26 % in Uganda) failed to meet the USP specifications for quality.<sup>15</sup>

15. In 2005, WHO carried out a quality survey of antiretrovirals in seven African countries in collaboration with the respective national medicines regulatory authorities.<sup>16</sup> Of the 394 samples collected, the overall failure rate was 1.8% and none of the samples had any critical quality deficiencies which would pose a serious risk to patients. Information on registration by the NMRAs was available for 285 samples, of which 84% were registered. Products not registered comprised 12% of the total samples and these had mostly been sampled from private sector facilities.<sup>17</sup> This underscores the positive effects of common efforts between NMRAs, WHO and other organizations involved in prequalification and procurement policies for essential medicines that have contributed to secure supply chains for ARVs, thus minimizing the problem of substandard/spurious/falsely labelled/falsified/counterfeit products.

16. In October 2008, an interregional meeting on combating counterfeit medical products was convened in Abuja, Nigeria. Medicines regulatory authorities, police and customs authorities from 13 countries<sup>18</sup> attended the meeting. Recommendations were made to amend and reinforce the implementation of the IMPACT's legislative principles and to facilitate experience sharing using IMPACT assessment tools. A strategy was developed to improve collaboration among regulatory, police and customs authorities at the national and subregional levels in order to strengthen their capacity to combat counterfeit medical products. Moreover, the meeting recommended that IMPACT activities be included in existing medicines regulatory harmonization initiatives; IMPACT desks be

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<sup>11</sup> Antimalarial medicines in Kenya: Availability, quality and registration status. Nairobi, Ministry of Health, WHO and Health Action International –Africa, December 2007.

<sup>12</sup> A study of Counterfeit and substandard Medicines in Nigeria, NAFDAC in collaboration with WHO, 2005.

<sup>13</sup> Quality of antimalarial drugs provided by public and private health care providers in south-east Nigeria. *Malaria Journal* 2009, 8:22, 10 February 2009.

<sup>14</sup> Cameroon, Ethiopia, Ghana, Kenya, Madagascar, Nigeria, Senegal, Tanzania and Uganda.

<sup>15</sup> Survey Report on the Quality of Selected Antimalarial Medicines Circulating in Selected African Countries, USP, November 2009.

<sup>16</sup> Cameroon, Democratic Republic of Congo, Kenya, Nigeria, Tanzania, Uganda and Zambia.

<sup>17</sup> Survey of the quality of antiretroviral medicines circulating in selected African countries, Geneva, WHO, September 2007.

<sup>18</sup> Benin, Burkina Faso, Cameroon, Côte d'Ivoire, Ghana, Mali, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda and Zimbabwe.

established in all Member States; and assessments using the IMPACT tool be conducted in Member States.

17. Subsequently in 2009, 11 countries<sup>19</sup> carried out assessments using IMPACT tool to examine the situation of counterfeit medicines. The findings of the assessments indicated that 10 countries had established cooperation between national medicines regulatory authorities (NMRAs), customs and police and five countries had conducted joint operations with police and/or customs. In addition, customs authorities in ten countries required NMRA's authorization to clear medicines at customs. All countries indicated that they would welcome specific legislation to fight counterfeit medicines.<sup>20</sup> Other outcomes of the assessment included the need for strengthened cooperation among national law enforcement agencies and establishment of single points of contact to enhance information sharing at the national, regional and international levels.

18. WHO and International Criminal Police Organization (INTERPOL), under the auspices of IMPACT, organized a two-day regional conference in Johannesburg, South Africa, in November 2009. The conference brought together representatives of national medicines regulatory, police and customs authorities from 15 countries.<sup>21</sup> An overview of the situation regarding counterfeit medicines across Southern Africa, particularly within countries of the Southern African Development Community (SADC) was presented and discussed. The conference made recommendations to enhance cooperation and collaboration among the various agencies involved. Participants proposed to establish legal frameworks to support the prosecution of offenders; create national multiagency taskforces with links to IMPACT and expand concerted law enforcement efforts.

19. Between 2008 and 2009, the East African NMRAs and the INTERPOL in collaboration with other national law enforcement agencies such as police and customs authorities carried out two joint operations code-named *Operation Mamba I and II* to identify and confiscate counterfeit medical products. Some of the counterfeit medical products confiscated in the Region included antimalarial products. These operations resulted in strengthened cooperation and collaboration among law enforcement agencies at both national and regional levels and created awareness of the general public on the implications of the use of counterfeit medical products for public health.

20. The assessment of the status of counterfeit medical products in Member States of the Economic and Monetary Union of West Africa (UEMOA) highlighted concerns related to weaknesses of NMRAs. The West African Health Organisation (WAHO) has made this issue a priority in its strategic plan which was adopted during the workshop held in Senegal from 28 to 29 June 2010.

21. Furthermore, SADC medicines regulators met in March 2010 in Johannesburg, South Africa, to develop a strategy and strengthen national and regional efforts to combat counterfeit medicines. The meeting stressed the need for amending national policies and regulations; strengthening medicines quality control laboratory capacities and collaboration among relevant national authorities; harmonizing medicines legislation; ensuring effective border controls; facilitating international collaboration; promoting multidisciplinary approach; and providing consumers' education.

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<sup>19</sup> Botswana, Burkina Faso, Cameroon, Mali, Mauritania, Niger, Senegal, Seycheles, Swaziland, Tanzania and Uganda.

<sup>20</sup> Report of the situation of counterfeit medicines based on IMPACT Data Collection Tool. WHO Regions for Africa and Eastern Mediterranean (WHO, 2009).

<sup>21</sup> Angola, Botswana, Democratic Republic of the Congo, Lesotho, Mauritius, Mozambique, Namibia, Nigeria, Seychelles, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

22. In October 2009, the Chirac Foundation organized a one-day campaign against counterfeit medicines in Cotonou, Benin. Cognizant of the growing danger that trafficking and consumption of counterfeit medicines pose to public health, the Heads of State,<sup>22</sup> the former Presidents of France and Mauritania, the representatives of the United Nations, African Union, European Union and countries including Chile, France, Laos, Mali and Nigeria signed the Cotonou Declaration on International Campaign Against Production, Trade and Circulation of Counterfeit Medicines.<sup>23</sup> The Declaration calls upon the signatories to (a) contain the production and sale of fake medicines; (b) support the public and private actors already engaged in the fight against fake medicines; and (c) create awareness of the risks posed by falsified medicines.

## ISSUES AND CHALLENGES

23. Counterfeiting is primarily motivated by the potentially huge profits that can be made and is perpetrated by criminals who compromise peoples' health for illegal profits. The illegal production, smuggling and use of falsified medical products are real public health problems and constitute financial losses for individuals, communities and Member States. Counterfeiters smuggle illegal goods including medical products through illicit channels or through lawful but poorly regulated supply systems.

24. Many factors contribute to the manufacture and distribution of substandard/spurious/falsely labelled/falsified/counterfeit medical products. They include (a) lack of harmonized definition of counterfeiting; (b) globalization; (c) the rapid expansion of the internet; (d) establishment of free trade zones; (e) porosity of borders; (f) corruption; (g) conflicting interests; (h) poor governance; and (i) increasingly easier access to sophisticated printing and manufacturing technologies that considerably contribute to these illegal practices. National policies that fail to comprehensively direct trade issues as they relate to public health result in the importation, exportation and sale of medical products without adherence to good manufacturing and distribution practices.

25. In many Member States of the Region medicines regulatory authorities do not have adequate capacities for effective enforcement of legislations. In particular, legislations against substandard/spurious/falsely labelled/falsified/counterfeit medical products are not yet in place, and where they exist, they lack effective enforcement. Weak regulatory systems and lack of coordinated and strict measures result in the proliferation of substandard/spurious/falsely labelled /falsified/counterfeit medical products in national and international markets.

26. Adequately trained and sufficient numbers of staff is critical for effective performance of medicines regulation functions. However, many NMRAs have limited financial and human resources. Inadequate number of staff, low staff morale and salaries, and lack of incentives contribute to high staff turnover which further weakens regulatory capacity.

27. A fragmented and weak supply and distribution system increases the opportunities for counterfeiters to infiltrate the supply chain with substandard/spurious/falsely labelled/falsified/counterfeit medical products. Inadequate access to basic health services coupled with chronic shortages and frequent stock out of essential medicines in public health facilities could lead to the purchase of counterfeit medicines by patients.

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<sup>22</sup> Benin, Burkina Faso, Central Africa Republic, Congo, Niger, Senegal and Togo.

<sup>23</sup> [www.fondationchirac.eu](http://www.fondationchirac.eu) accessed on 16 June 2010.

28. Illiteracy and poverty put the population at risk. In many countries in the Region, there are insufficient or no health insurance and social security schemes, leading to payment by households of exorbitant prices out of their pockets for their medical needs. These factors hinder access to quality medicines and predispose patients, especially the poor, to seek care through informal channels. Such situations provide an opportunity for counterfeiters to offer cheaper prices for substandard/spurious/falsely labelled/falsified/counterfeit medical products.

29. Timely, independent and objective information on substandard/spurious/falsely labelled/falsified/counterfeit medical products are vital for evidence-based regulatory decisions. In addition, interventions to combat such products can be effectively applied when the magnitude and nature of the problem is fully understood. However, the extent of the problem is not well documented in most countries in the Region.

30. Cooperation and collaboration among the authorities concerned (e.g. regulatory authorities, trade officials, police, customs and the judiciary) within and across countries in the Region are generally weak.

### **ACTIONS PROPOSED**

31. Given the diverse and complex nature of the issues and challenges related to substandard/spurious/falsely labelled/falsified/counterfeit medical products, a wide range of interventions are needed to effectively address them.

32. Member States should **reaffirm their commitment** to the fight against counterfeit medical products and engage in updating, developing, implementation and monitoring of national medicines policies.

33. Member States should **establish NMRA that have adequate legal mandate, independence and institutional capacity** to ensure and strictly enforce compliance of medical products with standards of quality, safety and efficacy; and to effectively control the manufacture, export, import and distribution of substandard/spurious/falsely labelled/falsified/counterfeit medical products.

34. In order to address the problem of sufficient training and availability of qualified staff, Member States should **develop and implement a sustainable human resource strategy for the pharmaceutical sector** that ensures adequate human resource capacity including specialized training and retention of regulatory personnel. Continuing education and training programmes should be constituted into training curricula to enhance the knowledge and skills of health personnel to enable them to prevent, recognize and appropriately deal with cases of substandard/spurious/falsely labelled/falsified/counterfeit medical products.

35. Member States should **put in place reliable supply systems and the requisite financial resources** to ensure the availability of quality and affordable essential medical products in public health facilities. Comprehensive quality assurance systems for procurement and distribution should be strengthened for the public, private and other health care providers. Necessary measures to ensure access to affordable medical products that meet quality and safety standards should be incorporated and given due emphasis in national health policies and strategic plans. Government authorities should monitor and regulate the prices of medical products to ensure their availability and affordability.

36. Member States should **establish effective systems** to carry out specific studies and routine market surveillance to quantify the magnitude of the problem of substandard/spurious/falsey labelled/falsified/counterfeit medical products to inform the development and implementation of appropriate policies and regulations. Based on the findings of the studies, Member States should develop information, education and communication strategies to increase awareness of policy makers, health workers and the general public about the dangers of using substandard/spurious/falsey labelled/falsified/counterfeit medical products. The strategy should involve all activities aimed at fighting illegal production, distribution and use of substandard/spurious/falsey labelled/falsified/counterfeit medical products.

37. Member States should **establish effective national, regional and interregional cooperation and collaboration mechanisms** including reinforcing regulatory networks and exchange of information among public health, law enforcement, professional associations, NGOs and other relevant authorities to improve prevention, detection, investigation and prosecution of cases related to substandard/spurious/falsey labelled/falsified/counterfeit medical products;

38. WHO should (a) further **develop tools and guidelines** enabling Member States to adapt and implement policies and strategies; (b) **continue to assess and strengthen NMRAs** in order to ensure the quality, efficacy and safety of medical products; (c) **support Member States to mobilize more resources** for developing human resource capacity for the pharmaceutical sector; (d) **continue to facilitate** the exchange of objective and independent regulatory information among Member States; (e) **intensify the promotion and implementation of good governance, accountability and transparency** in Member States; (f) **strengthen the conduct and dissemination of operational research** on substandard/spurious/falsey labelled/falsified/counterfeit medical products and encourage Member States to use evidence for policy actions; and (g) strengthen **monitoring and evaluation of programmes** dedicated to combating the manufacture, distribution and use of substandard/spurious/falsey labelled/falsified/counterfeit medical products.

39. In line with the decision of the Sixty-third session of the World Health Assembly,<sup>24</sup> Member States should **establish a time-limited and results-oriented Regional working group on substandard/spurious/falsey labelled/falsified/counterfeit medical products**. The working group will examine, from a public health perspective, WHO's role in (i) measures to ensure the availability of quality, safe, efficacious and affordable medical products; (ii) relationship with the International Medical Products Anti-Counterfeiting Taskforce and; (iii) the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsey labelled/falsified/counterfeit medical products.

40. The Regional Committee is invited to review this document and adopt the actions proposed to prevent and control the production, smuggling and use of substandard/spurious/falsey labelled/falsified/counterfeit medical products in the WHO African Region.

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<sup>24</sup> WHA63 (10) Decision.