THERAPEUTIC GOODS ADMINISTRATION (TGA)

&

MEDICINES AND HEALTH CARE PRODUCTS REGULATORY AGENCY (MHRA)

List of contents:

TGA

- **What is TGA ?**
- **Objective of TGA**
- **Role of TGA**
- **TGA structure**
- **Committees**
- **Australian register of therapeutic goods (ARTG)**
- **The guidelines of TGA for**
  - ✓ Listed Medicines
  - ✓ Registered Medicines
  - ✓ Complementary Medicines
  - ✓ OTC Medicine
  - ✓ Prescription Medicines

- ✓ Medical devices
- ✓ Blood and Tissues
- ✓ Chemicals
- ✓ Exempt or excluded medicines

UK-MHRA

- **What is MHRA ?**
- **Aims of MHRA**
- **Objectives of MHRA**
- **Activities of MHRA**
- **Structure of MHRA**

- **What MHRA regulates ?**
  - ✓ Device
  - ✓Medicine
  - ✓ Advanced therapeutic medicinal product
  - ✓Nanotechnology
  - ✓Blood
- **References**

THERAPEUTIC GOODS ADMINISTRATION(TGA)

WHAT IS TGA?

- The TGA is responsible for conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of acceptable standards.

- Established on 15 February 1991.

Objective of TGA…

- To provide a national framework for the regulation of therapeutic goods in Australia to **ensure the quality, safety and efficacy of medicines** and ensure the quality, safety and performance of **medical devices**.

- Essentially therapeutic goods must be entered on the **Australian Register of Therapeutic Goods (ARTG)** before they can be supplied in Australia.

Role of the TGA

The TGA carries out an overall control through five main processes:

- **Pre-market evaluation** and approval of registered products intended for supply in Australia;
- **Development, maintenance and monitoring** of the systems for listing of medicines;
- **Licensing** of manufacturers in accordance with international standards of GMPs

- **Post-market monitoring**, through sampling, adverse event reporting, surveillance activities, and response to public inquiries;

- The **assessment** of medicines for export.

TGA STRUCTURE

- The TGA's offices are grouped into following core groups

1. TGA Executives
2. Market Authorization Group (MAG)
3. Monitoring and Compliance Group (MCG)
4. Regulatory Support Group
5. Office of Regulatory Integrity (ORI)

1. TGA Executives

The TGA Executives has overall responsibility for the management of the TGA's regulatory functions and activities.

The TGA Executives comprises:

- TGA National Manager
- Principal Medical Adviser,
- Principal Legal Adviser,
- Chief Regulatory Officer,
- Chief Operating Officer

2. Market Authorization Group (MAG)

- The Market Authorization Group is responsible for undertaking evaluations of applications to approve new therapeutic products for supply in Australia. The MAG makes decisions whether to approve or reject market authorization of medicines, medical devices and blood and tissues that are imported, exported, manufactured and supplied in Australia.

3. Monitoring and Compliance Group (MCG)

- The Monitoring and Compliance Group is responsible for ongoing monitoring of therapeutic products approved for supply in Australia to ensure they meet the necessary standards throughout their lifecycle.

4. Regulatory Support Group

- Provides whole-of-agency regulatory support services to the TGA, this includes the legal, finance, information technology and information management, communications, parliamentary and human resource management services.

5. Office of Regulatory Integrity(ORI)

- The Office of Regulatory Integrity (ORI) provides an independent and objective review and advisory service to provide assurance to the National Manager of the TGA that the TGA's financial and operational controls are operating in an efficient, effective and appropriate manner and that its regulatory controls are operating in an efficient, effective and appropriate manner and are consistent with relevant legislative requirements.

AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG)

- A 'therapeutic good' is broadly defined as a good which is represented in any way to be taken, for therapeutic use.

Therapeutic use means use in connection with

- Preventing, diagnosing, curing a disease, ailment, defect or injury;
- Inhibiting or modifying a physiological process;
- Testing for pregnancy;
- Replacement or modification of parts of the anatomy

The Australian Register of Therapeutic Goods (ARTG) was established under the Therapeutic Goods Act 1989.

The ARTG is a computer database of therapeutic goods. Therapeutic goods are divided broadly into **two classes: medicines and medical devices.**

Unless exempt, medicines must be **entered as either 'registered' or 'listed'** medicines and medical devices must be included before they may be supplied in or exported from Australia.

- **AUST R** medicines are assessed for safety, quality and effectiveness and **higher risk medication**.

- They include all prescription medicines.

- Many over-the-counter products such as those for pain relief, coughs and colds and antiseptic creams.

- **AUST L** medicines are **much lower risk self-medication products.**

- They are used for minor health problems and are reviewed for safety and quality. They include sunscreens and many vitamin, mineral, herbal and homoeopathic products

- Listed and Registered medicines are differentiated on the product label by the designation, 'AUST L' or 'AUST R' respectively, followed by a unique number.

Assessment criteria

Whether a product is listed or registered in the ARTG depends largely on three things:

- The ingredients;
- The dosage form of the product; and,
- The promotional or therapeutic claims made for the product.

In assessing the level of 'risk', factors such as

- strength of a product
- side effects,
- toxicity, and
- the seriousness of the medical condition for which the product is intended to be used.

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

- **What is MHRA?**

The MHRA was **set up in April 2003** from a merger of the Medicines Control Agency and the Medical Devices Agency. The MHRA is the **government agency** which is **responsible for ensuring that medicines and medical devices work, and are acceptably safe**.

Aims of MHRA

- **Protecting** public health through regulation, with acceptable benefit-risk profiles for medicines and devices.
- **Promoting** public health by helping people who use these products to understand their risks and benefits.
- **Improving** public health by encouraging and facilitating developments in products that will benefit people.

Objectives of MHRA

- Safeguard public health through MHRA's primary role in ensuring that the products MHRA regulate meet required standards, that they work and are acceptably safe;
- Carry out communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public;
- Support research, ensuring through the application of Better Regulation principles that regulation does not stifle innovation;
- Influence the shape of the future regulatory framework through use of our effective European and International relationships;
- Run an organisation with a skilled and equipped workforce that is fit for the future

The MHRA's activities

- **Assessing the safety, quality and efficacy** of medicines, and authorising their sale or supply in the UK for human use.
- Overseeing the UK Notified Bodies that **audit** medical device manufacturers.
- **operating post-marketing surveillance** and other systems for reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices and taking any necessary action to safeguard public health, for example through safety warnings, removing or restricting the availability of products or improving designs.
- **Operating a proactive compliance programme** for medical devices.

- **Operating a quality surveillance system** to sample and test medicines and to address quality defects, monitoring the safety and quality of imported unlicensed medicines and investigating Internet sales and potential counterfeiting of medicines.
- **Regulating clinical trials** of medicines and medical devices.
- **Monitoring and ensuring** compliance with statutory obligations relating to medicines and medical devices through inspection, taking enforcement action where necessary.

- **Promoting good practice** in the safe use of medicines and medical devices.
- **Managing** the General Practice Research Database **(GPRD)** and the British Pharmacopoeia **(BP)** and contributing to the development of performance standards for medical devices.
- **Offering scientific, technical and regulatory advices** on medicines and medical devices.
- **Providing** the public and professions with **authoritative information** to enable informed dialogue on treatment choices.

MHRA'S STRUCTURE:

Corporate governance

1. **The Agency Board** is made up of a non-executive Chairman, six non-executive members and the Agency's Chief Executive Officer who is responsible for service delivery and resources.
2. **The Executive Board** consisting of the Agency's directors takes overall responsibility for day-to-day management, strategic decision-making, line management, and all financial, policy, operational and resource management issues.
3. **The Risk and Audit Committee** provides independent feedback to the Chief Executive and the Management Board on the effectiveness of risk management processe

What MHRA regulates?

- **Medicine**

✓ Licencing of medicines

✓ Medicines for children

✓ Inspection and standards

✓ Importing and exporting medicines

✓ Best practice guidance on labelling and packaging of medicines

✓ The safety of medicines

The role of MHRA

- Assess applications for marketing medicinal products
- Assess applications to undertaken clinical trials
- Inspect the manufacturers and wholesalers of medicines-licensing
- Undertake post-marketing surveillance including:
  - Pharmacovigilance
  - Quality defect monitoring
  - Sampling and testing
  - Product recalls.

- Issue certificates to companies wishing to export their medicinal products to countries outside the EU.
- Enforce the statutory requirements covering medicines control and good clinical practice guidelines.
- Publish quality standards for drug substances through the "British Pharmacopoeia

References:

http://www.tga.gov.au

http://www.mhra.gov.uk

THANK YOU