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Review

Procedure And Regulations For Drug Registration In UK

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Abstract

MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and efficacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the drug so that patients will be provided with the best drug with minimal risk.

Keywords: MHRA, United Kingdom, Product license, eCT, CTD

INTRODUCTION

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health and Social Care. MHRA (Medicines And Health Products Regulatory Agency) is the regulatory authority body for pharmaceuticals approval in the UK union. MHRA is formed by the merging of two separate agencies in 2003 i.e., Medicines Control Agency and Medical Device Agency. This agency works to maintain safety, quality and efficacy of the drug product before it enters into the country. The main aim of this work is to know about the practice and the regulatory requirements for the registration of a drug in the UK as per the regulations of MHRA. They are responsible for ensuring that the medicines and medical devices are acceptably safe and don't cause any harm to the patients. MHRA provides a license which is a marketing authorization to the manufacturer, required before a drug is being used by the patients of that country. Good Manufacturing Practice (GMP) is the minimum requirement that a manufacturer should possess during the period of production of the drug product. New drugs are being invented and also being distributed as per the needs of the patients. It is

known that no drug product is completely safe or is 100% safe for use, but MHRA tries to minimize as many problems regarding the drug so that patients will be provided with the best drug with minimal risk. To get a Marketing Authorisation in UK the applicant may choose any one of the four procedures those are Centralised Procedure (CP), National Procedure (NP), Decentralised Procedure (DCP) and Mutual Recognition Procedure (MRP). In these procedures the Centralized Procedure is mandatory for certain types of medicines and optional for others. To get a Marketing Authorisation in UK the generic manufacturer should provide quality data, bioequivalence with EU reference product and applicable Clinical and Non- Clinical reports in CTD/eCTD format. Under the medicines legislation which was implemented on the 30 October 2005, Marketing Authorisations are be valid for five years and then may be renewed on the basis of a re-evaluation of the risk-benefit balance.

Drug Regulation

The process of testing, developing and marketing of medicines has to regulated to protect the interests of the public. Major regulatory bodies include the Food & Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe. These bodies have various functions.

Licensing new medicines. New drugs are given a 'market authorisation' based on the evidence of quality, safety and efficacy presented by the manufacturer. The regulator will not only approve the drug but will also take great care to ensure that the accompanying information reflects the evidence that has been presented. This document is known as the Summary of Product Characteristics (SPC) or 'label' provides detailed information about indications, dosage, adverse effects, warnings, monitoring etc.

Drug regulatory authorities often have other important functions including:

- Pharmacovigilance .
- Regulating clinical trials.
- Regulating herbal and homeopathic medicines.
- Inspecting and maintaining standards of drug development and manufacture.

AIM AND OBJECTIVES

AIM

The main *aim* of this work is to know about the practice and the *regulatory requirements* for the *registration* of a *drug* in the *UK*.

OBJECTIVE

The regulation of drugs and medicine is crucial to the health and safety of the public. Ensuring that a medicine is high quality is achieved by checking the efficacy, quality and safety of the drug.

The registration of drugs that subjects all pharmaceutical products to pre-marketing evaluation, marketing authorization (registration), and post-marketing review to ensure that they conform to required standards of quality, safety and efficacy ensured by NRA.

Dossier

Dossier is a collection of papers giving detailed information about a particular person or subject. (or) a bundle of papers in reference to some matter or relating to a person[1]. (or) Dossier is a file document submitted to the Regulatory Authorities which contains detailed information about the drug product. In United Kingdom all drug products are classified into 3 categories based on their safety profile. Prescription only medicines (POM), Supervision of Pharmacist (P) and General Sale List (GSL). New medicines are usually authorized for use as Prescription Only Medicines (POM). After some years use, if adverse reactions to the medicine are few and minor, it is possible that the medicine may be safely used without a doctor's supervision. If there is sufficient evidence of safety, a medicine may be reclassified for sale or supply under the supervision of a Pharmacist (P). Pharmacy medicines which have been safely used for several years may be suitable for General Sale and may be reclassified as GSL[2]. The Medicines and Healthcare products Regulatory Agency (MHRA) is the regulatory agency in United Kingdom. MHRA is a government body which was set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA)[3]. These include the regulation of medicines and medical devices and equipment used in Healthcare and the investigation of harmful incidents.

A license, also referred to as a Marketing Authorization (MA), from the MHRA is required before any medicine can be used to treat people in the UK. Licenses for medicines are granted only when a product meets high standards of quality, safety and works for the purpose intended (efficacy). There are four types of procedures that applicants can take to obtain a Marketing Authorisation. To get a Marketing Authorisation in UK the applicant may choose any one of the four procedures those are Centralised Procedure (CP), National Procedure (NP), Decentralised Procedure (DCP) and Mutual Recognition Procedure (MRP)[4]. In these procedures the Centralized Procedure is mandatory for certain types of medicines and optional for others. The Centralised Procedure is administered by the European Medicines Agency (EMA) in London. It consists of a

single application which, when approved, grants marketing authorisation for all markets within the European Union consisting of 28 countries and 3 EEA countries. CP is mandatory for Biotechnological Products and New Active substances for which the therapeutic indication is the treatment of AIDS, Cancer, Diabetes, Neurodegenerative disorder and Orphan products. In cases where national authorisations are requested for the same medicinal product in more than one Member State and the marketing authorisation holder has received a marketing authorisation in a Member State, the applicant/marketing authorization holder shall submit an application in the Member States concerned using the procedure of mutual recognition. If no marketing authorisation has been granted in the Community, the applicant may make use of a decentralised procedure and submit an application in all the Member States where it intends to obtain a marketing authorisation at the same time, and choose one of them as reference Member State. In order to obtain a national marketing authorisation, an application must be submitted to the MHRA. The MHRA is responsible for granting Marketing Authorisations for medicinal products which are placed on United Kingdom markets, except for medicinal products which are authorised under Centralised Procedure. To get a Marketing Authorisation in UK the generic manufacturer should provide a Dossier with quality data, bioequivalence with EU reference product and applicable Clinical and Non-Clinical reports in CTD/eCTD format. In assembling the dossier for application for Marketing Authorisation, applicants shall also take into account the scientific guidelines relating to the quality medicinal products for human use as adopted by the Committee for Medicinal Products for Human Use (CHMP) and published by the European Medicine Evaluation Agency (EMEA). All data should be submitted following the relevant headings of the EU-CTD according to Notice to Applicants (NTA), Volume 2B[5]. The safe use of all medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented. The primary purpose of medicines labelling and packaging should be the clear unambiguous identification of the medicine and the conditions for its safe use. So the labelling requirements must have been followed by the applicant while preparing the drug product label[6]. The purpose of establishing bioequivalence is to demonstrate equivalence in Bio-pharmaceutics quality between the generic medicinal product and a reference medicinal product in order to allow bridging of preclinical tests and of clinical trials associated with the reference medicinal product. So bioequivalence with reference medicinal product is required for a drug product and the data of bioequivalence should be included in a dossier[7]. Under the new medicines legislation which was implemented on 30 October 2005, Marketing Authorisations (MAs) will be valid for five years and then may be renewed on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the marketing authorisation will be valid for an unlimited period unless there are justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal[7].

Drug Registration

It has been defined as: “a system that subjects all pharmaceutical products (under the scope of the NRA) to pre-marketing evaluation, marketing authorization (registration), and post-marketing review to ensure that they conform to required standards of quality, safety and efficacy established by NRA” .

Registration of a new product is the first step of launching drug to the market of the Russian Federation. The registration is a state procedure of drug quality, efficiency and safety evaluation to obtain an approval for medical use of a drug in the Russian Federation. Registration of a new drug - the first step in the process of withdrawal of the pharmaceutical market of the Russian Federation. This procedure is essentially a state examination quality, efficiency and safety of the drug, which is held for the subsequent issuance of the permit on its medical use.

In 2010, the drug registration procedure was essentially modified due to the adoption of new Federal Law No. 61-ФЗ “On circulation of medicines” of April 12, 2010 which became effective on September 01, 2010. To date, 4 modifications of the law have been adopted: No. 192-ФЗ of July 27, 2010, No. 271-ФЗ of October 11, 2010, No. 313-ФЗ of November 29, 2010, No. 409-ФЗ of December 06, 2011.

Law of Russian Federation on December 22, 2014 N 429-FZ on "Amendments to the Federal Law" "On Circulation of Medicines ". Some of the introduced amendments will enter into force on 1 July 2015, another part - on 1 January 2016 and the last - more than a year, that is from January 1, 2017.

The procedure of drug registration

Stages of drug registration

Foreign and Russian drugs undergo identical registration procedure.

The registration procedure consists of 4 sequential stages:

1. Creation of a Registration dossier including documents necessary for clinical study initiation, and submission of the Registration dossier to the Ministry of Health of the Russian Federation.
2. Obtaining a permission for the conduct of a clinical study in the Russian Federation.
3. Drug quality evaluation and evaluation of the expected benefit to possible risk ratio which is done after the clinical study of a drug:

The third stage may be divided into 2 sub-stages for convenience:

1. Drug quality control at the FSBI SCEMP's laboratory and approval of a Normative document (specification and analytical procedures;
2. Evaluation of the expected benefit to possible risk ratio and approval of Instruction for medical use of a drug.
4. Decision by the Ministry of Health of the Russian Federation on registration of the pharmaceutical product, it's entering in the State Register of pharmaceutical products and marketing authorization issuance.

1.Creation of a Registration dossier
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3. Drug quality evaluation and evaluation of the expected benefit to possible risk ratio which is done after the clinical study of a drug.
4. Decision by the Ministry of Health of the Russian Federation on registration of the pharmaceutical product, it's entering in the State Register of pharmaceutical products and marketing authorization issuance.

Registration time-frames

According to Law No.61-Federal Law "On circulation of medicines", the period of the registration procedure is 210 working days. This period does not include the time required for conduction of a clinical study.

Stages of active pharmaceutical ingredient (API) registration, time-frames and costs.

The active pharmaceutical ingredients (API) can be approved for use (registered) in the territory of the Russian Federation in the following two ways:

1. As part of registration of a finished pharmaceutical product for which this API will be used.
   If the manufacturer intends to supply the API to a specific plant only, then information is provided and API quality evaluation is performed as part of the finished pharmaceutical product registration procedure. In this case, the API may only be used for the pharmaceutical product so evaluated.
2. Registration of an active pharmaceutical ingredients (API) not used in drug manufacturing. If the manufacturer has no decision to which plants he will supply his product and is going to expand the scope of his market, he is entitled to apply for registration of a API not used in drug manufacturing.

The API will be included in the State Register of registered medicinal products under a separate number.
Stages of registration of an active pharmaceutical ingredients (API) not used in drug manufacturing
Registration of a active pharmaceutical ingredient (API) consists of 2 stages:

1. API evaluation (quality control and approval of a Normative document (specification and analytical procedures));
2. Entering an API in the State Register of medicinal products.

The period of registration of a active pharmaceutical ingredients (API) not used in drug manufacturing: 5-7 months.

Drug Registration and Approval process in UK

- he medicines and healthcare products regulatory agency
- (MHRA) regulate medicines, medical devices and other medical
- products for their approval in the United Kingdom. The agency
- protects and improves public health and supports all the innovations
- through scienti□c research and development programs.

The agency has three centers

- The Clinical Practice Research Datalink (CPRD), a data research service which aims to improve public health with the help of NHS clinical data.
- The National Institute for Biological Standards and Control (NIBSC) which is a worldwide pioneer in maintaining the standards and Control of biological products.
- The Medicines and Healthcare Products Regulatory Agency (MHRA) which is the UK administrative body for medicines, medical devices and blood transfusion and furthermore in charge of guaranteeing the wellbeing, quality and viability of pharmaceuticals.
- Not all the drugs can be considered as safe for use. In some cases, the drug can be effective as well as in some cases it may even lead to serious complications, resulting in death. The response of the people for medicines is different. Sometimes the medicines may cause severe side effects. The side effects are in□uenced based upon the following-prescribed doses, treatment conditions, age and sex of the patient taking treatment.
- Medicines that are to be marketed will have to take a license from the regulatory authority based on the summary of the study that has been conducted on thousands of the people. When the study is done on

thousands of people, some of the side effects are identi□ed. Based on the safety of the drug the permission for the marketing of the drug will be issued

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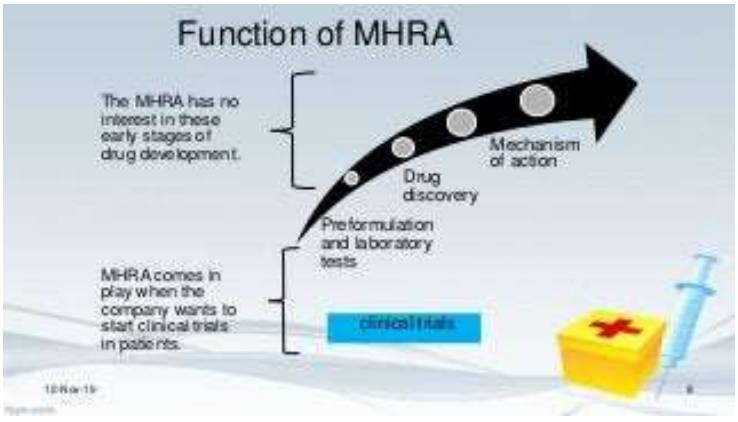

Fig 1: Function of MHRA

MHRA Process

The Process Licensing Office sits within the Inspectorate and Process Licensing Group of the Inspection, Enforcement and Standards division. It typically deals with the manufacture, assembly and wholesale distribution of medicinal products under UK and EU legislation, these licences are often called process licences and include:

- licences for the manufacture/importation of licensed medicinal products for human use, commonly abbreviated to MIA
- 'specials' licences for the manufacture/importation of unlicensed medicinal products for human use, commonly abbreviated to MS
- authorisations for the manufacture/importation of investigational medicinal products for human use, commonly abbreviated to MIA(IMP)
- authorisations for the manufacture/importation of licensed medicinal products for veterinary use (ManA)
- 'specials' licences for the manufacture of unlicensed medicinal products for veterinary use, (ManSA)
- manufacturer's licences for exempt advanced therapy medicinal products (MeAT)
- licences for the wholesale distribution of medicinal products for human use, commonly abbreviated to WDA (H) (including those covering unlicensed medicines obtained from another EEA member state)
- licences for the wholesale distribution/importation of medicinal products for veterinary use - WDA (V)
- blood establishment authorisations (BEA)
- non-orthodox practitioners (NOP)
- broker registrations
- active substance manufacturer, importer or distributor registrations

- certificates of Good Manufacturing Practice (GMP)
- certificates of Good Distribution Practice (GDP)

The MHRA Process Licensing Portal

The MHRA Process Licensing Portal is part of the government's Digital by Default agenda and is a web application which provides a secure environment and an easy to use platform which allows customers to submit new applications and variations to existing wholesale distribution authorisations electronically.

The portal should be used for wholesale distribution authorisations [WDA(H)] and active substance manufacturers, importers and distributors – new applications, variation applications and annual compliance reports (active substance manufacturers, importers or distributors only).

MHRA 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're risk-proportionate and effective at protecting public health.
- Scientific innovation
- Healthcare access
- Patient safety
- Dynamic organisation
- Collaborative partnerships
- Financial sustainability

These are underpinned by their priority to develop and improve patient and public involvement.

Types of MHRA licenses

1. Pharmaceutical manufacturers
2. Import of medicines
3. Biological compounds and chemical compounds

How to license a medicine for sale in UK

License for sale of a drug can be done by different procedures:

National procedure

This procedure is used when the drug has to be marketed only in the UK.

A 5-digit company number and a PL number is to be obtained in the being of the procedure. The application process takes about 210 days.

All the dossier and the informed consent checklist should be submitted, if the applicant is making an application for an informed consent marketing authorization.

Centralised procedure: It is required when the drug manufac-tured is to be marketed throughout Europe.

All the new substance that is produced will take a single license when the substance has to be marketed in all European states as well as Norway, Iceland and Liechtenstein.

Decentralised procedures (DCP): It is needed if the drug has to be manufactured and marketed in the UK and other European.

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- Centralised procedure: It is required when the drug manufac-tured is to be marketed throughout Europe. All the new substance that is produced will take a single license when the substance has to be marketed in all European states as well as Norway, Iceland and Liechtenstein.
- Decentralised procedures (DCP): It is needed if the drug has to be manufactured and marketed in the UK and other European countries.[9]

The one state which will lead manufacturer's assessment of the application is called as Reference Member State. The other state to which a manufacturer wants to apply is called Concerned Member States (CMS).

A DCP submission date should be booked if applicant wish applies for the Reference Member State (RMS). The reply from MHRA is obtained within 24 hours after con□rming of booking. Product license (PL) number and the DCP number will be issued along with the reply. MHRA acts as RMS to another member state, that applicant has planned to apply (CMSs). It takes up to 210 days for the procedure, excluding the time taken for submission of further data and information required.

If the application is approved then the MHRA and the CMS will issue a national license for the product to market within 30 days of the approval grantedA DCP submission date should be booked if applicant wish applies for the Reference Member State (RMS). The reply from MHRA is obtained within 24 hours after conforming of booking. Product license (PL) number and the DCP number will be issued along with the reply. MHRA acts as RMS to another member state, that applicant has planned to apply (CMSs). It takes up to 210 days for the procedure, excluding the time taken for submission of further data and information required. If the application is approved then the MHRA and the CMS will issue a national license for the product to market within 30 days of the approval granted A DCP submission date should be booked if applicant wish applies for the Reference Member State (RMS). The reply from MHRA is obtained within 24 hours after con□rming of booking. Product license (PL) number and the DCP number will be issued along with the reply. MHRA acts as RMS to another member state, that applicant has planned to apply (CMSs). It takes up to 210 days for the procedure, excluding the time taken for submission of further data and information required. If the application is approved then the MHRA and the CMS will issue a national license for the product to market within 30 days of the approval granted.

Mutual recognition procedure (MRP): If drug already has a marketing license in at leastone or more European countries but want to market the drug in any other countries, this license is applied Mutual recognition procedure (MRP): If drug already has a marketing license in at leastone or more European countries but want to market the drug in any other countries, this license is applied. The MHRA verify whether the item can be acknowledged for mutual recognition procedure and issue MRP number which is to be utilized as a part of the application. After the issue, the MHRA acts as RMS and will lead the assessment of the application. The processing of the application takes about 90 days. If the application is approved then the national license will be issued within 30 days by the CMS.[10]

Mutual recognition procedure can be used more than one time-this is called as repeat use procedure. How does MHRA classify the medicine or medical device?

Some substances are difficult to be classed as medicines or medical devices example in the case of cosmetics biocidal products, herbal products, medical devices, laboratory and machinery equipment, food products etc. Such products are called a Borderline product. /Borderline medicines.

Types of application

• Full application- Article 8(3)
• Hybrid, generic or similar biological applications - Article 10
• Well established use application- Article 10a
• Fixed combination application- Article 10b
• Informed consent application- Article 10cAbridged application procedure can be used in a certain application where pre-clinical and clinical studies are not needed. The types of application that can be used in this route are generic/biosimilars (Article 10), informed consent (Article 10c) and well-established use (Article 10 a) application.The legal basis for all types of application is set out in Directive 2001/83/EC and also in Regulation (EC) No726/2004.FeesPayment for the application should be done before submitting the document. The payment receipt should be attached along with application form.MHRA fee depends on the route of administration of the product that a manufacturer wishes to market. The proof of payment should be placed in the form of a PDF along with the application (eCTD).[11,12]

It should be one of the following:

• BACS or CHAPS electronic confirmation form.
• A photocopy of the cheque for the required sum with date and sign
• MHRA iRIS email account receipt (preferred for iRIS account holders)
• Email confirmation from MHRA finance department

Application process

Electronic common technical documentation method is used for the submission of application. In case if the applicant cannot submit by this method, non-electronic submission (NeeS) is also acceptable. MHRA checks whether the NeeS and e CTD are technically valid using the ExtendoEurs tool validation.

Active substance master files (ASMFs)

Active substance master file holders should submit their dossier to MHRA. Applicant must submit his active substance master file before the application being submitted or along with the submission of the application. If the active substance master file is not submitted then the application will not be valid unless the dossier of the active substance is submitted. ASMF holder will have to register with the Common European Submission Platform (CESP) and then will have to submit their application through CESP.

Summary of product characteristics (SPC)

Using SPC (summary of product characteristic) template the manufacturer should submit a summary of the product characteristic to MHRA in the proper format using MS Word Document (36KB).

Ways to make a submission

Via Central European System Platform (CESP) manufacturer can submit the application. From January 2016, it is mandatory to submit electronic application forms (eAFs) for new marketing authorization, renewal and variation application submissions. This application submission is same for all the procedures (centralized, national or decentralized procedures). If submission of application is through portal way, then both portal form, as well as eAFs, should be submitted. If the application is submitted through CESP then, only eAFs submission is required.

Rejection of submissions

If the application that has been sent has any error or does not comply according to the need of MHRA, the application will be rejected. An email will be sent by the MHRA agency along with the correction that should be made in the application. Once the mail is received, the applicant will have to correct the mentioned errors and then resend the along with the correction. For the correction, no extra charges will be charged.[12,13]

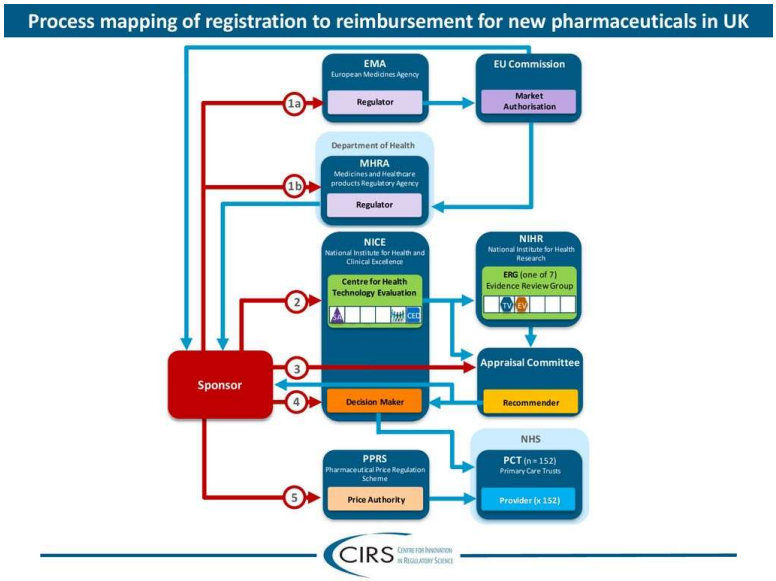

Fig 2: Process mapping of registration to reimbursement for new pharmaceuticals in UK

The European Union (EU) medicines regulatory system

The European Medicines Agency (or EMA) is the regulatory body in Europe that ensures that medicines are safe and that they work as expected. Located in London, the Agency is responsible for both human and veterinary medicines and has an important role in protecting public health in the EU.

CONCLUSION

Any medicinal agent to be marketed in the United Kingdom has to follow the guidelines and regulations framed by MHRA, a regulatory authority which approves the drug products. The objective of this review article is to highlight information regarding the requirements, the different types of submissions for the registration of a medicinal product in a market in the UK. It also includes all the details about the fee for the application and the time period for the approval of the application after the submission of the application. By knowing the requirements of the MHRA guidelines and regulations, it is easy for a product to get into the UK market.

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