REGULATORY BODY:

Medical & Healthcare Products Regulatory Agency (MHRA)

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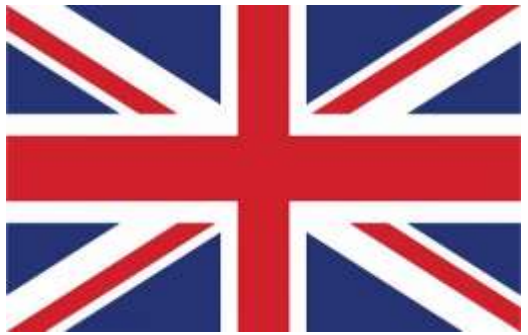
Asst. Professor
SIPS



1. INTRODUCTION

- The MHRA (1903) is a government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

- Medical Control Agency (MCA) + Medical Devices Agency (MDA) = MHRA

- It was located in Vauxhall, London and is now relocated to New London.

AIMS

- 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 benefits and risks.

- Improving public health by encouraging and facilitating developments in products that will benefit people.

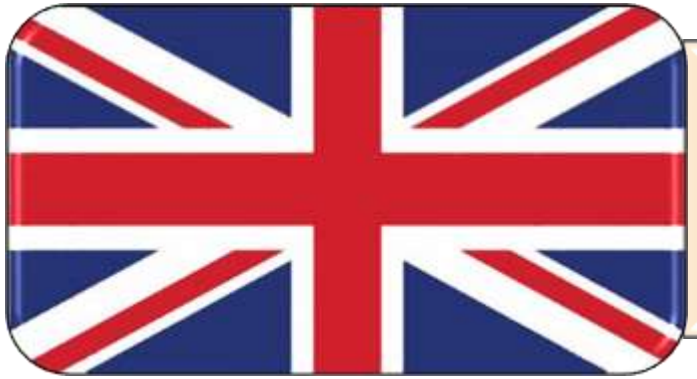
2.

COMPOSITION AND STRUCTURE

- The agency board is made up of

- ❑ Non-Executive Chairman
- ❑ Six Non-Executive Member
- ❑ Agency's Chief Executive Officer

- The Agency's Chief Executive is responsible for service delivery and resources.
- The Executive Board consisting of Agency's Directors.
- The Agency Board is chaired by the MHRA Chairman.



- Government Agency of UK
- Department of Health and Social Care

- FOUNDED : 1 April 2003

CEO

- Executive Agency Executive: Michael Rawlins
- Chairman: Ian Hudson

AGENCY BOARD

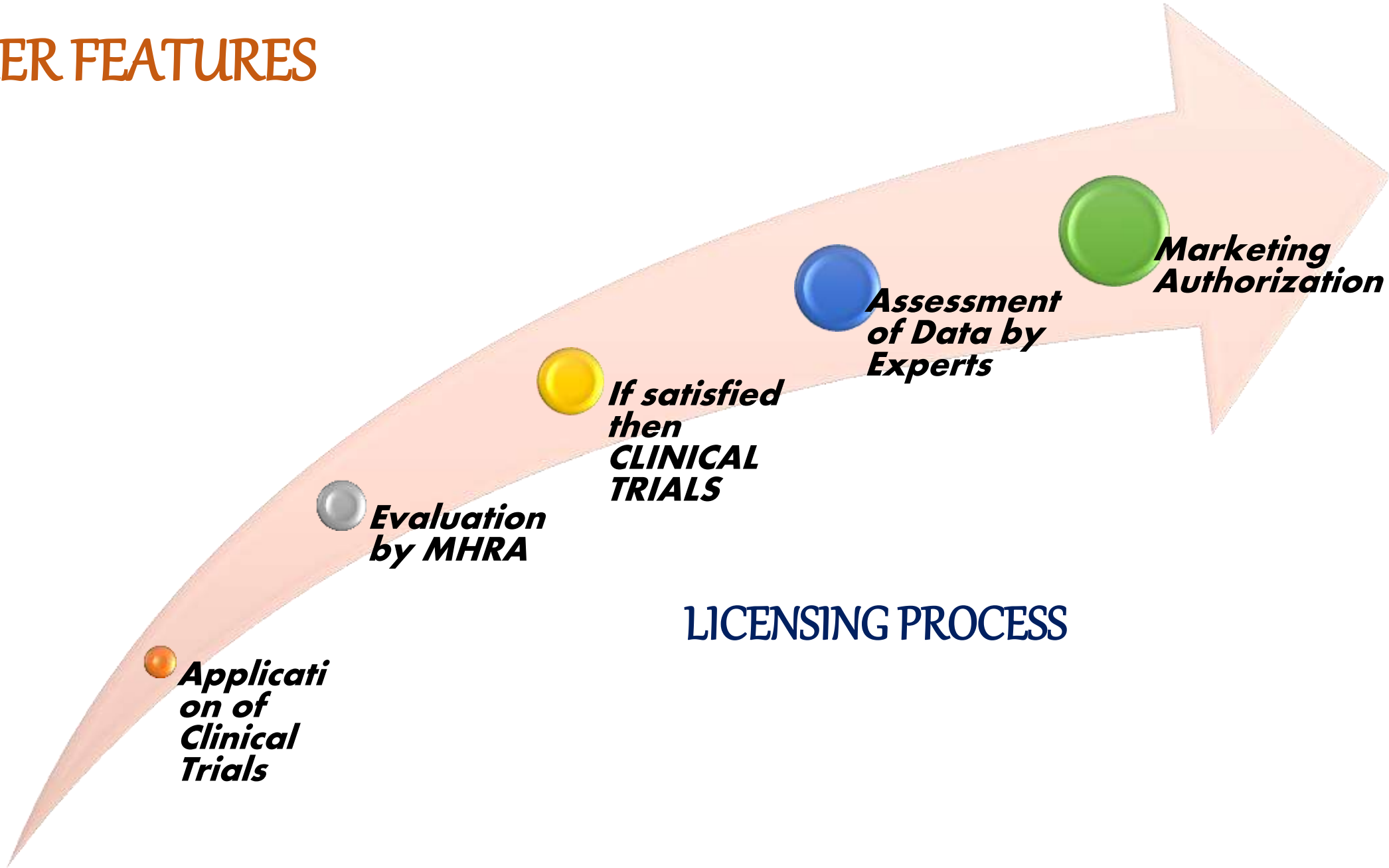
The agency is responsible for:

- Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy
- Ensuring that the supply chain for medicines, medical devices and blood components is safe and secure
- Promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- Helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- Supporting innovation and research and development that's beneficial to public health
- Influencing UK, EU and international regulatory frameworks so that they are risk-proportionate and effective at protecting public health

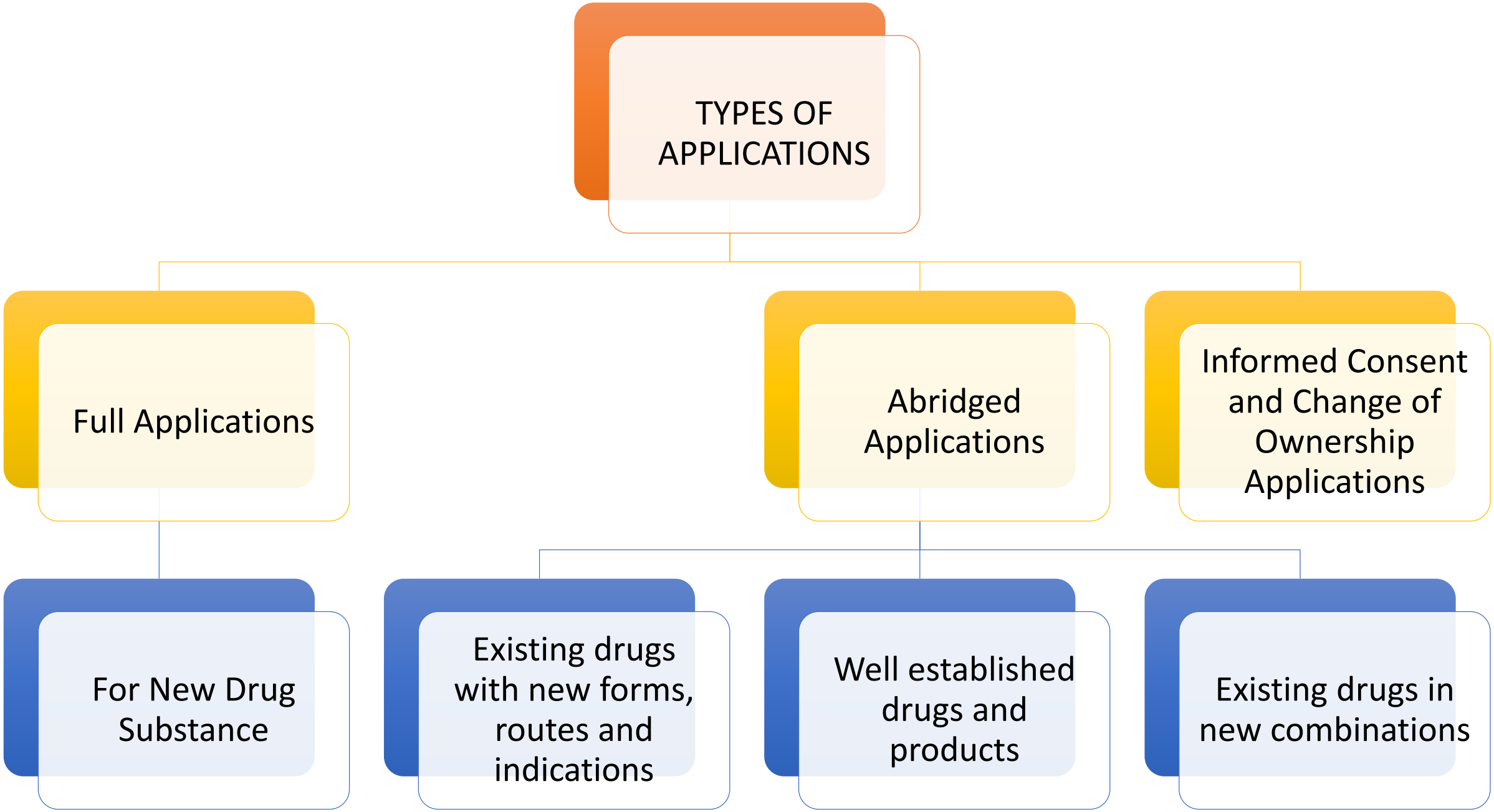
3.
SALIENT FEATURES, COMMITTEES/WORKING GROUPS:

- ✓ MHRA has the power to withdraw a product from market and suspend production of medicines
- ✓ A manufacturer or distributor can be prosecuted if the law has been broken
- ✓ Regulatory decisions are impartial
- ✓ Different products are treated differently
- ✓ MHRA collaborates with:
  - **US Food and Drug Administration**
  - **NPSA National Patient Safety Agency**
  - **NICE National Institute for Health and Clinical Excellence**

OTHER FEATURES

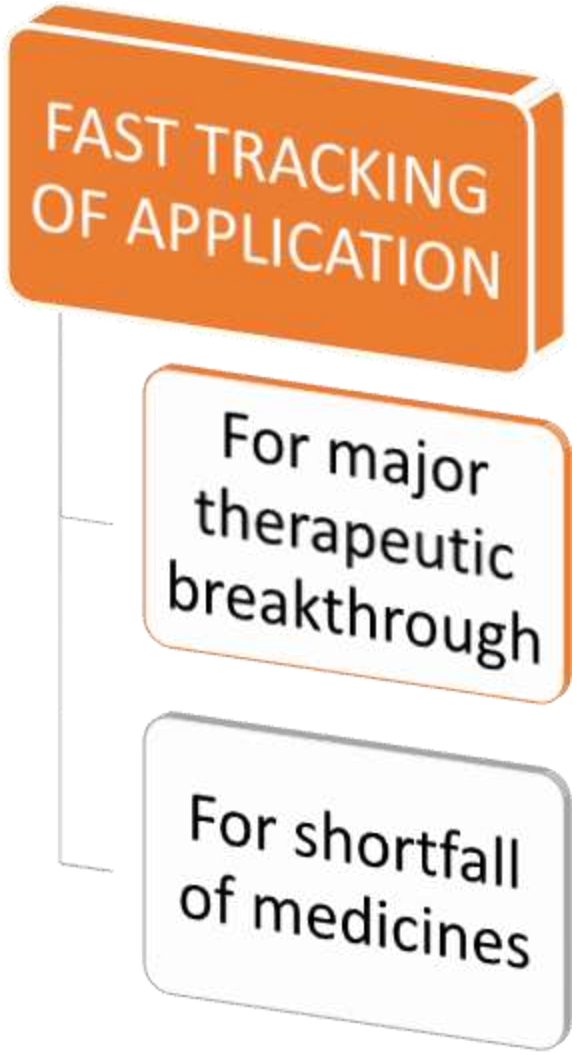


LICENSING PROCESS


TYPES OF APPLICATIONS
Full Applications
Abridged Applications
Informed Consent and Change of Ownership Applications
For New Drug Substance
Existing drugs with new forms, routes and indications
Well established drugs and products
Existing drugs in new combinations

SUBMISSION OF APPLICATION

- CTD Common Technical Dossier
- e-CTD Electronic Common Technical Dossier
- PDF only format



TYPES OF PROCEDURE

- Centralized
- National
- Mutual Recognition
- Decentralized

RENEWAL OF LICENSE

- New Marketing Authorization are valid for 5 years
- Renewal is done on the basis of re-evaluation of risk benefit balance
- Once renewed, Marketing Authorization will be valid for either 5 years or unlimited period
- Application for renewal should be submitted at least 6 months before expiry

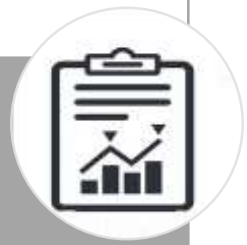
CANCELLATION OF LICENSE

- If MA holder does not file an application for renewal within specified time, MA expires
- If MA holder does not wish to renew the license, a letter should be sent indicating cancellation
- MHRA has authority to cancel license of product if it affects public health

COMMITTEES

- **A non-executive Chairman**
- **Six non-executive members**
- **Chief executive officer**
- Responsible for service delivery and resources

AGENCY BOARD



- **Agency's Directors**
- Responsible for day to day management, strategic, policy, operational and resource management

EXECUTIVE BOARD

- Provides independent feedback to chief executive and management board on the effectiveness of risk management procedures

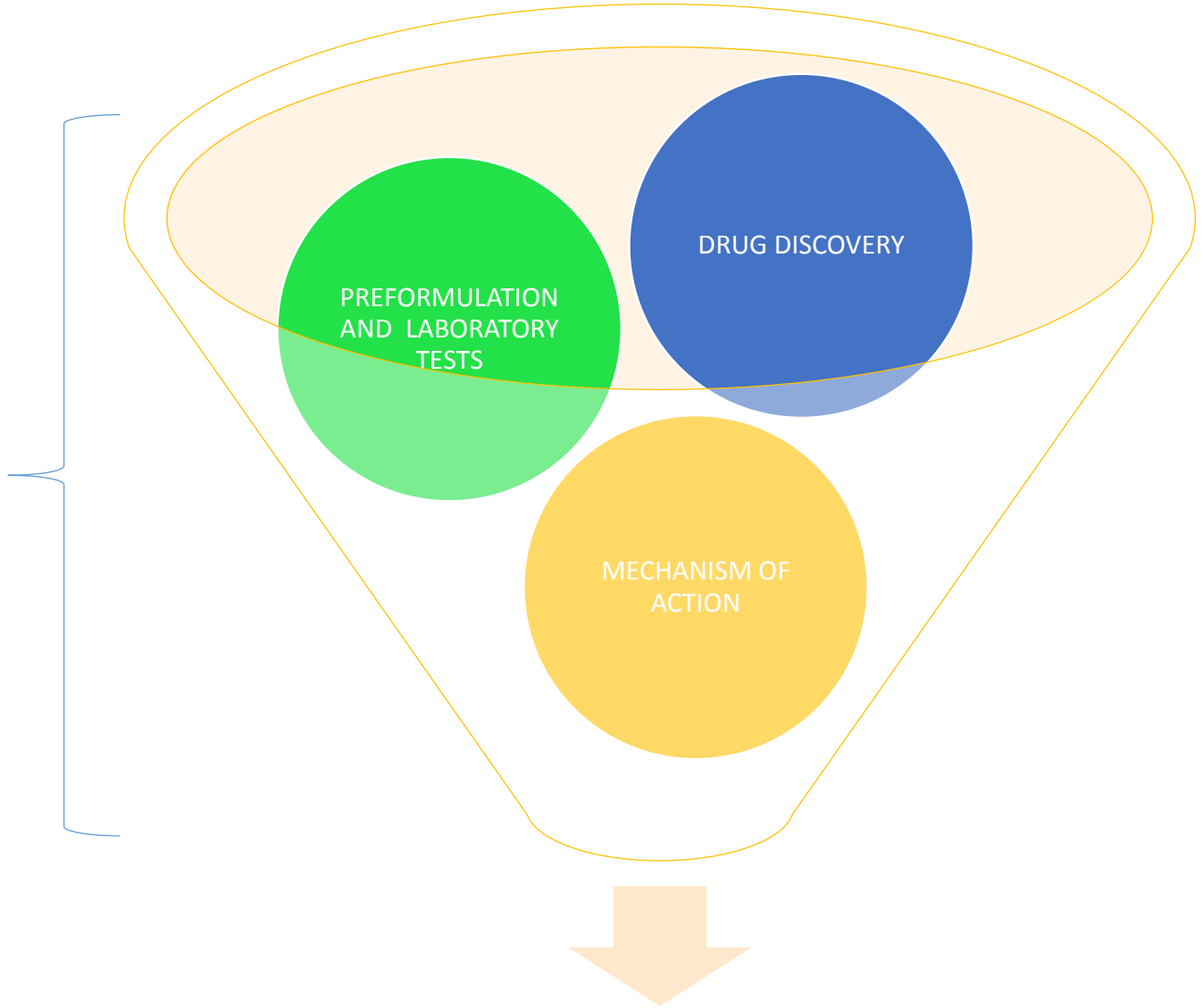
RISK AND AUDIT COMMITTE

WORKING GROUPS

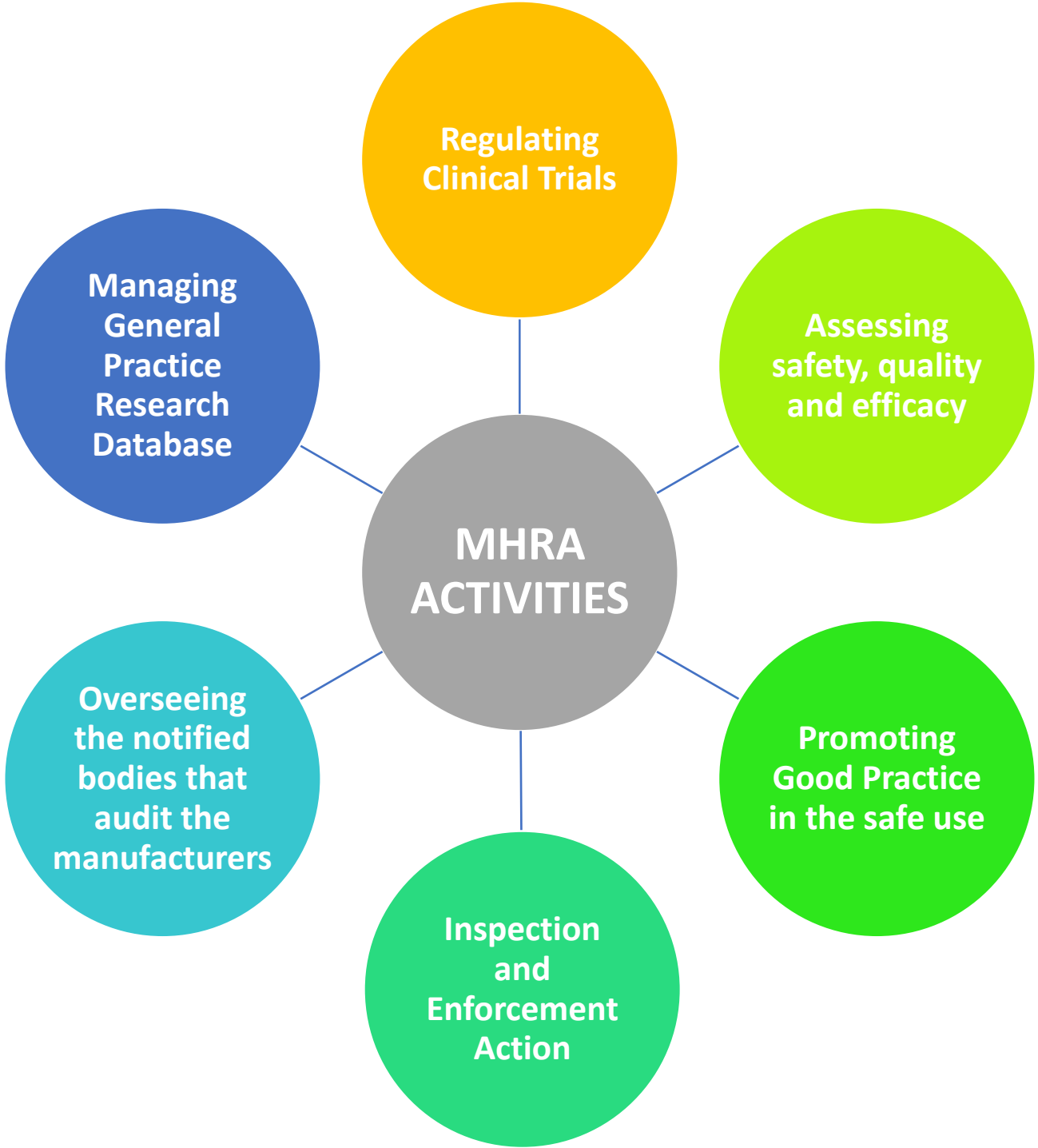
- Advisory Board on the Registration of Homeopathic Products
- Herbal Medicines Advisory Committee
- The Review Panel
- Independent Scientific Advisory Committee for Database Research
- Medicines Industry Liaison Group
- Innovation Office
- Blood Consultative Committee
- Devices Expert Advisory Committee

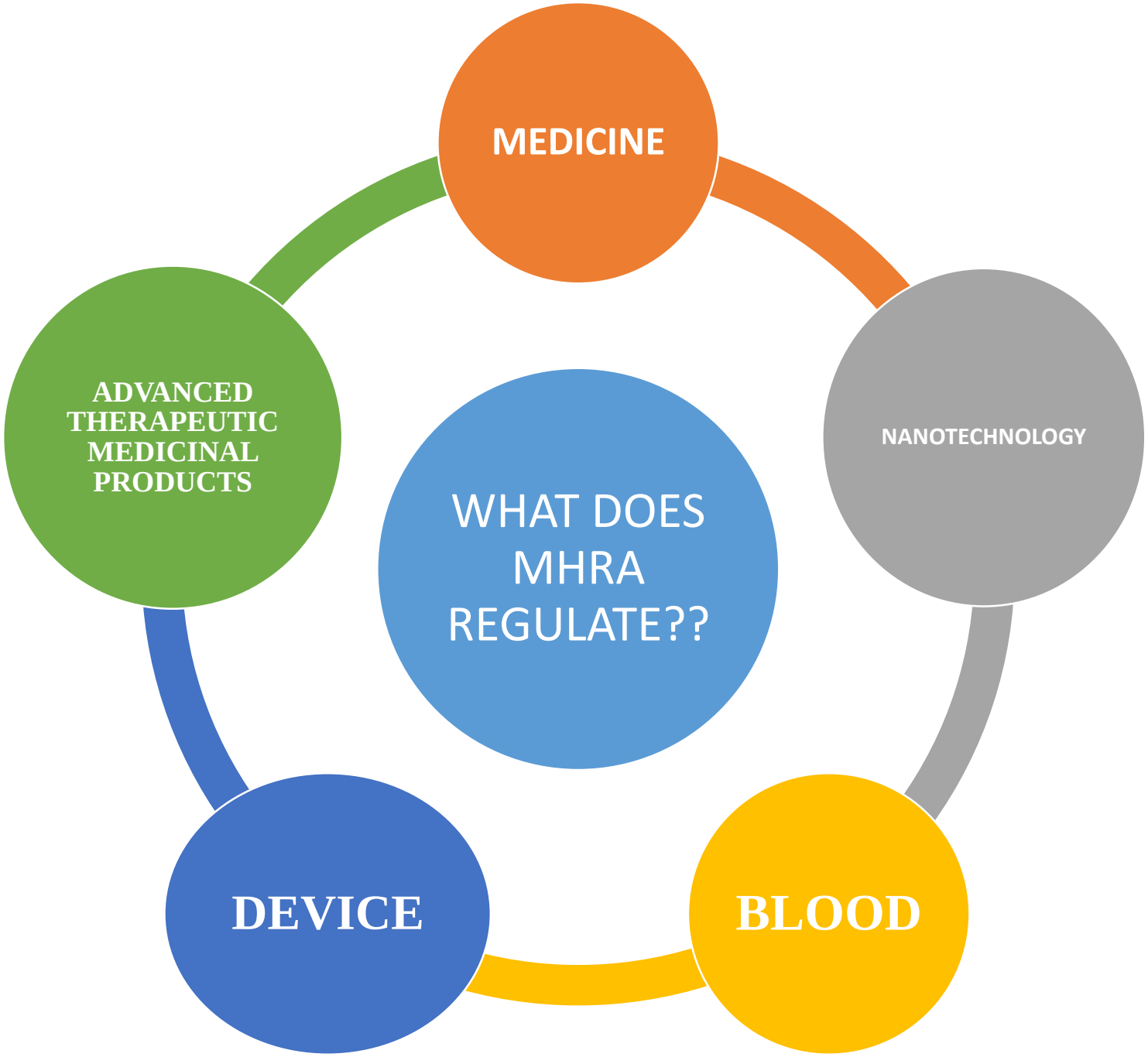
4.
KEY FUNCTIONS

MHRA has no interest in these early phases of drug development.



MHRA comes to play when the company wants to start the clinical trials.


Regulating Clinical Trials
Assessing safety, quality and efficacy
Promoting Good Practice in the safe use
Inspection and Enforcement Action
Overseeing the notified bodies that audit the manufacturers
Managing General Practice Research Database
MHRA ACTIVITIES


MEDICINE
NANOTECHNOLOGY
BLOOD
DEVICE
ADVANCED THERAPEUTIC MEDICINAL PRODUCTS
WHAT DOES MHRA REGULATE??

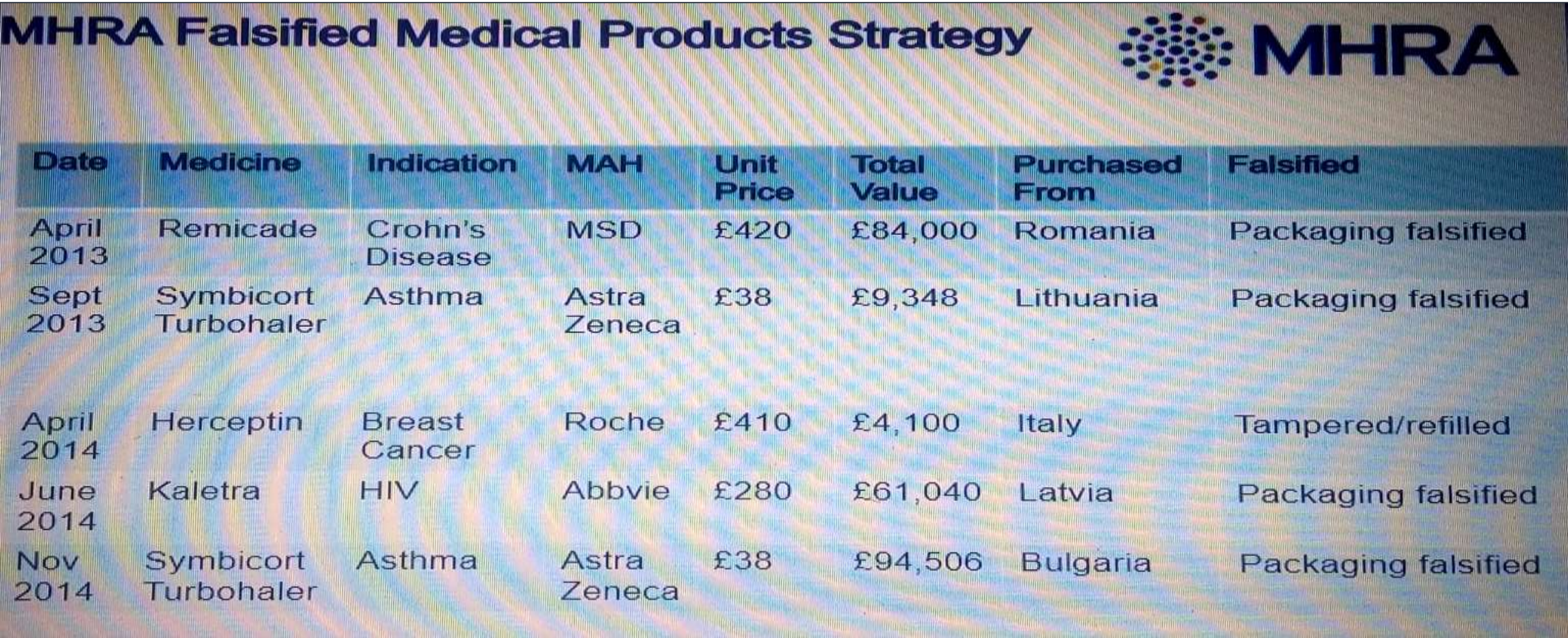
- INSPECT MANUFACTURERS AND WHOLESALERS OF MEDICINE LICENSING
- ACCESS APPLICATIONS TO UNDERTAKE CLINICAL TRIALS
- ACCESS APPLICATIONS FOR MARKETING MEDICINAL PRODUCTS
- Post Marketing Surveillance- Pharmacovigilance, quality defect monitoring, sample testing, product recalls
- Issue certificates to companies wishing to export their medicinal products to countries outside the EU
- ENFORCE STATUTORY GUIDELINES COVERING GCP AND MEDICINE CONTROL
- PUBLISH QUALITY STANDARDS FOR DRUG SUBSTANCES THROUGH BRISTISH PHARMACOPOEIA

4.
GUIDELINES

- Guidelines for Manufacturers on Clinical Investigations to be carried out in the UK.
- Inspected UK Contract GMP Quality Control Laboratories.
- **BLUE GUIDE:** Advertising and Promotion of medicines in the UK.
- **ORANGE GUIDE:** Rules and Guidelines for Pharmaceutical Manufacturers and Distributors.
- Good Pharmacovigilance Practice Guide.

- Guidelines on Process Validation
- Guide to UK GLP Regulations 1999
- Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products.
- Guide to defective medicinal products.
- Introduction of a Risk Based Inspection Programme for GMP Labs.

5.
GLOBAL IMPACT



Date	Medicine	Indication	MAH	Unit Price	Total Value	Purchased From	Falsified
April 2013	Remicade	Crohn's Disease	MSD	£420	£84,000	Romania	Packaging falsified
Sept 2013	Symbicort Turbohaler	Asthma	Astra Zeneca	£38	£9,348	Lithuania	Packaging falsified
April 2014	Herceptin	Breast Cancer	Roche	£410	£4,100	Italy	Tampered/refilled
June 2014	Kaletra	HIV	Abbvie	£280	£61,040	Latvia	Packaging falsified
Nov 2014	Symbicort Turbohaler	Asthma	Astra Zeneca	£38	£94,506	Bulgaria	Packaging falsified

REFERENCES

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Thank You

- *APOORVA PATNI*
- *PRIYAL BAGWE*
- *OMKAR JOSHI*
- *SHREYA SHAH*
- *ISHA KALGUTKAR*