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EUROPEAN UNION



- Intergovernmental *political and economic union of 28 European countries having internal single market through the standardized systems of laws.*
- Established under the name in 1992 by the *Treaty on European Union* (the Maastricht Treaty)
- **European Medicines Agency (EMA)** is a decentralized agency of the European union.
- **EMA protects public and animal health by ensuring that all medicines available on the EU market are safe, effective and of high quality.**



- The Agency is responsible for the **scientific evaluation, supervision and safety monitoring of the medicines developed by pharmaceutical companies for the use in EU.**
- EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information.
- *By working closely together, Member States reduce duplication, share the workload and ensure the efficient and effective regulation of medicines across the EU.*

MARKET AUTHORIZATION



- To protect public health and ensure the availability of high quality, safe and effective medicines for European citizens, all medicines must be authorized before they can be placed on the market in the EU.
- The Agency's Committee for Medicinal Products for Human Use (CHMP) or Committee for Medicinal Products for Veterinary Use (CVMP) carries out a scientific assessment of the application and gives a recommendation to the European Commission on whether or not to grant a marketing authorization.
- **EMA enables one application, one assessment, one market authorisation for the whole of the EU.**
- A European Public Assessment Report, or EPAR, is published for every human or veterinary medicine that has been granted or refused a marketing authorization following an assessment by EMA.



Regulatory Tracker

THE ROLE OF EMA

EMA plays an important role in the regulation of medicines in the EU. On the basis of scientific assessments carried out, it grants or refuses, changes or suspends marketing authorizations for medicines that have been submitted via the centralized procedure.

The European Commission can also take action concerning other aspects of medicine regulation:

- **Right of initiative** – *it can propose new or amended legislation for the pharmaceutical sector;*
- **Implementation** – *it can adopt implementing measures as well as oversee the correct application of EU law on pharmaceuticals;*
- **Global outreach** – *it ensures appropriate collaboration with relevant international partners and promotes the EU regulatory system globally.*

GUIDELINES AND SCIENTIFIC ADVICE

- EMA prepares **scientific guidelines in cooperation with experts from its scientific committees and working groups.**
- These guidelines reflect the latest thinking on developments in biomedical science.
- They are available to guide the development programmes of all medicine developers who wish to submit an application for a marketing authorisation in the EU, and to ensure that medicines are developed consistently and to the highest quality.
- EMA also gives *product-specific scientific advice* to companies for the development of medicines.

AUTHORIZATION AND SUPERVISION OF MANUFACTURERS

- Manufacturers, importers and distributors of medicines in the EU must be **licensed** before they can carry out those activities.
- The regulatory authorities of each Member State are responsible for granting licences for such activities taking place within their respective territories.
- All manufacturing and importing licenses are entered into **EudraGMDP**, the publicly-available European database operated by EMA.
- Manufacturers listed in the application of a medicine to be marketed in the EU are inspected by an EU competent authority.
- *Inspection outcomes can be accessed by all Member States and are made publicly available across the EU through EudraGMDP.*

- In order to be imported into the EU, an active pharmaceutical **ingredient needs to be accompanied by a Written Confirmation issued by the competent authority of the country where it is produced, confirming that the good manufacturing practice (GMP) applied is at least equivalent to the recognized EU GMP standards.**
- Every batch of medicines must be certified as having been manufactured and tested in accordance with GMP and in conformance with the marketing authorization before it can be released onto the market in the EU.
- If the product is manufactured outside the EU and has been imported, it needs to undergo full analytical testing in the EU.

SAFETY MONITORING OF MEDICINES

- The European regulatory system for medicines monitors the safety of all medicines that are available on the European market throughout their life span.
- *All suspected side effects that are reported by patients and healthcare professionals must be entered into **EudraVigilance**, the EU web-based information system operated by EMA that collects, manages and analyses reports of suspected side effects of medicines.*
- These data are continuously monitored by EMA and the Member States in order to identify any new safety information.
- **The committee provides advice and recommendations to the European medicines regulatory network on risk management planning and benefit-risk assessment for medicines after marketing.**

CLINICAL TRIALS

- The authorisation and oversight of a clinical trial is the responsibility of the Member State in which the trial is taking place.
- **The European Clinical Trials Database (EudraCT) tracks which clinical trials have been authorised in the EU. It is used by NCAs and clinical-trial sponsors to enter information protocols and results of clinical trials.**
- *A subset of this information is made publicly available by EMA via the EU clinical trials register.*



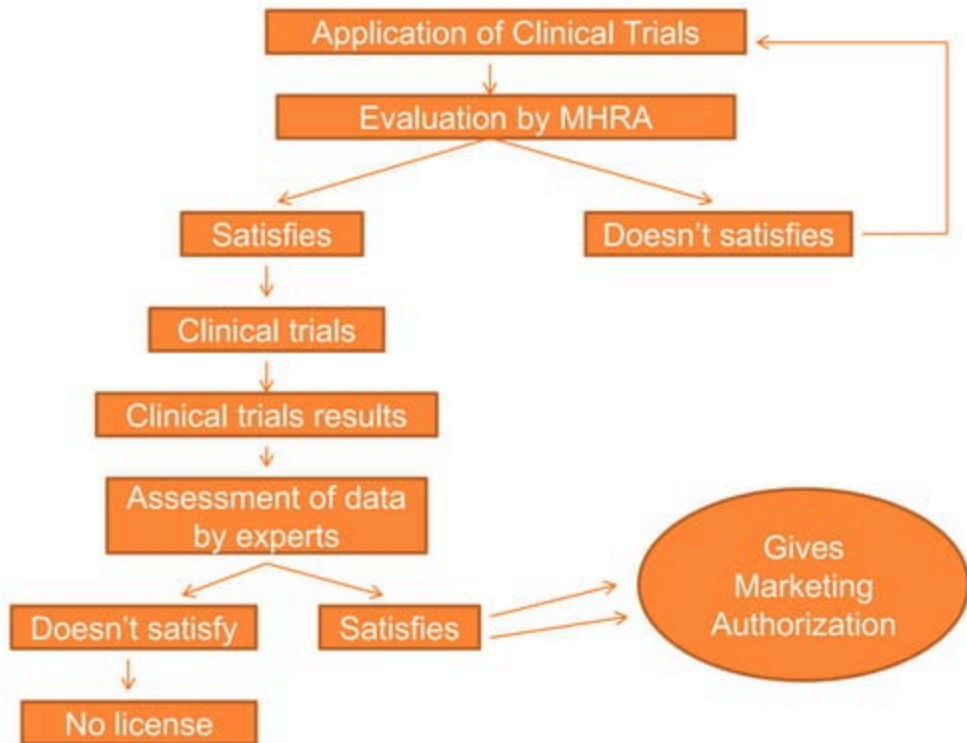
MHRA

- **Medicines and Healthcare products Regulatory Agency** is an executive agency of the Department of Health of United Kingdom.
- **MHRA** was set up in April, 2003 bringing together the function of **medicines Control Agency (MCA)** and the **Medical Devices Agency (MDA)**.
- **MHRA** is responsible for ensuring that medicines and medical devices work, and are acceptably safe.
- **MHRA** *functions when the company wants to start clinical trials in patients.*

ROLES

- Licensing
 - Manufacturer and dealer licenses
 - Clinical trial licences
 - Parallel import licenses
 - Safety and efficacy monitoring
 - Enforcements of laws
 - Regulation of clinical trials
 - Providing information to public and health professionals
-
- MHRA does not regulate dietary supplements, veterinary products and cosmetics.

LICENSING PROCESS



MARKETING AUTHORIZATION

o Majorly by 4 processes:

1. **Centralized procedures**

- In EU, a company may submit a single application to the EMA for a marketing authorization that is valid simultaneously in all EU Member States.

2. **National procedures**

- Each EU member states has its *own procedures for the authorization of medicines* that fall outside the scope of the centralized procedure.
- Applicants must submit an application to the competent authority of the Member State.

3. Decentralized Procedure

- Using the decentralized procedure, *companies may apply for simultaneous authorization on more than one EU country of products that have not yet been authorized in any EU country and do not fall within the mandatory scope of the centralized procedure.*

4. Mutual recognition procedure

- Here, a medicine is first authorized in *one EU member state, in accordance with the national procedures of that country.* Following this, **further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.**

RENEWAL OF LICENSE

- New Marketing Authorization (MA) are valid for 5 years and then may be renewed on the basis of a re-evaluation of the risk-benefit balance.
- Applications for renewal should be submitted at least six months before expiry.





Australian Government

Department of Health
Therapeutic Goods Administration

TGA

- Therapeutics Goods Administration is the regulatory body for therapeutic goods in **Australia**.
- TGA is *responsible for conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard.*
- The objectives of **Therapeutic Goods Act 1989**, which came into effect on 15 Feb, 1991 is **to provide a national framework for the regulation of therapeutic goods in Australia to ensure quality, safety and efficacy of the medicines and ensure quality, safety and performance of medical devices.**

- Essentially therapeutic goods must be entered on the **Australian Register of Therapeutics goods (ARTG)** before they can be supplied in Australia.
- ARTG is a *computer database of information about therapeutic goods for human use approved for supply in, or export from, Australia.*
- Australian manufacturers of all **medicines must be licensed under part 4 of the Therapeutic Goods Act 1989** and their manufacturing process must comply with the principles of GMP.
- Once approved for marketing in Australia, medicines are included in the **ARTG** and can be identified by the **AUST R** number (for registered medicines) or an **AUST L** number (listed medicines) that appears on the packaging of the medicines.

- Medicines that are assessed to be higher risk are individually evaluated for quality, safety and efficacy. Higher risk products approved by the TGA are included on the **ARTG** as **registered medicines**.
- **Listed medicines** are low risk medicines and are included on the **ARTG** via low-cost and streamlined electronic application and validation process.

REGULATORY FRAMEWORK

- In consultation with industries, TGA has developed **Australian Regulatory Guidelines For The Complementary Medicine (ARGCM)** to assist sponsors of complementary medicines to meet their legislative obligations.
- Products are evaluated by the TGA for *quality, safety and efficacy* under the provision of section 25 of the Therapeutic Goods Act 1989.
- Products in category include:
 - Products included in *Schedule of Pharmaceutical Benefits*
 - Products containing sunscreen active ingredient that is not included in the list of *sunscreening agent permitted as active ingredient in listed products*
 - Products that make therapeutic claims other than sun screening.

Elements to Regulate

- o **Licensing and Audit of Manufactures**

Act requires each Australian manufacturer of medicinal products for human use to hold a manufacturing license. *License holders are required to comply with the manufacturing principles of the Act, including compliance with GMP.*

- o **Pre-Market Assessment**

This includes study of *toxicity and dosage form* of medicines. The product risk is determine by *side effects, inappropriate self medication, adverse effect for prolonged use.*

o **Post-Market Regulatory Authority**

The essential elements of this systematic risk-based approach include:

1. **Monitoring of adverse reactions to medicines.**
2. **Targeted and random surveillance in the market place.**
3. **An effective, responsive and timely recalls procedure.**
4. **Audit of GMP.**
5. **Effective controls for the advertising of therapeutic goods.**



REGULATORY REQUIREMENTS IN ROW COUNTRIES

o Key function of RA:

1. Product registration
2. Regulation of drug manufacturing, importation and distribution
3. Adverse drug reaction monitoring
4. Licensing of premises, person and practices.
5. Main goal of the agency is to guarantee the safety, efficacy and quality of the available drug product.

INDIA: REGULATORY BODIES



- **Central Drug Standard Control Organization (CDSCO)**
- Ministry of Health and Family Welfare (MHFW)
- Indian council of Medical Research (ICMR)
- Indian Pharmaceutical Association (IPA)
- Drug Technical Advisory Board (DTAB)
- Central Drug Testing Laboratory (CDTL)
- Indian Pharmacopoeia Commission (IPC)
- National Pharmaceutical Pricing Authority (NPPA)

Drugs Controller General (I)





- Nepal: <http://www.dda.gov.np/>
- Bangladesh: <http://www.ddabd.org/>
- Bhutan: <http://www.health.gov.bt/dra.php>
- Maldives: <http://www.mfda.gov.mv/web/>
- Sri Lanka: <http://203.94.76.60/DRA/home.htm>
- Thailand: <http://www.fda.moph.go.th/eng/index.stm>
- Singapore:
<http://www.hsa.gov.sg/publish/hsaportal/en/home.html>
- Vietnam: <http://www.dav.gov.vn/>
- Philippines: <http://www.bfad.gov.ph>
- Republic of Korea: <http://ezdrug.kfda.go.kr/>
- New Zealand: <http://www.medsafe.govt.nz/>
- Japan: <http://www.pmda.go.jp/english/index.html>
- China: <http://www.sfda.gov.cn/>
- Pakistan: <http://www.dcomoh.gov.pk/>



Thank you...