

REPORT OF THE SITUATION OF COUNTERFEIT MEDICINES BASED ON DATA COLLECTION TOOL WHO REGIONS FOR AFRICA AND EASTERN MEDITERRANEAN

The word "Counterfeit" has been used in accordance to the following definition: "A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging."

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Abbreviations

AFRO	WHO Regional Office for Africa
EMRO	WHO Regional Office for Eastern Mediterranean
IMPACT	International Medical Products Anti-counterfeiting Taskforce
NMRA	National Medicines Regulatory Authority
SADC	Southern African Development Co-operation
SPOC	Single Point of Contact
TFDA	Tanzania Food and Drugs Authority
WHO	World Health Organization

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1. Background

Counterfeit medicines pose a significant danger to public health in developing as well as developed countries. Counterfeit medicines may be distributed through different channels such as government and private hospitals, pharmacies or other legitimate or illegitimate distributors. Licensed distributors, pharmacists, health care providers or patients may be unable to detect or differentiate between counterfeit and genuine medicines.

It has been difficult to assess the extent of the problem of counterfeit medicines in many settings because of the lack of resources/skills to detect counterfeit medicines, the absence or weak medicines regulatory systems, the different definitions of counterfeit medicines in different countries worldwide, as well as the variations in the distribution systems. As such the actual extent of the problem may vary from country to country.

Taking this situation into account, a questionnaire (annex 2B) was developed based on the “data collection tool for the review of national situations concerning counterfeit medicines” (annex 2). This report is the outcome of the implementation of the tool in 14 African countries (8 in phase I and 6 in phase II) and 13 Eastern Mediterranean countries. The findings from the survey provide a quick overview of the situation of counterfeit medicines in the countries surveyed and form the basis for recommending appropriate interventions at national, regional and international levels to combat this global menace.

2. Data Collection Tool

The process of developing the tool (table 1) was pioneered by the Tanzania Food and Drugs Authority (TFDA) and started in April 2007 as part of the work of IMPACT Regulatory Implementation Working Group. It involved a series of consultations among members of Regulatory Implementation Working Group and the Second IMPACT General Meeting held in Lisbon in December 2007.

The tool provides a unified approach of assessing the problem of counterfeit medicines. It addresses existing national legislations on counterfeit medicines, the

capacity of national medicines regulatory authorities (NMRAs) in the control of counterfeit medicines, and market control, and it raises awareness and efforts of the government and other stakeholders in combating counterfeit medicines. The latter part of the tool addresses the issues of cooperation among stakeholders at national and international levels.

This tool was developed based on the *WHO Guidelines for the development of measures to combat counterfeit drugs*, 1999 and the *WHO Data Collection Tool for the Review of Drug Regulatory Systems*, 2008. The new data collection tool for the review of national situations concerning counterfeit medicines was approved during the Third General Meeting of IMPACT held in Hammamet Tunisia, 3-5 December 2008. The tool is intended to be used by policy makers and regulators in assessing the problem of counterfeit medicines in a country, sub-region or region so that appropriate interventions for combating medicines counterfeiting could be developed based on the identified problems. In addition, the findings could assist countries in developing a National Plan of Action for combating counterfeit medicines that encompasses all the key players including policy-makers, NMRAs, law enforcement agencies, health professionals and associations, manufacturers, wholesalers and other distributors, retailers and the consumers at large. Furthermore, the results could support the establishment of sub-regional, regional and international collaborations that are geared to fight the problem.

In implementing the tool, either one of two options can be adopted. The first consists of an expert conducting interviews of key stakeholders in a country using the data collection tool (Annex 2, A). The second option involves sending out a questionnaire to a country for self administration, ideally by a single point of contact (SPOC) usually located within the national medicines regulatory authorities (NMRA) (Annex 2, B).

Table1: Development of the data collection tool

S/N	Event	Date and Place	Responsible
1	Initial drafting of the tool	March 2007, Dar Es Salaam, Tanzania	Tanzania Food and Drugs Authority
2	Review of zero draft of the tool	April 2007, Washington DC, USA	IMPACT Regulatory Implementation Working Group
3	Review of draft tool	December 2007, Lisbon, Portugal	2 nd IMPACT General Meeting
4	Incorporation of the comments by the General Meeting	May 2008, Rome, Italy	IMPACT Regulatory Implementation Working Group
5	Approval of the data collection tool	December 2008, Hammamet, Tunisia	3 rd IMPACT General Meeting

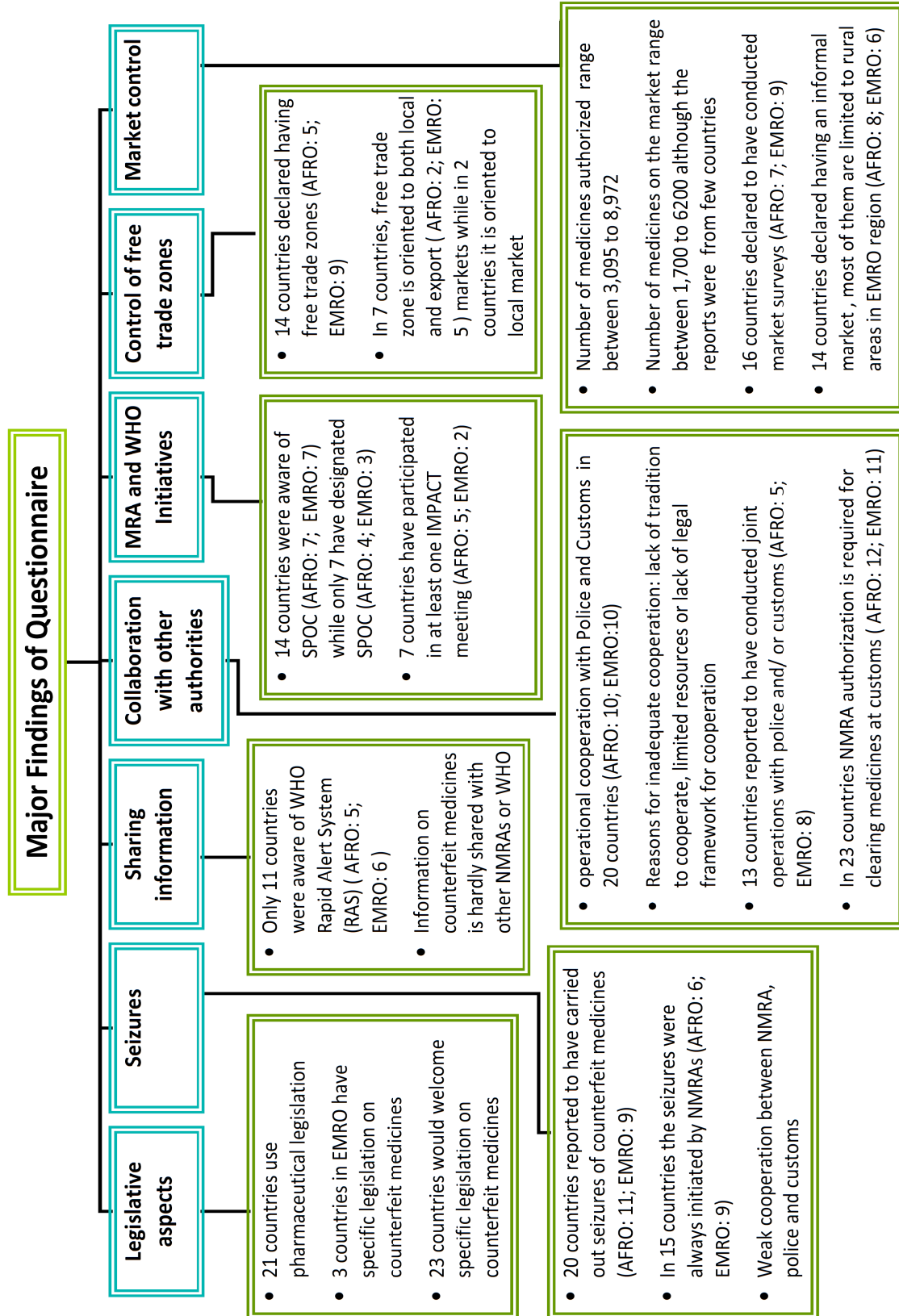
3. Methodology

The questionnaire was developed from the data collection tool and pretested in Tanzania in August 2008. Based on the experience obtained in Tanzania, the questionnaire was circulated to 8 African countries to collect information for self-administration. These countries included Burkina Faso, Cameroon, Mali, Morocco, Niger, Senegal, Tanzania and Uganda. The findings from these countries were presented and discussed during the IMPACT - Interregional Meeting on Combating Counterfeit Medical Products held in Abuja, Nigeria on 29-30 October 2008. The Abuja meeting recommended using the questionnaire in other countries and regions, as well as disseminating the findings during the Third IMPACT General Meeting in Hammamet, Tunisia on 2-5 December 2008. The IMPACT General Meeting also recommended the wider use of the tool in order to establish the status in those countries with a view to propose appropriate interventions to address the global problem of counterfeit medical products.

Prior to IMPACT Regional Conference on Combating Counterfeit Medical Products held in Kempton Park, South Africa on 9-10 October 2009, the questionnaire was circulated to all countries in the WHO EMRO region, as well as African countries located in SADC Region. The questionnaire was sent to the countries by WHO through its country representatives. Thirteen countries out of the 22 in the EMRO region provided feedback. The 13 EMRO countries that provided responses included Afghanistan, Djibouti, Egypt, Iraq, Jordan, Lebanon, Oman, Pakistan, Somalia, Sudan, Syria, Tunisia and Yemen. The SADC countries which provided responses to the questionnaire were Botswana, Mauritius, Seychelles, Tanzania and Swaziland. Uganda though not a SADC country also provided feedback prior to the Kempton meeting.

4. Findings

As discussed above, the questionnaire had 44 questions addressing various issues around legislative aspects, anti-counterfeit actions, sharing information, collaboration with other departments, initiatives by WHO and NMRAs, free trade zones, and market control. The findings are summarized as follows:



Major Findings of Questionnaire

Legislative aspects

- 21 countries (78%) use pharmaceutical legislation
- 3 countries in EMRO have specific legislation on counterfeit medicines
- 23 countries would welcome specific legislation on counterfeit medicines (AFRO: 13; EMRO: 10)

Seizures

- 20 countries reported to have carried out seizures of counterfeit medicines (AFRO: 11; EMRO: 9)
- In 15 countries the seizures were always initiated by NMRAs (AFRO: 6; EMRO: 9)
- Weak cooperation between NMRA, police and customs

Sharing information

- Only 11 countries were aware of WHO Rapid Alert System (RAS) (AFRO: 5; EMRO: 6)
- Information on counterfeit medicines is hardly shared with other NMRAs or WHO

Collaboration with other authorities

- operational cooperation with Police and Customs in 74% of all countries (AFRO: 10; EMRO:10)
- Reasons for inadequate cooperation:
 - lack of tradition to cooperate
 - limited resources
 - lack of legal framework for cooperation
- 48 % of all countries reported to have conducted joint operations with police and/ or customs (AFRO: 5; EMRO: 8)
- In 23 countries NMRA authorization is required for clearing medicines at customs (AFRO: 12; EMRO: 11)

MRA and WHO Initiatives

- 14 countries were aware of SPOC (AFRO: 7; EMRO: 7) while only 7 have designated SPOC (AFRO: 4; EMRO: 3)
- 7 countries have participated in at least one IMPACT meeting (AFRO: 5; EMRO: 2)

Control of free trade zones

- 52% of all countries declared having free trade zones (AFRO: 5; EMRO: 9)
- In 7 countries, free trade zone is oriented to both local and export (AFRO: 2; EMRO: 5) markets while in 2 countries it is oriented to local market

Market control

- Number of medicines authorized range between 3,095 to 8,972
- Number of medicines on the market range between 1,700 to 6200 although the reports were from few countries
- 60 % of all countries declared to have conducted market surveys (AFRO: 7; EMRO: 9)
- 14 countries declared having an informal market , most of them are limited to rural areas in EMRO region (AFRO: 8; EMRO: 6)

5. Conclusions and recommendations

5.1 Conclusions

This survey shows that countries call for a specific legislation that empowers NMRAs and criminalizes counterfeit medical products. There is weak cooperation among the various key players at national, regional and global level, while a strong collaboration would be required to effectively combat counterfeit medical products. Information is not shared with other NMRAs and other law enforcers within the country. There are weak market control systems in most surveyed countries.

5.2 Recommendations

Based on the findings from this survey and discussions of the findings during the Abuja and Kempton Regional meetings, as well as the IMPACT Third General meeting, it is recommended that:

- I. Member States should develop a specific legislation that empowers NMRAs and criminalizes counterfeit medical products;
- II. information sharing between NMRAs and police and customs as well as with other regional and international organizations should be strengthened, in a joint effort to combat counterfeit medicines;
- III. Single Points of Contact (SPOC) should be established to facilitate exchange of information on counterfeit medicines at national, regional and international levels;
- IV. Member States are encouraged to declare cases of counterfeit medicines to WHO and INTERPOL;
- V. pharmaceutical trade in free trade zones should be controlled by legislation;
- VI. information on counterfeit medicines should be shared with other NMRAs and other law enforcers within the country.

6. Annexes

Annex 1 List of countries participating in this survey

AFRO:

Botswana, Burkina Faso, Cameroon, Mali, Mauritius, Morocco, Niger, Senegal, Seychelles, Swaziland, Tanzania and Uganda



EMRO:

Afghanistan, Djibouti, Egypt, Iraq, Jordan, Lebanon, Oman, Pakistan, Somalia, Sudan, Syria, Tunisia and Yemen



Annex 2 Data Collection Tool for the Review of National Situations concerning Counterfeit Medicines¹

Annex 2.A Questions for Interview

This assessment tool is attempting to provide a unified approach of assessing the problem of counterfeit medicines in a particular country, sub-regional or regional setting. The tool addresses existing national legislations on counterfeit medicines, capacity of National Medicines Regulatory Authorities (NMRA) in the control of counterfeit medicines, market control, as well as determining the awareness and efforts of the government and other stakeholders in combating counterfeit medicines. The last part of the tool addresses the issues of collaboration and cooperation among stakeholders at national and international levels.

Legislation

1. What are the elements of the current legislation² on the control of the manufacture, importation, exportation, distribution, supply and sale of medicines that are essential for combating counterfeit medicines?
2. Is there a provision³ for the control of counterfeit medicines in the legislation?
3. Does the legislation define counterfeit medicines?
4. Is the definition consistent with that of WHO?
5. How does legislation penalize against criminals of counterfeit medicines?

Capacity of NMRAs

¹ Medicines, in this document encompass finished products, APIs, excipient and packaging materials.

² Focus on identifying gaps and limitations and issues of coordination between different institutions.

³ Focus on identifying gaps/limitations and if there are prohibitions against counterfeit products, packaging and related activities?

6. Provide available statistics on number of cases of counterfeit medicines providing product names and cases prosecuted/convicted/penalties
7. What are the deadlines or performance indicators for investigation/prosecution cases?
8. What legal/regulatory measures are actually being used to combat counterfeit medicines?
9. What national guidelines/policies are being used for combating counterfeit medicines?
10. Provide statistics on inspectors and other officials conducting inspections, sites to be inspected, inspections carried out, etc in the country.
11. Provide statistics on training initiatives aimed for inspectors, enforcement officials, judiciary, health professionals and supply chain stakeholders on the techniques for identification, detection, documentation, reporting and communication on counterfeit medicine?
12. What procedures or SOPs are used for the following:
 - a. Managing records, evidence and other information related to individual counterfeit medicines cases.
 - b. Visual inspection and other non-analytical procedures such as determining authenticity for the detection of counterfeit medicines.
 - c. Sampling procedures, including instructions regarding the size of samples, methods of sampling and procedures for sealing samples and submitting to the quality control laboratory for testing.
 - d. Methods and special precautions for isolating and preventing further distribution of suspect counterfeit medicines.
 - e. The system for recording actions taken, including basic tests on suspect counterfeit medicines.

- f. Methods of seizing and destroying counterfeit medicines, where required.
 - g. Communication of suspected and/or confirmed cases of counterfeit medicines.
13. What systems are in place for reporting suspected cases of counterfeit medicines and identifying signals of possible counterfeit cases?
14. What system/mechanism is in place to manage conflicts of interest for NMRA staff?

Market control

15. Are there designated ports of entry for importation of pharmaceuticals?
- a. What measures are being taken to prevent importation through points of entry that are not the designated ones, where applicable?
 - b. What operational measures are being used to prevent the importation of unauthorized medicines?
16. Are there free trade zones for pharmaceutical products in the country?
17. What monitoring and enforcement is done in these free trade zones?
18. Are there several trade intermediaries for imported medicines? If yes, describe them briefly,
19. Are all drug distribution channels licensed or authorized?
- a. If yes; what are the licensing criteria for pharmaceutical manufacturers, wholesalers and other distributors, retail pharmacies and other dispensing outlets?
 - b. What is the percentage distribution of medicines through different distribution channels?
 - i. Public
 - ii. Private (including Non-Governmental Organization (NGOs))
20. What estimated proportion of medicines is sold without original packaging or without proper labelling (wholesaler-wholesaler, wholesaler-retail, retail-patient, any other combination)?

21. What is the estimated number of illegal outlets?
22. What measures are being taken to control illegal distribution?
23. Is there a significant proportion of medicines on the market without a proper marketing authorization?
24. Provide available statistics on samples collected and tested for the purposes of detecting counterfeit medicines.
25. What measures are in place to manage situations of short supply of medicines?
26. What measures are in place to ensure access to medicines where affordability is a problem?

Documentation and reporting mechanism

27. Is it mandatory to report any incidents of suspect/detected counterfeit medicines by various stakeholders to NMRA? Tick where appropriate.
 - a. Pharmaceutical industry.....
 - b. Wholesalers.....
 - c. Retailers.....
 - d. Health professionals and associations.....
 - e. Consumers.....
 - f. Other government agencies.....
28. Is there a formalized reporting⁴ mechanism? Yes () No () If yes, describe briefly.....

Awareness Programmes

29. Does your country offer any awareness programmes on medicines counterfeiting? If yes, who is the target audience and how is the effectiveness of the programmes assessed?
30. Are confirmed counterfeit cases made public? If yes, how is the information disseminated⁵?

⁴ Linkage with other vigilance systems

⁵ For example, public list of cases, press releases, public alerts

National Collaboration

- 31. Provide information on the national medicines anti-counterfeiting taskforce⁶.
- 32. Describe collaboration with different stakeholders such as manufacturers, wholesalers, retailers etc.

International Collaboration

- 33. Describe any international collaboration in which your country is involved concerning counterfeit medicines.
- 34. Describe examples of information exchange, cooperation in investigating cases and other operational collaboration with different partners at the international level and discuss limitations.
- 35. Include activities involving capacity building and exchange of knowledge, intelligence and experience.

Annex 2.B Questionnaire

The objective of this tool is to get a quick overview of the situation concerning counterfeit medicines in a country.

LEGISLATIVE ASPECTS

- 1. The legislation you use to combat counterfeit medicines (CM) is⁷:
 - a. General legislation on counterfeiting ()
 - b. Specific legislation on CM ()
 - c. Pharmaceutical legislation ()
 - d. Legislation on intellectual property rights ()
 - e. Other (specify)
- 2. Do you consider that you need more specific legislation to combat CM in your country?
Yes () No ()
- 3. What is the legal definition of CM in your country?
- 4. What is the operational definition of CM in your country?
- 5. What are the areas where your legislation needs revision?

⁶ Mention participating stakeholders, legal basis, plans and resources, etc.

⁷ For all the questions you can check multiple answers. Feel free to add comments to further clarify the information you are providing.

- a. Definition of CM ()
- b. Cooperation between national authorities/stakeholders ()
- c. Regional cooperation ()
- d. International cooperation ()
- e. Strengthening the operational capacity of the Medicines Regulatory Authority (MRA) ()
- f. Criminalizing the trade of CM ()
- g. More severe sanctions for crimes related to CM ()
- h. Other (specify).....

ANTICOUNTERFEIT ACTIONS

6. Number/volume of seizures of counterfeit medicines during these years
- a. 2006:.....
 - b. 2007:.....
 - c. 2008:.....
7. For these seizures who was at the origin of the information about the case?
- a. MRA: occasionally (), often (), always ()
 - b. Police: occasionally (), often (), always ()
 - c. Customs: occasionally (), often (), always ()
 - d. Health professionals (specify):
..... : occasionally (), often (), always ()
..... : occasionally (), often (), always ()
 - e. Others (specify):
..... : occasionally (), often (), always ()
..... : occasionally (), often (), always ()
8. What authority carried out the seizure?
- a. MRA: occasionally (), often (), always ()
 - b. Police: occasionally (), often (), always ()
 - c. Customs: occasionally (), often (), always ()
 - d. Others (specify):
..... : occasionally (), often (), always ()
..... : occasionally (), often (), always ()

9. If there is no seizure during the last three years what are the reasons?

- a. Absence of CM in the country ()
- b. Lack of quality testing capacity ()
- c. Weakness of inspection ()
- d. Inadequate drug registration system ()
- e. Insufficient cooperation with Police ()
- f. Insufficient cooperation with Customs ()
- g. Other (specify).....

10. Number of disciplinary, administrative, civil or penal prosecutions initiated

	disciplinary/administrative	Civil	penal
2006	less than 5 () 5 or more ()	less than 5 () 5 or more ()	less than 5 () 5 or more ()
2007	less than 5 () 5 or more ()	less than 5 () 5 or more ()	less than 5 () 5 or more ()
2008	less than 5 () 5 or more ()	less than 5 () 5 or more ()	less than 5 () 5 or more ()

11. What has been the outcome of prosecutions and administrative action (please choose the statements that best describe the situation)?

- a. Administrative/disciplinary sanctions are timely and effectively applied ()
- b. Administrative/disciplinary sanctions often difficult to apply ()
- c. Number of manufacturers/wholesalers prosecuted or shutdown during the period 2006-2008:
- d. Number of retailers prosecuted or shutdown during the period 2006-2008:.....
- e. Civil prosecution timely conducted and effective ()
- f. Civil prosecution very slow and ineffective ()
- g. Penal prosecution timely conducted and effective ()
- h. Penal prosecution very slow and ineffective ()
- i. Very difficult to obtain information about sanctions()
- j. Cases remain pending for many years ()
- k. Other:

SHARING INFORMATION

12. Number of CM cases reported during:

	to WHO	to others
2006		
2007		
2008		

13. Do you know WHO's Rapid Alert System? Yes: () No: ()

14. Number of cases of CM where you informed at least one country of your region:

- a. 2006 : officially..... informally.....
- b. 2007 : officially..... informally.....
- c. 2008 : officially..... informally.....

15. Did you identify the origin of the above cases as:

- a. National Origin ()
- b. International Origin ()
- c. Undetermined origin ()

16. In the case of an external origin did you contact the MRA of the suspected country of origin?

- a. Always ()
- b. Sometimes ()
- c. Never ()

COLLABORATION WITH OTHER AUTHORITIES

17. Is there an operational coordination mechanism in your country between

- a. MRA-Customs : ()
- b. MRA-Police: ()
- c. MRA-Police-Customs: ()
- d. MRA-Police-Justice : ()
- e. Others (Specify):

18. Number of joint actions carried out with Police:

- a. 2006:
- b. 2007:
- c. 2008:

19. In absence of joint action with Police, what are the main reasons?

- a. No cases to act upon ()
- b. Absence of legal framework ()
- c. Absence of tradition of cooperation ()
- d. Limited human resources in your department ()
- e. Limited human resources in the two departments ()
- f. Other:.....

20. Number of joint actions carried out with Customs

- a. 2006 :
- b. 2007 :
- c. 2008 :

21. In absence of joint actions with Customs, what are the main reasons?

- a. No cases to act upon ()
- b. Absence of legal framework ()
- c. Absence of tradition of cooperation ()
- d. Limited human resources in your department ()
- e. Limited human resources in the two departments ()
- f. Other:.....

22. Number cases you could not investigate because of lack of coordination with:

- a. Police :
- b. Customs :

23. Does Customs services systematically require MRA permit before releasing medicines at ports of entry?

- a. For private sector Yes () No ()
- b. For public sector Yes () No ()
- c. For NGOs Yes () No ()

- 24.** Number of permits issued by MRA in 2007:
- a. For private sector
 - b. For public sector
 - c. For NGO
- 25.** Number of counterfeit cases handled by courts in
- a. 2006 :
 - b. 2007 :
 - c. 2008 :
- 26.** In these cases did the court ask for input from
- a. MRA
 - b. Other MOH experts
 - c. Health professionals (specify):.....
 - d. others:.....
- 27.** Number of meetings on counterfeit medicines with Police, Customs and other stakeholders during:
- a. 2006:
 - b. 2007:
 - c. 2008 :

MRA AND WHO INITIATIVES

- 28.** Do you know that IMPACT recommends the designation of a SPOC (Single Point of Contact) in each country to coordinate the fight against CM?
- Yes No
- 29.** Did your government designate a SPOC in your country?
- Yes No
- 30.** If yes, provide SPOC details:.....
- 31.** Did your country participate in IMPACT meetings in?
- a. 2006 :
 - b. 2007 :
 - c. 2008 :

FREE TRADE ZONES IN YOUR COUNTRY

- 32. Are there free trade zones in your country? Yes () No ()

- 33. Is the trade on medicines in these zones oriented to:
 - a. Your local market
 - b. Only export
 - c. Export and local market

- 34. Are these free trade zones under the supervision of the MRA?
Yes () No () Yes but difficult to supervise ()
Specify issues of concern:.....

- 35. Is the National Pharmaceutical Legislation applicable in the free trade zones: Yes () No ()
If no specify what legislation is applicable (customs, trade.....):
.....

- 36. What kind of inspections are conducted in the free trade zones:
Pharmaceutical () Customs () Other (specify):

- 37. How many pharmaceutical inspections were conducted in the free trade zones in
 - a. 2006 :
 - b. 2007 :
 - c. 2008 :

MARKET CONTROL

- 38. Number of medicinal products authorized for marketing in your country (same marketing authorization number = same product): number date

- 39. Number of authorized medicinal products estimated to be actually on the market:
number date

- 38. Number samples collected in market surveys in 2007 from
 - a. Public sector
 - b. Private sector

- 40. Number of samples analysed in 2007 from
 - a. Public sector
 - b. Private sector

- 41. Is there an informal market for medicines in your country?
Yes () No ()

- 42.** What is the relative importance of this informal market?
- a. Very marginal ()
 - b. Important (some of the population depend on it for their medicines supply) ()
 - c. Very Important (large population depend on it for their medicines supply) ()
 - d. Limited to some areas of the country ()
 - e. Limited to rural areas ()
 - f. Limited to some metropolitan areas ()
 - g. Widespread ()

43. Number of raids conducted in the informal market

Year	NRA alone	NRA+Police	Other arrangement (specify)
2006			
2007			
2008			

44. Additional information/remarks or problem not covered by the questionnaire:

.....

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