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**MEDICINES REGULATORY AUTHORITIES:
CURRENT STATUS AND THE WAY FORWARD**

Report of the Regional Director

EXECUTIVE SUMMARY

1. The Medicines Regulatory Authority (MRA) is the body in charge of coordinating and overseeing the pharmaceutical sector for the purpose of protecting public health.
2. A study carried out by the WHO Regional Office for Africa in 2004 showed that 90% of MRAs in the African Region lack the capacity to carry out medicines regulatory functions and, therefore, cannot guarantee the quality, efficacy and safety of medicines, including traditional medicine. This situation can have adverse implications for public health protection and promotion.
3. In order to address the situation, Member States should clearly define the mission of MRAs and give them the needed legal authority, appropriate organizational structure and facilities, and adequate and sustainable resources.
4. The Regional Committee is invited to review this document and adopt the recommended actions.

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INTRODUCTION

1. The use of inefficacious and low-quality medicines causes treatment failures, aggravates side effects and leads to drug resistance. It is the responsibility of each Member State to set up a system for regulating not only medicines and traditional medicine but also the entire pharmaceutical sector in order to address this situation.
2. The regulatory system is managed by a Medicines Regulatory Authority (MRA) whose mission is to coordinate and oversee the medicines sector in order to protect public health. A medicines regulatory authority should have a national medicines policy and related legislation as well as norms, guidelines, procedures and adequate financial and human resources.
3. The main functions of MRAs are to issue licenses to pharmaceutical companies, evaluate their products, carry out medicines inspections, control and monitor the quality of medicines circulating on the local market, authorize clinical trials, oversee medicines promotion and advertising, conduct surveillance of adverse reactions to medicines and provide medicines-related information.
4. A study conducted out by the WHO Regional Office in 2004¹ showed that 90% of MRAs in the Region lack the capacity to carry out all the medicines regulatory functions and, therefore, cannot guarantee the quality, efficacy and safety of medicines. This situation can adversely affect the quality of care considering the central role that medicines play in health care provision.
5. This document reviews the current status of MRAs, the regulation of medicines including vaccines and narcotic medicines, and proposes the way forward to enhance the performance of MRAs in the African region.

CURRENT STATUS

6. The World Health Organization (WHO) has carried out a survey² on the situation of medicines regulatory authorities in the African Region. The survey outcome shows that of the 38 countries that filled the questionnaire, 66% have MRAs represented by the directorate of pharmacy, 34% have MRAs represented by an autonomous public agency, while medicines legislation in 37% of the countries is either ill-suited or non-existent.
7. Eighty-four percent of MRAs have inadequate staff. In addition, the staff lack the qualifications and experience needed to carry out all MRA functions. External expertise is solicited only in 42% of cases.
8. The MRA is financed mainly from the State budget. The revenue generated by MRAs is paid into the public treasury in 58% of cases.
9. It was noted that 42% of MRAs issue or renew licenses for the various practitioners without checking or referring to the records of inspection reports.
10. An estimated 63% of MRAs are unable to evaluate the quality, efficacy and safety of new medicines for lack of adequate resources. In the specific case of vaccines, 87% of MRAs answered that they were not capable of evaluating them. This problem is serious considering that

¹ WHO/AFRO/EDP//04.5, Availability of Drug Regulatory and Quality Assurance Elements in Member States of the WHO African Region, 2004 Brazzaville.

² WHO/AFRO and TCM/HQ, Survey on the National Systems of Medicines Regulation in the African Region, 2005.

African countries support the development of new vaccines through the Meningitis Vaccine Project and the African AIDS Vaccine Programme.

11. Some 50% of MRAs do not carry out medicines inspections due to inadequacy of material and human resources. This can encourage the circulation, in the countries, of counterfeit or poor-quality medicines. Besides, 50% of MRAs do not regulate medicines advertising and promotion due to failure to enforce existing rules.

12. For medicines quality control and monitoring purposes, the African Region has two WHO collaborating centres in charge of medicines quality assurance, three operational regional reference laboratories and 15 national laboratories.³ Even though Member States have made substantial efforts, significant levels of noncompliance were still noted in studies^{4,5} conducted on anti-malarial products and anti-tuberculosis products.

13. A national committee whose membership includes the MRA is responsible for authorizing clinical trials of new medicines including vaccines. In 84% of cases, the capacity to carry out clinical trials is hampered by lack of clear legislation, skilled human resources and guidelines.

14. Surveillance of adverse reactions to medicines is not effective in 68% of cases, although this function has become crucial given the large increase in antimalarial and antiretroviral combination therapies and the implementation of post-vaccination reaction surveillance. Furthermore, in general, MRAs are not able to provide independent information on medicines to professionals and the public.

15. In accordance with international conventions,⁶ the regulation of narcotic medicines is the responsibility of the MRA. In this regard, it is notable that on 1 November 2005, all countries of the Region are parties to these international conventions with the exception of: one country that is not yet party to the three conventions; two countries that have yet to accede respectively to the 1972 Protocol and the 1971 Convention; and two countries that have yet to accede to the two 1988 Conventions.⁷

16. These medicines are useful for the treatment of patients who are in intense pain, e.g., due to cancer, HIV neuropathy, diabetic neuropathy, injury and surgery. Their prolonged use or their abuse, as in the case of psychotropic medicines in treating drug dependence, leads to addiction. This explains why they are subjected to stringent controls, sometimes resulting in their shortage on the market.

THE WAY FORWARD

17. Given the scope and the magnitude of the problems facing MRAs, some interventions are needed in order to establish or strengthen the capacity of MRAs and promote effective regulation of medicines.

³ WHO/AFRO/EDP, Medicines Quality Control Laboratories in the WHO African Region, 2006 (in press) Brazzaville.

⁴ WHO/AFRO/EDP/02.7, Quality Screening of Antimalarial products in six African countries, WHO/AFRO, Brazzaville, 2002.

⁵ WHO/AFRO, Quality Screening of Antituberculosis Products in nine African countries, WHO/AFRO, Brazzaville, 2004 (in press).

⁶ United Nations, Single Convention on Narcotic Drugs, 1961, United Nations, February 2001, Vienna.

United Nations, Convention on Psychotropic Substances, 1971, United Nations, 2001, Vienna.

United Nations, United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988, United Nations, June 1994, Vienna.

⁷ INCB, International Narcotic Control Board Report, 2005, Vienna, United Nations.

Institutional and organizational framework

18. Member States should spare no effort to ensure that MRAs have a clearly-defined mission and adequate legal authority to accomplish their mission. To that end, countries should formulate national medicines policies that underscore the importance of public health over the monetary value of medicines.

19. The related legislation should be appropriate for the national and regional contexts. They should be comprehensive and equitable, take account of all aspects of medicines regulation and provide for appropriate sanctions for noncompliance.

20. Member States should ensure that MRAs have the appropriate organizational structure, facilities, autonomy and qualified, experienced and motivated staff in sufficient numbers. Countries should provide the MRAs with adequate and sustainable financial resources. For example, the resources generated from the services provided by MRAs could be allocated back to MRAs for operational use.

21. Countries should provide MRAs with modern communication facilities, computers, internet access, websites and appropriate logistics.

22. MRAs should, for their part, develop the tools they need for their work, including norms, procedures, guidelines and management handbooks.

Strengthening the capacities of MRAs

23. To address the problem of availability of sufficiently competent and qualified staff, Member States and MRAs should draw up a sustainable human resource development plan to be implemented with the support of partners. Training programmes conducted internally or externally will also contribute to enhancing the knowledge and skills of MRA staff.

Carrying out regulatory functions

24. In order to carry out their functions effectively, MRAs should develop or update written guidelines and procedures related to: the issuing of licenses; good practices in medicines manufacture and distribution; evaluation of medicines including vaccines; oversight of medicines promotion and advertising; reporting of adverse post-vaccination reactions and side effects; clinical trials of medicines including vaccines; and medicines promotion and advertising.

25. MRAs should establish stable and transparent cooperation with university experts, health care and research institutions, and professional associations to improve their performance in areas such as the evaluation of medicines including vaccines, clinical trials and monitoring of side effects.

26. MRAs should operate within a network and exchange information among themselves. They should be able to learn and benefit from decisions taken by other reliable MRAs when making their own decisions. Initiatives taken within subregional economic communities to harmonize medicines regulation should be encouraged and supported by partners including WHO.

27. In the specific case of control of narcotic medicines, the practice of following international conventions should continue. Member States should, in collaboration with WHO and the International Narcotic Control Board, find a more appropriate balance between the regulatory

requirement for control of narcotics and the need to make them available and accessible for medical and scientific use.

CONCLUSION

28. With globalization and the rapid introduction of high-tech medicines into the distribution chain, the issue of the quality, efficacy and safety of medicines is becoming a concern for Member States and WHO. Failure to enforce regulations would result in the proliferation of harmful, inefficacious, counterfeit or substandard medicines on national and international markets.

29. Member States should establish or strengthen MRAs to enable them to carry out their missions better, ensure the availability of medicines of good quality and encourage regional collaboration.

30. The Regional Committee is invited to review this document and adopt the recommended actions.