

## **Presentation note**

Drugs for human use, industrially manufactured, are essential and common health products in the prevention and treatment of diseases.

However, they can have negative or even dangerous effects on the human body for several causes, especially if their manufacture and marketing do not respect the scientific and legal standards.

Due to the above considerations and the fact that " Medicines marketing authorization" is a decisive step in the commercialization of the medicine, locally manufactured or imported, as well as official recognition of its safety and effectiveness by the competent public authority. Law No. 17-04 establishing the drug and pharmacy code, has posed the marketing authorization as a basic rule and has surrounded it by certain conditions, in Section I Chapter II of the first book, and has refers to regulatory to determine the modalities for granting this permission, the transfer, suspension and removal.

To this end, this draft decree prepared by the Ministry of Health, in consultation with representative national institutions of industrial pharmaceutical establishments in accordance with the Law No. 17-04 and the commonly accepted international rules in the field of drug registration.

Finally, this decree repeal the regulatory provisions relating to the first title of Decree No. 2.72.266 of 6 May 1977 on the approval and the authorization of pharmaceutical specialties and their advertising, as amended and supplemented.