FIRST MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/ FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
Provisional agenda item 4

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Substandard/Spurious/Falsely-labelled/ Falsified/Counterfeit medical products

Situation report by the Secretariat

INTRODUCTION

1. This document has been compiled at the request of Member States.[1] It is intended to provide an overview of the current situation regarding substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC), to support discussion at the first meeting of the new SSFFC Member State mechanism.

2. The manufacture, distribution and sale of SSFFC medical products is an international issue threatening the health of people in every region and every Member State. It threatens public confidence in life saving medicines, health care systems and undermines trust in health care professionals, in addition to wasting precious resources. This topic has been widely and regularly recognized as an unacceptable risk to public health by Member States and in various international forums.

3. Globalization, free markets, and internet technology have all had a positive and major impact on the way in which consumers and patients obtain their medicines, and on the structure of medicine supply chains. These benefits have also provided opportunities to those engaged in the manufacture, distribution and supply of SSFFC medical products. The availability of manufacturing equipment, bulk pharmaceutical ingredients, digital printing facilities and internet access to previously inaccessible global markets have combined to make the trade in SSFFC products a truly global and profitable phenomenon. With this fast changing landscape there is a need to identify gaps in our understanding in order that proportionate measures can be put in place to mitigate the risks to public health.

4. This paper is in two parts. Part 1 sets out, by objective,[2] current and planned WHO work. Part 2 identifies the knowledge gaps that constrain that work and suggests further action by the Secretariat that will both help to address the deficiencies and reinforce achievement of the objectives specified for

[1] At the preparatory meeting open to all Member States (Geneva, 3 July 2012).

[2] For the objectives, see resolution WHA65.19, Annex.

the Member State mechanism. The gaps in Part 2 are grouped in relation to SSFFC medical products in terms of the scope of the problem; public health consequences attributable to SSFFC medical products; issues in relation to their manufacture, distribution and supply; regulatory oversight; detection of SSFFC products; and their definition.

PART 1 CURRENT WHO ACTIVITIES RELATED TO THE OBJECTIVES OF THE MEMBER STATES MECHANISM

5. This part sets out the agreed objectives of the new Member State mechanism on SSFFC medical products,[1] and provides an overview of the activities being undertaken to support those objectives.

Objective (1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of "substandard/spurious/falsely-labelled/ falsified/counterfeit medical products" in order to strengthen national and regional capacities.

6. All WHO's normative work in the area of quality, safety and efficacy is intended to support capacity building of the national medicine regulatory authorities and is developed with them through global consultative processes.

7. The Secretariat continues to support the organization of ad hoc quality control analyses of medicines at the request of countries and partners. It also performs large scale quality surveys of selected priority medicines in developing countries in close cooperation with national medicines regulatory authorities.

Examples of action taken:

- The survey of antimalarial medicines in **six African countries** involved 935 samples from 218 sampling cites and 64 individual manufacturing sites from which, after primary quality screening, 267 samples underwent full scale laboratory quality control testing. The study revealed that 28.5% of the samples failed to comply with quality specifications.[2]

- The survey of anti-tuberculosis medicines in **six selected Newly Independent States of the Former Soviet Union** involved 291 samples from 84 collection sites originating from 33 manufacturers. Overall, 33 samples (11.3%) failed to meet the quality specifications.[3] Both surveys resulted in detailed recommendations being discussed and agreed with the national authorities in order to improve the situation.

- The Secretariat sent experts to **Pakistan** to assist with the conduct of laboratory and other investigations to find the root cause of adverse events that occurred in 2011 in Lahore, involving the death of 130 patients and serious adverse reactions in more than 850 patients.

[1] As established in resolution WHA65.19, Annex.

[2] *Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa*. WHO/EMP/QSM/2011.1, World Health Organization, Geneva, 2011.

[3] *Survey of the quality of anti-tuberculosis medicines circulating in selected Newly Independent States of the Former Soviet Union*. WHO/EMP/QSM/2011.2, World Health Organization, Geneva, 2011.

The substandard product concerned was Isotab® (isosorbide mononitrate 20 mg), which was contaminated with a significant amount of pyrimethamine.[1] A follow-up team went to Pakistan to assess local medicines quality control and laboratory and regulatory capacity for assuring the quality of medicines. The team made recommendations that have resulted in new legislation on the establishment of a national medicines regulatory authority.

8. Quality of medicines remains a major problem, globally threatening the health of people and undermining efforts to provide affordable, safe and effective treatment to those in need.

9. In spite of numerous individual reports about substandard/spurious/falsely-labelled/falsified/ counterfeit medical products, the data themselves on medical products also are often of poor quality and are not globally systematized. The variety of information sources makes the compilation of statistics a difficult task. Sources of information include reports from national medicines regulatory authorities, enforcement agencies, pharmaceutical companies and nongovernmental organizations, as well as ad hoc studies on specific geographical areas or therapeutic groups. The different methods used to produce reports and studies also makes it difficult to compile and compare statistics. Studies can only give snapshots of the immediate situation. Counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection. They can change these methods from day to day, so when the results of a study are released, they may already be outdated. In addition, information about a case under legal investigation is sometimes only made public after the investigation has been concluded.

Objective (2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.

10. The Secretariat's normative work is an essential aspect of national and regional capacity building. On the advice of the Expert Committee on Specifications for Pharmaceutical Preparations, the Secretariat has published the guideline *WHO good distribution practices for pharmaceutical products*.[2] The guideline provides reference standards for assessment of supply chain vulnerability and major drawbacks to be corrected. WHO, on the advice of its Expert Committees, has issued a number of further international standards supporting Member States and those involved in the supply chain, including the *Good pharmacy practice: standards for quality of pharmacy services;*[3] *Good trade and distribution practices for pharmaceutical starting materials;*[4] *A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products);*[5]

[1] Drug Alert No. 125. Contaminated Isotab® (isosorbide mononitrate) incident in Lahore Pakistan http://www.who.int/medicines/publications/drugalerts/drugalertindex/en/index.html.

[2] *WHO good distribution practices for pharmaceutical products*. WHO Technical Report Series, No. 957, World Health Organization, Geneva, 2010.

[3] *Good pharmacy practice: standards for quality of pharmacy services*. WHO Technical Report Series 961, World Health Organization, Geneva, Annex 8, 2011.

[4] *Good trade and distribution practices for pharmaceutical starting materials*. WHO Technical Report Series 917, World Health Organization, Geneva, Annex 2, 2003.

[5] *A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products)*. WHO Technical Report Series 937, World Health Organization, Geneva, Annex 6, 2006.

Guide to good storage practices for pharmaceuticals;[1] and *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical product*.[2]

11. Many other activities have been conducted by country, regional and headquarters offices as part of the provision by WHO of direct support to individual regulatory agencies (e.g. through independent assessments, consultancy support, training and international exchanges) (for details see objective 5).

Objective (3) To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.

12. In several WHO regions, the elements of exchange of experiences, lessons learnt, best practices and information is ongoing, with WHO's direct or indirect involvement at various levels (headquarters, regional and country offices) and with varying intensity. Examples can be found in the Pan American Network for Drug Regulatory Harmonization (PANDRH) framework (PAHO/AMRO), in the Association of Southeast Asian Nations (ASEAN) group, the Rapid Alert notification system (in the Western Pacific Region) and between countries belonging to the European Region (both inside the European Union and amongst the countries under the umbrella of the Council of Europe). Further details are given in document A/MSM/1/2.

13. Furthermore, WHO provides a platform for national medicines regulatory authorities worldwide in co-hosting with a Member State the International Conferences of Drug Regulatory Authorities (ICDRA). The 15th International Conference of Drug Regulatory Authorities (ICDRA) was held in Tallinn, Estonia, 23–26 October 2012.

Objective (4) To identify actions, activities and behaviours that result in "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" and make recommendations, including for improving the quality, safety and efficacy of medical products.

14. The first report of the Member States Working Group on SSFFC,[3] refers to the improvement of access to affordable, quality, safe and efficacious medicines as an important element in the effort to prevent and control medicines with compromised quality, safety and efficacy.

15. WHO's work in the area of medical products includes the promotion of the following: (i) universal availability of, and access to, essential medical products; (ii) assured quality and safety of medical products; and (iii) rational use of medical products. In each of these three technical areas, WHO is conducting public health advocacy; performing global normative functions, through the regular work of the WHO Expert Committee on Specifications for Pharmaceutical Preparations[4] and

[1] *Guide to good storage practices for pharmaceuticals*. WHO Technical Report Series 908, World Health Organization, Geneva, Annex 9, 2003.

[2] *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*. WHO Technical Report Series 961, World Health Organization, Geneva, Annex 9, 2011.

[3] Document A/SSFFC/WG/5.

[4] Expert committee reports and other materials related to its work are available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/en/index.html.

the WHO Expert Committee on Biological Standardization[1] among others; and providing technical support at country level. WHO's activities in the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products form a part of its work in the area of quality and safety of medical products.

Objective (5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.

16. Several WHO initiatives contribute to the improvement of regulatory capacity in the area of medicines and vaccines, and work is starting also in the area of medical devices. The Secretariat works with Member States to assess national regulatory systems in order to identify gaps, develop strategies for improvement and support countries in their commitment to build national regulatory capacity. To date, 61 assessments have been performed in 55 national regulatory systems. In addition to individual assessments, WHO also provides a regional view. In late 2010, for example, WHO published a synthesis of rapid assessment findings from national medicines regulatory authorities in 26 African countries over the last eight years, based mainly on the reports provided to the countries by the assessment teams.[2] Structures for medicines regulation existed in the countries assessed, and the main regulatory functions were addressed, although in practice, the measures were often inadequate and did not form a coherent regulatory system. Common weaknesses included a fragmented legal basis in need of consolidation, weak management structures and processes, and a severe lack of staff and resources. On the whole, countries did not have the capacity to control the quality, safety and efficacy of the medicines circulating on their markets or passing through their territories. The report concluded that regulatory capacity should be built in African countries as a matter of urgency.

17. In response to the needs identified globally, the Secretariat has organized training courses of varying nature, technical orientation and complexity, starting with training workshops or involvement in practical work jointly with experienced regulatory experts. Information exchange and worksharing have been facilitated via forums like the International Conferences of Drug Regulatory Authorities (ICDRA), harmonization initiatives (such as the African Medicines Registration Harmonization Initiative and PANDRH), professional networks (such as networks for specific medical products – WHO Paediatric Regulators Network and WHO Blood Regulators Network), and collaborative procedures. The focus is on countries that have substantial manufacturing capacity as well as on countries dependent on imports of medicines. Where there is insufficient regulatory capacity to ensure quality supplies of essential medicines, the Secretariat provides support in the form of prequalification of priority essential medicines and active pharmaceutical ingredients and organizes testing of medicines sampled in cooperation with national medicines regulatory authorities on national markets.

18. During the last two years, WHO has contributed substantially to regulatory collaboration and harmonization in Africa. The African Medicines Regulatory Harmonization Initiative was established as a joint effort by a consortium of partners[3] with the overall objective to improve health in the African

[1] Expert committee reports and other materials related to its work are available at: http://www.who.int/biologicals/WHO_ECBS/en/index.html.

[2] Assessment of medicines regulatory systems in sub-Saharan African countries. An overview of findings from 26 assessment reports. WHO/EMP/QSM/2010.4, World Health Organization, 2010.

[3] New Partnerships for Africa's Development Coordinating Agency, World Health Organization, Pan African Parliament, Bill & Melinda Gates Foundation, United Kingdom Department for International Development, the Clinton Health Access Initiative and the World Bank.

Region by increasing access to safe and effective quality medicines for the treatment of priority diseases. This can be accomplished by strengthening the technical and administrative capacity of participating national medicines regulatory authorities. Collaborative mechanisms can be established to create a more transparent, streamlined process for the marketing authorization of pharmaceutical products and follow-up of products already marketed. The East African Community was the first regional economic community in Africa to be granted funding under this project; implementation started in March 2012.

19. To build regulatory capacity in resource limited settings, the WHO Prequalification Programme for Medicines invites assessors from developing country authorities to spend three months at WHO headquarters in Geneva. Since 2006, a series of 16 assessors from nine different countries have completed the fellowship, which has had a clear impact on building regulatory capacity in national settings, and has thus indirectly facilitated access to good quality medicines.

20. WHO is also helping to build national capacity for quality control testing of medicines through issuing guidance documents and International Pharmacopoeia monographs, carrying out external assessment schemes and offering prequalification options for those quality control laboratories that are willing to improve their technical performance and quality management systems.

21. The WHO External Quality Assurance Assessment Scheme is a programme for the external evaluation of quality control management systems in pharmaceutical quality control laboratories, supplementing laboratories' internal quality assurance procedures by providing an external measure for their testing capabilities. The scheme has been operational for more than 10 years. At present, 60 laboratories from all six WHO regions participate.

22. Since the end of 2010, seven more quality control laboratories have been prequalified, reaching a total of 24, covering all six WHO regions, and a further 32 are working towards prequalification.

Objective (6) To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products".

23. Numerous WHO activities at country, regional and global level contribute to related Millennium Development Goals, including Goal 6 (Combat HIV/AIDS, malaria and other diseases) and Target 8.E of Goal 8: "In cooperation with pharmaceutical companies, provide access to affordable essential medicines in developing countries".

24. As outlined under objective 4, WHO's work in the area of medical products includes the promotion of: (i) universal availability of, and access to, essential medical products; (ii) assured quality and safety of medical products; and (iii) rational use of medical products.

25. To address the quality of medicines used in developing countries, the Secretariat organizes prequalification programmes and field testing of selected priority medicines, and, in cooperation with its partners, provides technical support to less experienced manufacturers of essential medicines. A network of quality control laboratories is in preparation in order to facilitate the exchange of information and experience, and to provide a network of expert bodies that can support manufacturers so as to coordinate activities, and increase their effectiveness.

26. The WHO Prequalification Programme for Medicines prequalified more than 70 products in the period 2010–2012, including the first generic tenofovir/lamivudine/nevirapine combination, and the first generic reproductive health medicines. As at 31 October 2012, the WHO list of prequalified medicines totals more than 300 products manufactured in 25 countries. In addition, the prequalification programme has prequalified 21 active pharmaceutical ingredients (15 for antimalarials, 4 for anti-tuberculosis medicines and 2 for HIV/AIDS medicines).

27. The prequalification programme routinely responds to requests from manufacturers in developing countries for advice on how to ensure the quality, safety and efficacy of their generic products. It provides technical support to manufacturers and national quality control laboratories that seek to resolve specific practical problems related to good manufacture practice, good practices for quality control laboratories, and/or meeting medicines regulatory requirements.

28. In 2011, the prequalification programme organized 17 missions to provide technical support to 13 pharmaceutical manufacturers in 5 countries (Bangladesh, China, Kenya, Nigeria and Pakistan), for five contract research organizations in China, and for two quality control laboratories in China, and one quality control laboratory each in Benin, Cameroon, Madagascar and Thailand. Support took the form of an audit, followed by the development of an improvement plan. Training in specific technical regulatory areas was also made available where needed. Additionally, staff in WHO's Regional Offices for the Americas, for the Eastern Mediterranean and for Europe provided technical support to manufacturers and quality control laboratories in their respective regions.

29. The prequalification programme also organized, co-organized or supported 32 training courses for nearly 1400 participants. Training on general or specific technical issues was given to manufacturers, and to national medicines regulatory authorities and quality control laboratory staff (see also activities under objective (5) above).

Objective (7) To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.

30. WHO is involved in numerous regional and interregional efforts in the regulatory area (as described under objective (3). It is anticipated that these functions will be further enhanced by efforts relating specifically to spurious/falsely-labelled/falsified/counterfeit medical products when the Member State mechanism becomes operational.

Objective (8) To promote cooperation and collaboration on surveillance and monitoring of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products".

31. WHO has initiated a project to establish a global surveillance and monitoring system for SSFFC medical products. This system will allow for systematic and subsequent analysis of incidents, collecting data through the submission of a rapid alert form. This system has the ability to capture a great deal of information concerning SSFFC medical products, link similar incidents, record adverse reactions in patients and permit the quantification and categorization of incidents based on a range of criteria. The gathering of this information will allow reporting and lead to evidence-based policy-making in the field of SSFFC medical products. A pilot scheme is currently being undertaken involving 10 Member States in 3 regions. This project will help to identify the common products and vulnerabilities in supply chains and will provide Member States with information that will enable them to undertake follow-up actions, as necessary.

Objective (9) To further develop definitions of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" that focus on the protection of public health.

32. In late 2009, WHO undertook a global survey on the use of the term "counterfeit medicine" and definitions of related words in various national legislations. A summary of the survey is posted on the WHO web site for information and additional feedback. The 45th WHO Expert Committee on Specifications for Pharmaceutical Preparations discussed the survey in October 2010 and recommended that (1) the working group of Member States considers WHO's and IMPACT's definitions in order to develop an appropriate definition including an explanation that will avoid confusion; (2) in so doing, WHO should address the issue and its public health consequences instead of concentrating on the terminologies; and (3) as the first step, the work of the Committee should concentrate on medicines. No further work has been carried out since then by the Secretariat as discussions amongst Member States have not yet provided a clear direction. It is anticipated that the newly established Member States mechanism will give direction on how to carry out work related to the further development of definitions for "substandard/spurious/falsely-labelled/falsified/counterfeit medical products", focusing on the protection of public health.

PART 2 KNOWLEDGE GAPS

Scope

33. Reported cases of SSFFC medical products are ubiquitous, varied and numerous. The Secretariat has been working with Member States to achieve a more systematic reporting of these cases, and is currently testing a new reporting instrument with 10 countries. There have been several detailed short-term initiatives, including market surveys, which have provided some accurate data at a local level, or have focused on a specific therapeutic category. However, experience has shown that it is difficult to make an accurate assessment of the extent of the issue and the overall picture remains far from clear.

34. What was historically regarded as a problem experienced only by low-income and developing countries has now become a global issue. The scale of expenditure in international markets has attracted the purveyors of SSFFC medical products. The means by which to access the global marketplace have become easier and this has led to a diversification in the types of SSFFC medical products now being offered. The manufacture and distribution of SSFFC medical products is driven by profit, often targeting products that are expensive, in high demand, or that generate a high turnover.

35. Generic medicines are as vulnerable as innovator medicines. Reports received by the Secretariat in the last 12 months include a range of therapeutic categories and types of medical products.

36. Medicines for the treatment of HIV and malaria have featured as have those for treatment of tumours, cardiac disease, erectile dysfunction and osteoporosis. These finished products have included capsules, tablets, and injectable and blood products, and reports have come from all six WHO regions. The same or similar types of products are sometimes seen in more than one region. Substandard herbal and naturally derived products used in traditional medicine have also been reported, resulting in a number of fatalities.

37. In some Member States the reporting of incidents involving SSFFC products is sporadic or non-existent. The private sector has its own reporting mechanisms that may not be available to other parties. Some formal and informal networks operate a rapid alert system, designed to alert other

Member States of potentially dangerous products available on their respective markets, and to help safeguard public health.

38. **Action:** The Secretariat has started work to address systematic global reporting, collection and analysis of data, which will start to clarify the scope of the problem. The systematic provision of reports by the national medicine regulatory authorities on SSFFC medical product incidents would begin to provide a validated body of evidence, enable regular reporting of the situation at regional and global levels, and help to inform stakeholders of the situation in a more comprehensive manner. The active participation of Member States in the collection of data concerning SSFFC medical products can provide a valuable evidence base for the Member State mechanism regarding future strategies and actions; at the same time providing information that may enable a Member State to take action.

Public health consequences

39. Approximately 150 deaths have been reported to WHO during the past 12 months, mainly attributed to three SSFFC incidents. This figure is suspected to be a gross under reporting of the true situation. The inclusion of toxic ingredients to a level that causes serious adverse reactions in patients is more likely to be reported quickly and provide clear evidence of harm if the adverse reactions are concentrated geographically.

40. Companies that produce SSFFC medical products may simply have been reckless or negligent in their manufacturing practices; however existing cases suggest that economic gain is the primary motivation. Causing demonstrable harm to patients that is directly attributable to their products would be detrimental to future sales and the interests of those engaged in this activity. It would also attract the attention of law enforcement to what is currently considered to be a low risk and high return venture.

41. Most cases feature products that fail to treat the disease for which they were intended, either through the absence of the correct active pharmaceutical ingredient or sub potency, thus leading to poor treatment outcomes and additional health care costs due to extra doctor visits.

42. **Action:** It is important to develop systems that support recognition of the linkage between lack of efficacy and a potentially SSFFC medical product. Once the scale of the issue and an understanding of the global threat have been established, the next step is to assess the likely harm and cost to health systems. It is this persuasive evidence that can convince policy-makers to devote resources to tackle the issue.

Manufacture, distribution and supply

43. The manufacturers of SSFFC medical products often take steps to conceal their identities through a complex web of false packaging, fraudulent documents, front companies, offshore bank accounts and a series of intermediaries. SSFFC medical product incidents reported during the past 12 months have included a number of distribution methods which can be divided into two broad categories – regulated and unregulated.

44. **Products distributed to patients via the regulated supply chain**, i.e. through licensed, registered or regulated entities including importers, wholesalers, hospitals, clinics and pharmacies, and distributed by health care professionals. This also includes those products procured and supplied via nongovernmental organizations.

45. Distributers of SSFFC medical products search for vulnerabilities in the regulated supply chain, exploiting any lack of policy, legislation, regulation, practices and procedures, or inconsistency in their application. Recent evidence exists to show manufacturers and suppliers of SSFFC medical products monitoring the web sites of national medicine regulatory authorities, and particularly their drug alerts and recall notices. This is because manufacturers of SSFFC products do not wish to manufacture further batches of products which are the subject of a recall and will be impossible to sell. They also wish to monitor national medicines regulatory authorities activities in preventing access to SSFFC products.

46. **The unregulated supply chain** includes street markets, unregulated vendors and, increasingly commonly, unregulated Internet web sites.

47. These distribution methods are used for the retailing of finished products, either directly to consumers, or to secondary suppliers. In addition, Internet business-to-business forums are increasingly advertising industrial scale quantities of active pharmaceutical ingredients.

48. Incidents suggest that those supplying SSFFC products are attracted to the markets that represent a high demand and profit, combined with a complex or loosely regulated supply chain. These two issues combine to create an environment ripe for the supply of SSFFC products.

49. **Action:** Capacity-building work with national medicine regulatory authorities is critical to improving this situation.

Regulatory oversight

50. A Member State is a prime target for those engaged in manufacturing, distributing and supplying SSFFC medical products if it does not have a fully functioning national medicines regulatory authority; has weak or non-existent relevant legislation; an absence of enforcement of medicines legislation; and porous borders. In addition, recorded incidents of SSFFC products entering the heavily regulated supply chains of wealthy countries are becoming more common as detection and reporting improve.

51. **Action:** Improved market surveillance vigilance at pinch points within the supply chain; increased and enhanced pharmacovigilance reporting; and more advanced laboratory facilities. These are areas with an impact on the detection and prevention of products reaching patients.

Detecting SSFFC medical products

52. SSFFC medical products can be difficult to detect and in many cases have been expressly designed to imitate the appearance of the genuine product. In most cases, in order to validate a suspect product as a SSFFC medical product, laboratory analysis is required, often with specialist knowledge in forensic analysis. Some Member States have limited access to laboratories. The collection and transmission of samples for testing can be complex and costly, and dispatch to other countries for analysis is sometimes necessary. This sometimes proves to be impossible, or causes lengthy delays, leaving patients vulnerable for extended periods.

53. There have been many incidents of SSFFC products containing a reduced amount of the correct pharmaceutical ingredient, which can lead to drug resistance issues. These types of case are particularly difficult to detect. It is rare that a product's lack of efficacy is suspected to be caused by being SSFFC.

54. **Action:** Identification of signals from existing pharmacovigilance data that may suggest the availability of SSFFC products on the market. This research may start to identify the levels of physical harm caused by SSFFC products.

Definition

55. Many Member States already have in place legislation that defines, in a way commensurate with their own jurisprudence, the category of SSFFC medical products. It is unlikely that this situation will significantly change in the short term, but common denominators do exist within most national legislation. In almost all cases an element of "misrepresentation" is present. Sometimes this misrepresentation is clearly intentional, sometimes it is not, but it invariably results in a patient receiving a product that is not of the nature and quality expected. It is this element of misrepresentation that sets apart the issue of substandard medicines (which has an internationally agreed definition) caused by unintentional manufacturing errors.

56. In May 2010 WHO published a preliminary draft survey on national legislation. Sixty Member States responded to the survey. An analysis is available on the WHO web site.

57. It may be possible to identify the behaviours, characteristics and components of an incident involving SSFFC medical products that would result in an incident being classified as a suspected SSFFC. These components would permit the later analysis and comparison of incidents categorized in accordance with their constituent parts.

Conclusion

58. The Sixty-fifth World Health Assembly adopted resolution WHA65.19 in which it decided to establish a new Member State mechanism for international collaboration among Member States. The overall goal and objectives provided have established the mandate and created the platform on which to move forward. The Secretariat is already undertaking work on this topic aligned to those objectives and welcomes the role of the Member State mechanism in taking that work forward.

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