
Medical Devices classification rules are provided in Annex 1 of this Order. Essential quality, safety and performance requirements for medical devices are provided in Annex 2. Good practices rules for their manufacturing, transport, storage, distribution and performance evaluation are available in the Moroccan standard NM ISO 13 485. The templates for the Inspection Report and the Offences Report are provided in Annex 3 and Annex 4.

Morocco - Decree No. 2-14-841: Marketing Authorization of Medicinal Products for Human Use, 05-Aug-2015 (Arabic and French versions)

Pursuant to Law No. 17-04: Code of Medicine and Pharmacy (IDRAC 209095), this decree provides the framework for the Marketing Authorization (MA) of medicinal products for human use in Morocco.

It is divided as follows:
Chapter I - Definitions
Chapter II - MA Application
Chapter III - MA Renewal
Chapter IV - MA Transfer
Chapter V - MA Withdrawal and Cancellation
Chapter VI - MA National Commission
Annex - Conditions related to the MA Application

The decree will come into force on 20-Feb-2016 and updated requirements should be implemented as follows:

The CTD format will be an official requirement (Article 2). Well-established products can be exempted from the requirement to provide non-clinical and clinical data (Modules 4 and 5) if the efficacy and safety profile of the active ingredient is already proved in the literature (Article 5).

Many timelines will be updated such as the ones for the admissibility of the registration file (Article 11), the DMP to study and approve the product safety and efficacy (Article 13), the DMP to decide on the MA approval will change (Article 15), the objection on decisions (Article 16), the issuance of the official MA certificate (Article 19), the submission for renewal (Article 26) and the renewal review (Article 27).

Pursuant to Chapter VI of this decree, a new National Commission for Marketing
Authorization will be established to give recommendation to the Minister of Health as to therapeutic relevance, efficacy and safety of new medicinal products and biosimilars, as well as withdrawal of MAAs.

A cover letter will be requested in the MA application and the applicant shall submit it according to the requirements provided in the Annex.

**Comments:** This decree revokes the provisions of Title I of Decree No. 2-76-266 of 06-May-1977 (IDRAC 207769), starting 20-Feb-2016.

Full report (IDRAC 218386)

**Document date:** 05-Aug-2015  
**Coming Into Force Date:** 20-Feb-2016  
**Document type:** Decree  
**Regulatory version:** None  
**Language:** Arabic, French  
**Source; Publication Date:** Bulletin Officiel No. 6388 of 20-Aug-2015.  
www.sgg.gov.ma  
20-AUG-2015

**Morocco - How To Market Medical Devices**  
This regulatory summary relates to medical devices. It provides definition of medical devices, explains the legal framework, outlines the requirement for registration and the format and content of the application. This document also provides details about fees, labeling, post-marketing requirements, advertising and pricing and reimbursement.

**Comments:** The last revision added a new Section 11: Future Developments, following the issuance of 4 new Orders on medical devices that will only be implemented on 01-Feb-2016.

Full report (IDRAC 213350)

**Document date:** 12-Oct-2015  
**Document type:** Other Document  
**Regulatory version:** None  
**Language:** English  
**Source; Publication Date:** Cortellis RI

**Morocco - Clinical Research: General Principles**  
This document outlines the overall principles that apply to clinical trials.

**Comments:** The last review added the new Law No. 28-13 on Protection of Participants in Biomedical Research. The sections updated are 2.2, 3, 4.3, 4.4, 5.1, 5.2 and 5.4

Full report (IDRAC 211596)

**Document date:** 14-Oct-2015  
**Document type:** Other Document  
**Regulatory version:** None  
**Language:** English  
**Source; Publication Date:** Cortellis RI
Morocco - Clinical Research: Initiation and Conduct of Clinical Trials
This document provides information concerning the initiation and conduct of clinical trials.

Comments:
The last review added the new Law No. 28-13 on Protection of Participants in Biomedical Research. The sections updated are 2, 4, 7, 9, 10, 12 and 13

Full report (IDRAC 211597)
Document date: 14-Oct-2015
Document type: Other Document
Regulatory version: None
Language: English
Source; Publication Date: Cortellis RI

Morocco - Clinical Research: Investigational Products
This document provides information on investigational medicinal products.

Comments:
The last review added the new Law No. 28-13 on Protection of Participants in Biomedical Research. The sections updated are 2, 5.1, 5.2, 5.3 and 5.4

Full report (IDRAC 211601)
Document date: 14-Oct-2015
Document type: Other Document
Regulatory version: None
Language: English
Source; Publication Date: Cortellis RI

Morocco - Law No. 28-13: Protection of Participants in Biomedical Research, 04-Aug-2015
This Law sets the legal framework for biomedical research conducted in Morocco in order to enhance the appropriate conditions for conducting biomedical research and to guarantee its transparency and the protection of participants in such research.

It provides the definitions for the following terms (Article 1): biomedical research, interventional biomedical research, non-interventional or observational biomedical research, multicenter biomedical research, sponsor, institutional sponsor, investigator, coordinator, participant, biological product.

According to Article 3, any biomedical research should respect the life, health, physical and psychological integrity of the participant in addition to its dignity and intimacy. The biomedical research shall respect the volunteering aspect of any trial and shall respect the fact of the non-commercial character of the human body.

According to Article 10, all participants shall undergo medical testing prior to the start of the biomedical research to verify that there are no contraindications preventing the participation in the research.

Chapter IV of Title I provides information related to Regional Committees (RC) responsible for the protection of patients participating in biomedical research.
According to Article 25, a biomedical research can be conducted in governmental civil or military establishments, in private establishments, in hospital and university centers benefiting from a special convention to act as a research site. A biomedical research covering genetic or blood derivative products can only be conducted in governmental establishments or hospital and university centers benefiting from a special convention to act as a research site.

***

**Comments:** Some provisions of this Law enter into force once the regulatory instruments needed for their application are published. For instance, the structure of the Regional Committees (RC) will not be in place before the issuance of regulatory texts defining these committees’ location, composition and number.

Full report (IDRAC 219816)  
**Document date:** 04-Aug-2015  
**Document type:** Law  
**Regulatory version:** Final  
**Language:** Arabic, French  
**Source:** Arabic version from BO 6388 of 20-Aug-2015 (pages 7132 to 7143). French version from BO 6396 of 17-Sep-2015 (pages 3458 to 3467).  
www.sgg.gov.ma  
20-AUG-2015