

4th Club

Friday 18 April 2025



Club Founder
Dr. Mahmoud Bahgat



Regulatory Affairs Club

ANMPS Drug Registration

Online Zoom

**7 pm Egypt - 8 pm KSA - 9 pm UAE
6 pm Tunisia**



Dr. Ghassen Bhouri
RA officer
MC Pharma
Tunisia



Co-Founder & Host:
Dr. Zeyad Anany



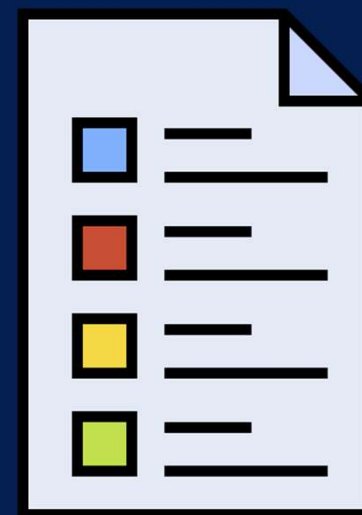
ANMPS Drug Registration

Ghassen Bhourri
RA officer MC Pharma

18 April 2025

Agenda

1. About me
2. What makes regulatory affairs so exciting?
3. ANMPS introduction
4. Guidelines
5. CTD
6. Submission and assessment of the dossier
7. Fast track assessment
8. Life cycle management.
9. eSubmission / eCTD transition



About me

I am Ghassen BHOURI, pharmacist with 6 years of experience in regulatory affairs.

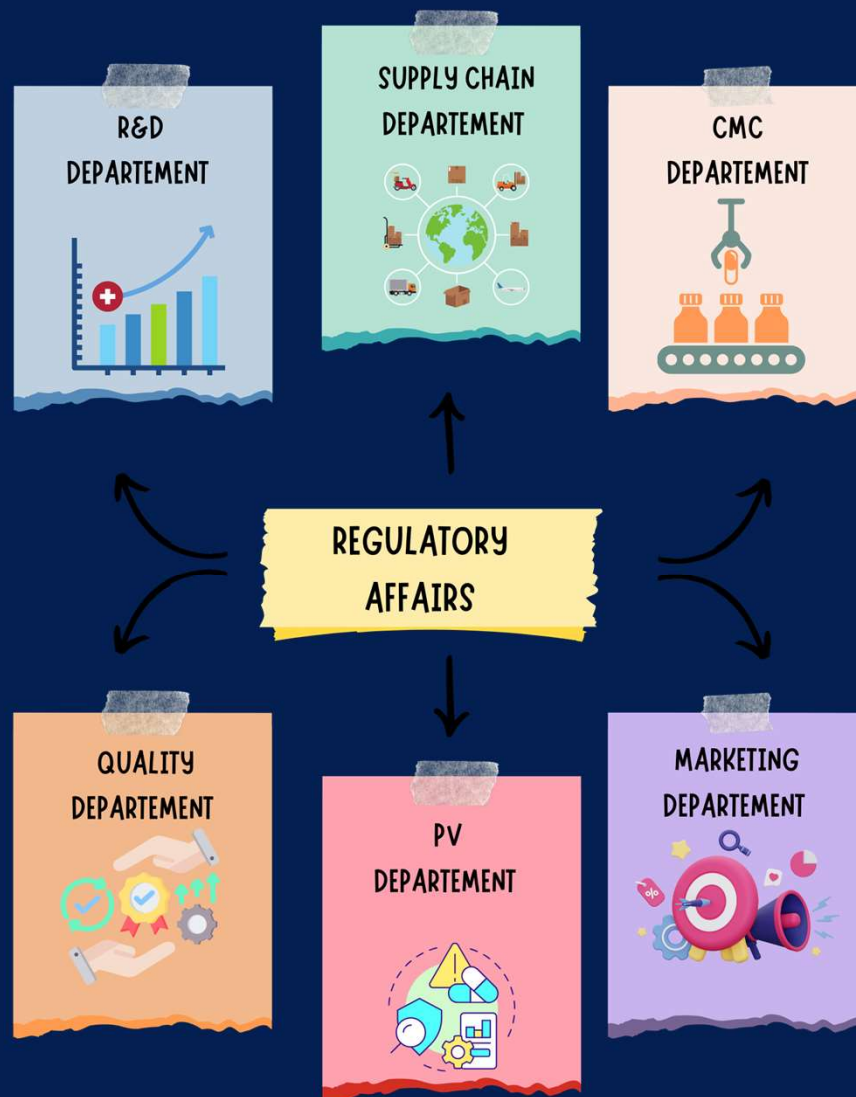
I currently hold the position of Regulatory and Pharmaceutical Affairs Officer at MC Pharma.

MC Pharma is a service provider representing more than 20 international laboratories in Tunisia.

I am also a RA trainer at AtawadacPharma and content creator.



What makes
regulatory
affairs so
exciting?



ANMPS



الوكالة الوطنية للدواء و مواد الصحة

AGENCE NATIONALE DU MÉDICAMENT ET DES PRODUITS DE SANTÉ

NATIONAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

قانون عدد 2 لسنة 2023 مؤرخ في 12 جويلية 2023
يتعلق بإحداث الوكالة الوطنية للدواء ومواد الصحة (1).

باسم الشعب،

وبعد مصادقة مجلس نواب الشعب.

يصدر رئيس الجمهورية القانون الآتي نصه :

الفصل الأول . تحدث مؤسسة عمومية لا تكتسي صبغة إدارية
تتمتع بالشخصية القانونية والاستقلال المالي تسمى "الوكالة الوطنية
للدواء ومواد الصحة". ويشار إليها فيما يلي بـ "الوكالة".

وتخضع الوكالة لإشراف الوزارة المكلفة بالصحة ويكون مقرها
بتونس العاصمة.

الفصل 2 - تسهر الوكالة عند تنفيذ مهامها على ضمان شفافية التصرف في الدواء ومواد الصحة واستقلالية أعمال وآراء وقرارات الهيكل والمؤسسات والخبراء المتدخلين في تنفيذ مهامها. وللغرض تكلف خاصة بالمهام التالية:

- المساهمة في اقتراح السياسة الوطنية في مجال الدواء ومواد الصحة.

- إسناد أو اقتراح إسناد التراخيص، وفقا للتشريع والتراتب الجاري بها العمل، في ميدان صنع وتسجيل وتوريد وتصدير وتوزيع وتسويق الدواء ومواد الصحة ومكوناتها.

- تعليق أو منع أو اقتراح تعليق أو منع تسجيل وصنع وتوريد وتصدير وتوزيع وتسويق الدواء ومواد الصحة ومكوناتها وذلك وفقا للتشريع والتراتب الجاري بها العمل.

- إسناد التراخيص في إجراء التجارب السريرية ومراقبتها وفقا للتشريع والتراتب الجاري بها العمل.

الفصل 15 . تلغى تدريجيا جميع الأحكام السابقة المخالفة لهذا القانون في أجل أقصاه ثلاث (3) سنوات من تاريخ نشره بالرائد الرسمي للجمهورية التونسية.

الفصل 4 . يضبط التنظيم الإداري والفني والمالي للوكالة وكذلك طرق سيرها بمقتضى أمر.

الفصل 5 . يضبط الهيكل التنظيمي للوكالة ونظام الخطط الوظيفية لأعوانها بمقتضى أوامر.

ANMPS



DPM
(Directorate of Pharmacy and Medicines) : It manages all administrative aspects related to pharmacy, medicines and related activities.



CNPV (National Pharmacovigilance Center) :
Responsible of Pharmacovigilance in Tunisia.



DIP (Directorate of Pharmaceutical Inspection) : It carries out the various inspection, evaluation and investigation operations required.



LNCM
(National Laboratory for Drug Control) : Controlling the quality of medicines and health products.

Guidelines in force



MEDICINAL PRODUCTS REGISTRATION GUIDE IN TUNISIA
(version of 2016)



Bioequivalence Guide for Medicinal Products for Human Use



Guide of biosimilars registration



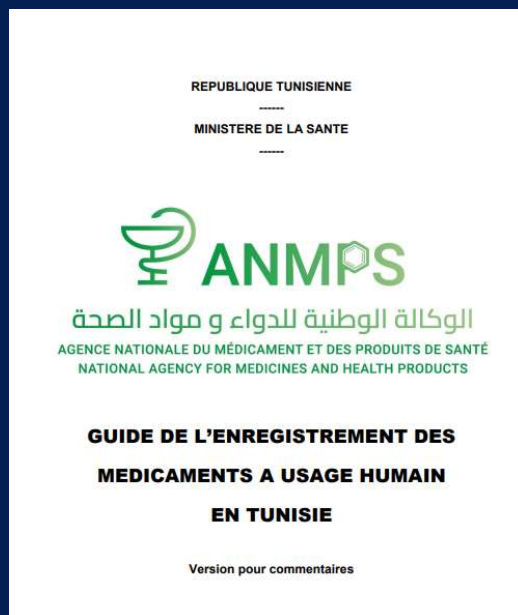
Guide to additional requirements for the manufacture and registration of medicinal products containing hazardous substances



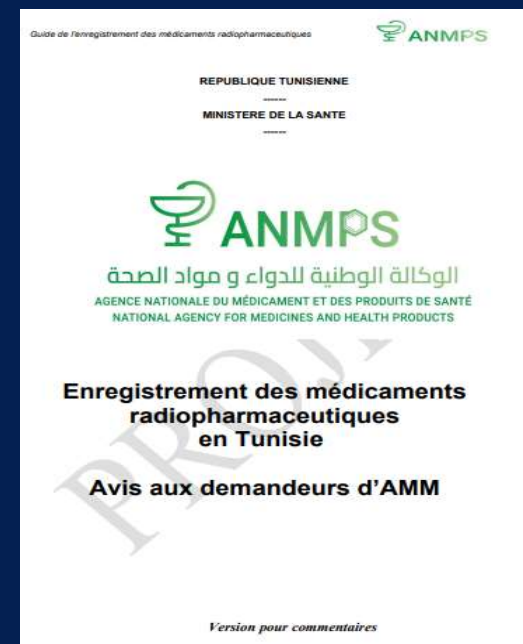
Guide to the Registration of Veterinary Drugs

Guidelines : Draft for comment

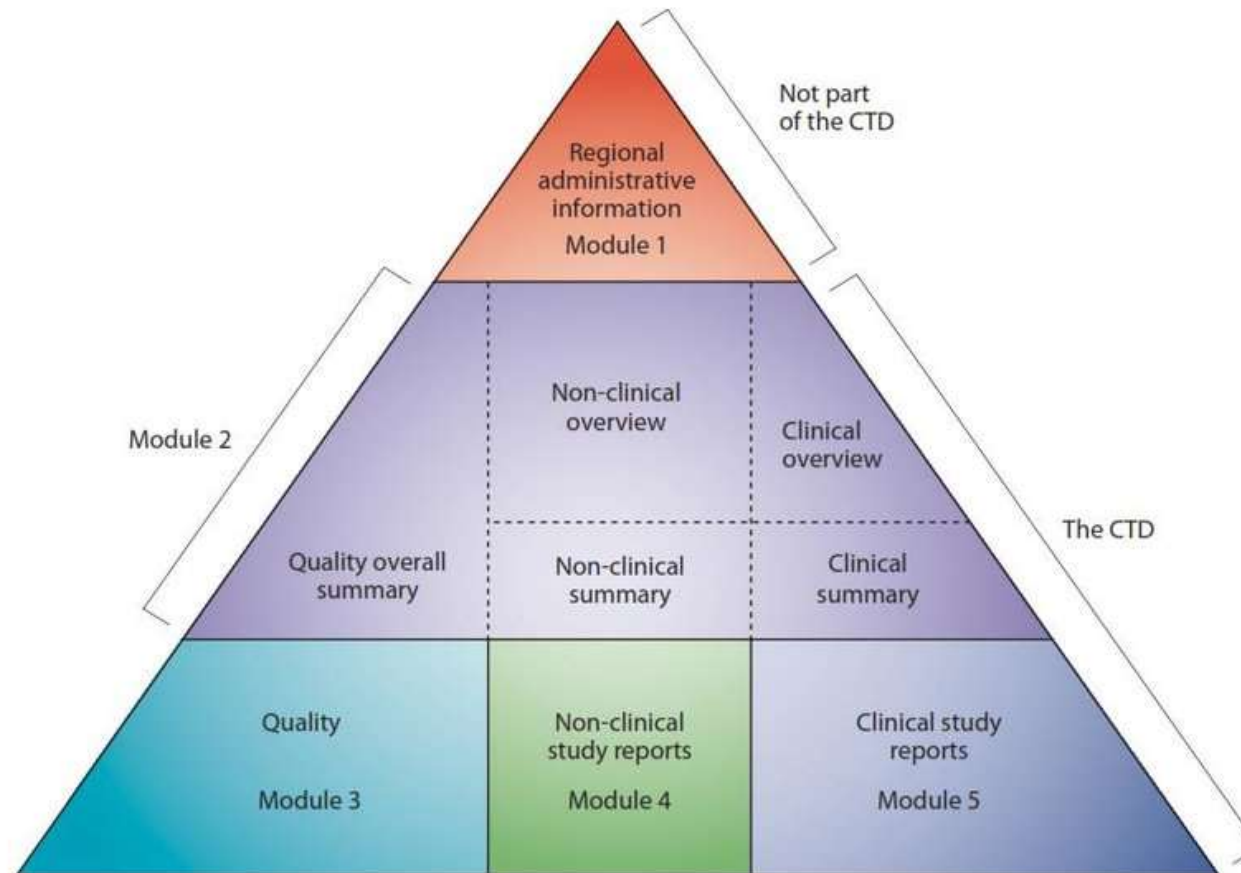
GUIDE OF MEDICINES FOR HUMAN USE REGISTRATION IN TUNISIA.



GUIDE OF RADIOPHARMACEUTICALS REGISTRATION IN TUNISIA



CTD : Common technical document



CTD : Common technical document



Module Type Of drug	Module 1	Module 2	Module 3	Module 4	Module 5
Reference Product	Required	Required	Required	Required	Required
Generic product	Required	Required (specific sections)	Required	Not required	Required (specific sections)
Biosimilars	Required	Required	Required	Required	Required

Module 1 requirements

1.0. APPLICATION LETTER

1.1. TABLE OF CONTENT

1.2. APPLICATION FORM

1.3. INFORMATION ON THE MANUFACTURE

- 1.3.1. Establishment license
- 1.3.2. Certificate of Good Manufacturing Practices
- 1.3.3. Case of subcontracting

1.4. INFORMATION ON THE PRODUCT

- 1.4.1. SmPC, Labelling, Patient Information Leaflet (PIL)
- 1.4.2. Mock-up : PIL and labelling
- 1.4.3. Samples
- **1.4.4. Imported medicinal product**
 - 1.4.4.1. Marketing authorization in the exporting country
 - 1.4.4.2. Certificate of a Pharmaceutical Product
 - 1.4.4.3. Status of the Marketing Authorization applications submitted worldwide
- **1.4.5. Under license medicinal product**
 - 1.4.5.1. Under license manufacturing agreement
 - 1.4.5.2. Marketing Authorization of the licensor
 - 1.4.5.3. Certificate of a Pharmaceutical Product
 - 1.4.5.4. Status of the authorization applications submitted worldwide

1.5. INFORMATION ON THE PRICE

- 1.5.1. Price proposal
- 1.5.2. Daily cost treatment and/or cost per cure
- 1.5.3. Price certification
- 1.5.4. Price list in the other countries
- 1.5.5. Refund status and corresponding rate

1.6. INFORMATION ON PHARMACOVIGILANCE

1.7. REGISTRATION PAYMENT RECEIPT

Submission and assessment of the dossier

The submission is currently in paper and CD format.



The submission of applications is organized by appointments on the DPM website.



The opening of the meetings is done the first Monday of the previous month :

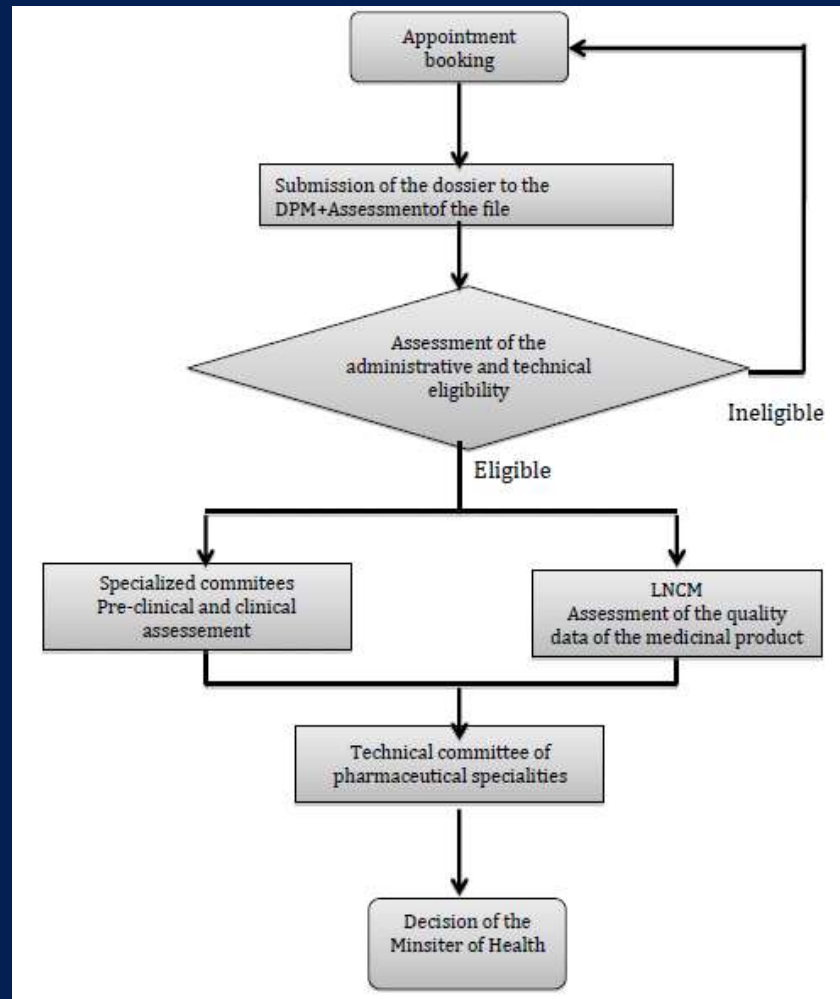
- For local human manufacturers, at 9 a.m.
- For human importation, at 11 a.m.



The number of appointments per month and per laboratory is limited to 6.



Submission and assessment of the dossier



Fastr track assessment

A fast-track assessment could be granted by the LNMC in the following situation:

- Tender products
- New product of major public health interest / orphan drugs
- First generic of a reference product
- Transfer to local manufacturing
- Launch of a new local manufacturer (in its first year)
- Justified Major Variations (Submit request directly to LNMC)

Life cycle management



The life cycle of an MA includes the following steps:

MA Granting

Variation /
transfer of a MA

MA renewal

MA withdrawal

Variation

A variation of MA (Marketing Authorization) is a change in the conditions or information related to a marketing authorization of a drug that has already been approved. This can concern various aspects such as:

- **Administrative specifications (change of MAH, change of manufacturer's contact details).**
- **Quality (e.g. changes in the manufacturing process, change of production site).**
- **Safety or efficacy (addition of a new indication, modification of dosage, update of safety information).**

Variations are classified in Tunisia as :

- **Minor variation (after submission the variation can be implemented)**
- **Major variation (This variation required approval to be implemented)**

Renewal



The MA is valid for 5 years. If the marketing authorisation has expired, the product can no longer be marketed.



A renewal application can be submitted 6 months before the expiry date of the MA at the earliest.

eSubmission / eCTD



eSubmission / eCTD (optional)

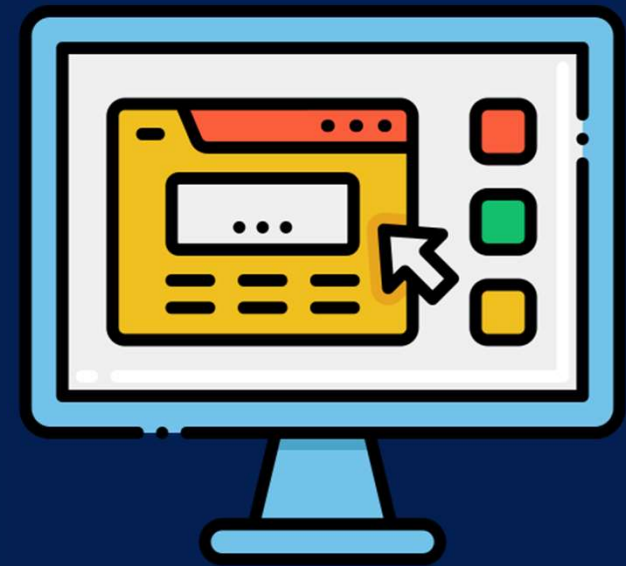
eSubmission / eCTD



eSubmission / eCTD (optional)

May

2025



eSubmission / eCTD



eCTD mandatory

March 2026



eSubmission / eCTD

SPÉCIFICATIONS

NB : The link to the new ANMPS portal mentioned in the specifications will be operational shortly.

Le lien du nouveau portail de l'ANMPS mentionnée dans les spécifications sera fonctionnel prochainement.

eCTD Specifications

- TN-ANMPS eCTD Specifications and Guidance for Module 1 and Regional information - 27 Février 2025, v1.1 [\[Link\]](#)
- TN-ANMPS CTD eSubmission Specifications - 27 Février 2025, v1.1. [\[Link\]](#)
- TN-ANMPS Trigger File Specifications - 27 Février 2025, v1.0 [\[Link\]](#)
- TN-ANMPS Validation criteria, v1.1 [\[Link\]](#)
- Feedback form [\[Link\]](#) (**email** : ectd.contact@rns.tn)
- TN-ANMPS eCTD Q&A v1.1 [\[Link\]](#)

Technical Files

- ANMPS Util folder (DTD and Style Sheets) for Module 1. [\[Link\]](#)
- MD5-checksums. [\[Link\]](#)
- Trigger-example.xml
- **Samples**
 - Comprehensive eSubmission Element Sample
 - Comprehensive eCTD Element Sample
- **Defined Lists & Validation Matrices**
- - application-type.xml
 - contact-type.xml
 - document-matrix.xml
 - evaluation-path.xml
 - sequence-type.xml
 - submission-type-matrix.xml
 - submission-lead.xml
 - submission-type.xml

eCTD System Sample URS

- ANMPS eCTD System-Sample User Requirement Specifications (URS). [\[Link\]](#)



THANK YOU!