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CURRENT APPROVAL PROCEDURE FOR NEW REGULATIONS, STANDARDS, POLICIES & GUIDANCE ISSUED BY REGULATORY AUTHORITIES

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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 ef□cacy 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.

Key words: MHRA, United Kingdom, Product license, eCT

A regulatory process by which a person/organization/sponsor/innovator gets authorization to launch a drug in themarket, is known as drug approval process. In general, a drug approval process comprises of various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. This article will focus the similarities and differences in drug approval process of various regulatory bodies.

Key Words: *Drug approval process, clinicaltrials, marketing.*

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INTRODUCTION:

National health authorities have the duty to ensure that available pharmaceutical products,whether imported or manufactured locally,are of good quality,safe and efficacious.This is particularly difficult for vaccines and biological products,the quality of which cannot be established entirely by tests on the material in the final container.A national control authority should therefore be established that is responsible for ensuring that the manufacturer is adhering to approved standards of good manufacturing practice and quality assurance specific to the product.The procedures through which the national control authority confirms the assurance of quality provided by the manufacturer will depend on the resources avalible and whether the product is manufactured locally or imported.

In general,biological products are distinguished from other drugs by being derived from living organisms(ranging from normal or genetically modified microorganisms to fluids and tissues derived from various animal and human sources) and frequently have a complex molecular structure.They require special quality considerations because of the biological nature of:(a) the starting materials; and /or (b) the manufacturing process;and/or (c)the test methods needed to characterize batches of the product.

Development in biological products have been extremely rapid in recent years,and the potential valve of such products in improving health care on a global scale is immense.There is an urgent need to match technological advances with appropriate mechanisms for assuring the safety,quality and efficacy of the products[1].

Laws & Regulations:

The Basics of the Regulatory Process:

Regulations are mandatory requirements that can apply to individuals, businesses, state or local governments, non-profit institutions, or others.

Congress passes the laws that govern the United States, but Congress has also authorized EPA and other federal agencies to help put those laws into effect by creating and enforcing regulations.

A basic description of how laws and regulations are developed, what they are, and where to find them, with an emphasis on environmental laws and regulations.

- Creating a law
- Putting the law to work
- Creating a regulation
- How you can get involved

Creating a law:

Step 1: Congress Writes a Bill

A member of Congress proposes a bill. A bill is a document that, if approved, will become law. To see the text of bills Congress is considering or has considered, go to Congress.gov

Step 2: The President Approves or Vetoes the Bill

If both houses of Congress approve a bill, it goes to the President who has the option to either approve it or veto it. If approved, the new law is called an act or statute. Some of the better-known laws related to the environment are the Clean Air Act, the Clean Water Act, and the Safe Drinking Water Act.

- Summaries of the laws EPA administers
- Congress.gov: for more information about the legislative process

Step 3: The Act is Codified in the United States Code

Once an act is passed, the House of Representatives standardizes the text of the law and publishes it in the United States Code (U.S.C.). The U.S.C. is the codification by subject matter of the general and permanent laws of the United States. Since 1926, the U.S.C. has been published every six years. In between editions, annual cumulative supplements are published in order to present the most current information.

United States Code: This database is available from the Government Printing

Office (GPO). GPO is the sole agency authorized by the federal government to publish the U.S.C.

Putting the law to work:

Once a law is official, here's how it is put into practice: Laws often do not include all the details needed to explain how an individual, business, state or local government, or others might follow the law. The United States Code would not tell you, for example, what the speed limit is in front of your house. In order to make the laws work on a dayto-day level, Congress authorizes certain government agencies - including EPA – to create regulations.

Regulations set specific requirements about what is legal and what isn't. For example, a regulation issued by EPA to implement the Clean Air Act might explain what levels of a pollutant - such as sulfur dioxide - adequately protect human health and the environment. It would tell industries how much sulfur dioxide they can legally emit into the air, and what the penalty will be if they emit too much. Once the regulation is in effect, EPA then works to help Americans comply with the law and to enforce it.

- Find out more about Compliance.
- Learn more about Enforcement.

Creating a regulation:
When developing regulations, the first thing we do is ask if a regulation is needed at all. Every regulation is developed under slightly different circumstances, but this is the general process:
Step 1: EPA Proposes a Regulation
The Agency researches the issues and, if necessary, proposes a regulation, also known as a Notice of Proposed Rulemaking (NPRM). The proposal is listed in the Federal Register (FR) so that members of the public can consider it and send their comments to us. The proposed rule and supporting documents are also filed in EPA's official docket on Regulations.gov.
Step 2: EPA Considers Your Comments and Issues a Final Rule
Generally, once we consider the comments received when the proposed regulation was issued, we revise the regulation accordingly and issue a final rule. This final rule is also published in the FR and in EPA's official docket on Regulations.gov.
Step 3: The Regulation is Codified in the Code of Federal

Regulations:
Once a regulation is completed and has been printed in the FR as a final rule, it is codified when it is added to the Code of Federal Regulations (CFR). The CFR is the official record of all regulations created by the federal government. It is divided into 50 volumes, called titles, each of which focuses on a particular area. Almost all environmental regulations appear in Title 40. The CFR is revised yearly, with one fourth of the volumes updated every three months. Title 40 is revised every July 1.

- Code of Federal Regulations database - a searchable database of the entire CFR from GPO.

How you can get involved:
Go to the "Get Involved with EPA Regulations" page to learn how you can comment on our regulations and keep tabs on rulemakings.

Regulatory Issues in the Indian Pharmaceutical Industry:
This section undertakes a review and assessment of regulatory issues in the Indian pharmaceutical industry. Understanding the regulatory scenario in this sector is extremely crucial not only due to the rapid and ongoing changes at the global level, largely with reference to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP) but also due to the onus on the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the Indian masses.

The present section begins with a brief description of the major regulatory bodies monitoring the Indian pharmaceutical sector. It then undertakes a review of the prevailing mechanisms for drug regulation and temporal progression of some predominant policy measures and Acts. The section subsequently provides a comprehensive account of the status and key guidelines pertaining to the dimensions of drug pricing, patent related issues, GMP and clinical trials, in addition to a brief review of standards for medical devices and biotech products. It concludes with an assessment of the deficiencies of present regulatory regime and some new initiatives by the State to ensure the production and marketing of safe and efficacious drugs at affordable prices in the domestic sphere and to sustain current growth prospects in the global markets.

Major bodies regulating drugs and pharmaceuticals:
The principal regulatory bodies entrusted with the responsibility of ensuring the approval, production and marketing of quality drugs in India at reasonable prices are:
The Central Drug Standards and Control Organization (CDSCO), located under the aegis of the Ministry of Health and Family Welfare. The CDSCO prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country; regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licences to manufacture the above-mentioned products;

The National Pharmaceutical Pricing Authority (NPPA), which was instituted in 1997 under the Department of Chemicals and Petrochemicals, which fixes or revises the prices of decontrolled bulk drugs and formulations at judicious intervals; periodically updates the list under price control through inclusion and exclusion of drugs in accordance with established guidelines; maintains data on production, exports and imports and market share of pharmaceutical firms; and enforces and monitors the availability of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.

The Department of Chemicals and Petrochemicals also oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceutical sector. The responsibilities assumed by this body are relatively

broader and varied in comparison to the other two bodies. The main aspects of pharmaceutical regulation are thus divided between the above two ministries. The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy. However, other ministries also play a role in the regulation process. These include the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. The process for drug approval entails the coordination of different departments, in addition to the DCGI, depending on whether the application in question is for a biological drug or one based on recombinant DNA technology. Issues related to industrial policy such as the regulation of patents, drug exports and government support to the industry are governed by the Department of Industrial Policy and Promotion and Directorate General of Foreign Trade, both under the aegis of Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers. With respect to licencing and quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology (DST) and Department of Environment, Ministry of Environment and Forests. State drug controllers have the authority to issue licences for the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO).

The role of pharmaceuticals has become more prominent on international agendas as health indicators have been increasingly linked with a country's successful development. In addition, the legal and economic issues that surround pharmaceuticals have become more complex and politi- cized because of the increase in global trade.

Pharmaceutical laws and regulations:

The use of ineffective, poor-quality, or harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines, and sometimes death. It also under- mines confidence in health systems, health professionals, pharmaceutical manufacturers, and distributors. To protect public health, governments need to approve comprehensive laws and regulations and to establish effective national regu- latory authorities to ensure that the manufacture, trade, and use of medicines are regulated appropriately and that the public has access to accurate information on medicines

Differences between pharmaceutical laws, regulations, and guidelines:

Laws today are usually written in fairly general terms to meet present and possibly future needs. Laws usually have language that enables the government to issueregulationsbased on the law. Passing new laws may require alengthyprocess, with the country's legislative branch givingfinalapproval.Regulationscanbepassedmorerapidlyandsim-ply than laws, sometimes requiring, for example, onlytheapproval of a single government minister on the adviceofexperts.Theycanalsobealteredmoreeasily.Afterapproval,aregulationhasthesamepowerasthelawitself.Guidelines,whichdonotcarrytheforceoflaw,canbemoreeasilymodi-fied and updated and offer informal information onwhatthe government's thinking is regarding the best waytoimplementregulations.Followingguidelineswill helpavoidmisinterpretationofandfacilitatecompliance withlawsandregulations.

Pharmaceuticals involve many parties, including patients, doctors, other health workers, salespeople, and manufacturers. The field also involves important risks: people can suffer or die not only from a lack of medicines, but alsofromdrugs that are impure, wrongly prescribed, or usedincor-rectly. Thus, it is easy to see why laws and regulations are needed. However, some argue that medicines—like many other commodities—should be subject only to the control of the ultimate user.

Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations:

Introduction:

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

The approval process for new drug and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMP. FDA inspectors determine whether the firm has the necessary facilities, equipment, and skills to manufacture the new drug for which it has applied for approval. Decisions regarding compliance with CGMP regulations are based upon inspection of the facilities, sample analyses, and compliance history of

the firm. This information is summarized in reports which represent several years of history of the firms.

FDA can issue a warning letter or initiate other regulatory actions against a company that fails to comply with Current Good Manufacturing Practice regulations. Failure to comply can also lead to a decision by FDA not to approve an application to market a drug.

This web page provides links to resources to help drug manufacturers comply with the Current Good Manufacturing Practice regulations.

Federal Regulations:

Code of Federal Regulations (CFR). The final regulations published in the Federal Register (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the CFR. The CFR is divided into 50 titles which represent broad areas subject to Federal regulations. The FDA's portion of the CFR interprets theFederal Food, Drug and Cosmetic Act and related statutes. Section 21 of the CFR contains most regulations pertaining to food and drugs. The regulations document the actions of drug sponsors that are required under Federal law.

- 21 Code of Federal Regulations Part 210. Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs.
- 21 Code of Federal Regulations Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals.
- Federal Register Notices for Proposed Changes and Final Changes to CGMP. The Office of Compliance, Division of Manufacturing and Product Quality web page provides links to in-process changes in CGMP regulations announced in the Federal Register.

Guidance Documents:

Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for FDA review staff and drug sponsors to provide guidelines for the processing, content, and evaluation of applications, and for the design, production, manufacturing, and testing of regulated products. They also provide consistency in the Agency's regulation, inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable. An alternative approach may be used if it satisfies the requirements of the applicable statute, regulations, or both.

- Guideline on the Preparation of Investigational New Drug Products (Human and Animal) (PDF - 795KB) (Issued 11/1992, Posted 3/2/1998). This guidance provides practices and procedures for preparing investigational new drug products that comply with certain section of the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals (Title 21 of the *Code of Federal Regulations*, Parts 210 and211.)
- Guidance for Industry: Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production (PDF - 98KB). 10/2006 This guidance provides the Agency's current thinking on how to evaluate suspect, or out of specification (OOS) test results. For purposes of this document, the term *OOS results* includes ***all***suspect results that fall outside the specifications or acceptance criteria established in new drug applications.

CDER Manual of Policies and Procedures (MaPPs):

MaPPs are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities. MaPPs define external activities as well. All MaPPs are available for the public to review to get a better understanding of office policies, definitions, staff responsibilities and procedures.

- 4723.1 Standing Operating Procedures for NDA/ANDA Field Alert Reports (PDF - 15KB). (Issued 10/30/1998, posted 11/02/1998). This MaPP establishes a system for evaluating new drug application (NDA) and abbreviated new drug application (ANDA) Field Alert Reports and provides instructions to the responsible CDER units for handling those reports.

Compliance Policy Programs and Guidelines:

- Compliance References. This web site from the Office of Regulatory Affairs provides links to compliance policy guides, regulatory procedures manuals, and other compliance related information. Chapter 4 of the Compliance Policy Guide covers human drugs.
- Compliance Program Guidance Manual. These programs and instructions are for FDA field inspectors.
- Consistent Application of Current Good Manufacturing Practice Determinations. FDA cannot approve applications to market new drugs from companies who have been cited for Current Good Manufacturing Practice violations. Similarly, disapproval of any drug marketing application based upon CGMP deficiencies must also lead to regulatory and/or administrative

action against other products produced under the same conditions.

Investigational New Drug (IND) Application:
Introduction:
Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

There are three IND types:

- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.23 orSec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories:

- Commercial
- Research (non-commercial)

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).
- Manufacturing Information - Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators--professionals (generally physicians) who oversee the administration of the experimental compound--to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Resources for IND Applications:
The following resources include the legal requirements of an IND application, assistance from CDER to help you meet those requirements, and internal IND review principles, policies and procedures.

Pre-IND Consultation Program:
CDER's Pre-Investigational New Drug Application (IND) Consultation Program fosters early

communications between sponsors and new drug review divisions to provide guidance on the data necessary to warrant IND submission. The review divisions are organized generally along therapeutic class and can each be contacted using the designated Pre-IND Consultation List (PDF - 19KB).

Guidance Documents for INDs:
Guidance documents represent the Agency's current thinking on a particular subject. These documents provide FDA review staff and applicants/sponsors with guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures.

Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts. An alternative approach may be used if it satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

For the complete list of CDER guidances, please see the Guidance Index.
Guidance documents to help prepare INDs include:

- Safety Reporting Requirements for INDs and BE/BA Studies (9/28/2010)
- Enforcement of Safety Reporting Requirements for INDs and BA/BE Studies (PDF - 41KB) (6/6/2011)
- CGMP for Phase 1 Investigational Drugs (PDF - 132KB) (7/2008)
- Exploratory IND Studies (PDF - 220KB) (1/12/2006)
- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well Characterized, Therapeutic, Biotechnology-Derived Products (PDF - 42KB). Provides description of required sections of an application. (Issued 11/1995)
- Q & A - Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (PDF - 14KB). This guidance is intended to clarify when sponsors should submit final, quality-assured toxicology reports and/or update the Agency on any changes in findings since submission of non-quality-assured reports or reports based on non-quality-assured data. (Issued 10/2000)
- Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (PDF - 268KB). (Issued 10/2000, Posted 10/27/2000). This guidance should be useful for applicants planning to conduct bioavailability (BA) and bioequivalence (BE) studies during the IND period for an NDA, BE studies intended for submission in an ANDA, and BE studies conducted in the postapproval period for certain changes in both NDAs and ANDAs.

- IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (PDF - 188KB). (1/2004)
- Guideline for Drug Master Files. A Drug Master File (DMF) is a submission to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- Required Specifications for FDA's IND, NDA, and ANDA Drug Master File Binders.
- Immunotoxicology Evaluation of Investigational New Drugs (PDF - 100KB) (Issued 10/2002, Posted 10/31/2002). This guidance makes recommendations to sponsors of INDs on (1) the parameters that should be routinely assessed in toxicology studies to determine effects of a drug on immune function, (2) when additional immunotoxicity studies should be conducted, and (3) when additional mechanistic information could help characterize the significance of a given drug's effect on the immune system.

Laws, Regulations, Policies and Procedures:
The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. *The Federal Food, Drug, and Cosmetic Act* is the basic food and drug law of the U.S. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

Code of Federal Regulations (CFR):
The final regulations published in the *Federal Register* (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *Code Of Federal Regulations (CFR)*. The *CFR* is divided into 50 titles that represent broad areas subject to Federal regulations. The FDA's portion of the *CFR* interprets the *The Federal Food, Drug, and*

Cosmetic Act and related statutes. Section 21 of the *CFR* contains most regulations pertaining to food and drugs. The regulations document all actions of all drug sponsors that are required under Federal law.

Manual of Policies and Procedures (MaPPs):
CDER's Manual of Policies and Procedures (MaPPs) are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities. All MAPPs are available for the public to review for a better understanding of office policies, definitions, staff responsibilities and procedures. MaPPs of particular interest to IND sponsors include:

- 4200.1 Consulting the Controlled Substance Staff on INDs and Protocols That Use Schedule I Controlled Substances and Drugs (Issued 5/8/2003)
- 5210.5 Review of Investigational New Drug Applications (Bio-INDs) by the Office of Generic Drugs
- 6030.1 IND Process and Review Procedures (Including Clinical Holds). Includes general IND review principles, policies and procedures for issuing clinical holds of INDs, and processing and responding to sponsors' complete responses to clinical holds.
- 6030.2 INDs: Review of Informed Consent Documents (Issued 11/13/2002)
- 6030.4 INDs: Screening INDs. (Issued 5/9/2001, Posted 5/14/2001). This MsPP describes procedures for the review of multiple active moieties or formulations under the single investigative new drug application (IND) called a screening IND.
- 6030.8 INDs: Exception from Informed Consent Requirements for Emergency Research. (Issued 2/4/2003)

Emergency Use of an Investigational Drug or Biologic:

- Final Rules for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs (8/12/2009)
- FDA proposes rules overhaul to expand the availability of experimental drugs. The Agency also clarifies permissible charges to patients. FDA News (12/11/2006)
- The Guidance for Institutional Review Boards and Clinical Investigatorscontains information on: Obtaining an Emergency IND, Emergency Exemption from Prospective IRB, Approval Exception from Informed Consent, and Requirement Planned Emergency Research, Informed Consent Exception.
- Federal Register notice for Emergency Use of an Investigational New Drug; Technical Amendment
- Physician Request for a Single Patient IND for Compassionate or Emergency Use
- Instructions for Sponsors of Emergency Investigational New Drug (EIND) Applications for Antimicrobial Products. From the Office of Antimicrobial Products, Division of Antiviral Products (11/29/2005)

Emergency use requests:

- For investigational biological products regulated by CBER, call 301-827-1800.
- For all other investigational drugs, call 301-796-3400.
- After working hours, call FDA's Office of Emergency Operations at 1-866-300-4374 or 301-796-8240

http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigatinalnewdrugindapplication/default.htm

The National Law outlines the powers of authorised officers:
An authorised officer is defined as a person authorised to be an authorised officer under Part 9 of the National Law. In addition, the National Law defines the responsibilities of Regulatory Authorities and ACECQA for the authorisation of authorised officers (section 195).
Each authorised officer will be issued with an identity card which must be carried whenever the officer is exercising their functions under the National Law and the National Regulations (section 196).
The National Law also prescribes the powers of entry that authorised officers have for assessing and monitoring services (section 197). Authorised officers have a range of powers, including to:
• enter and inspect education and care service premises
• obtain information, documents and evidence, and
• inspect and copy documents.
An authorised officer may exercise these powers in order to:
• monitor compliance with the National Law
• conduct a rating assessment, or
• obtain information requested by the Regulatory Authority.

PRINCIPLES FOR THE GOVERNANCE OF REGULATORS:

Regulation is a key tool for achieving the social, economic and environmental policy objectives of governments. Governments have a broad range of regulatory schemes reflecting the complex and diverse needs of their citizens, communities and economy.

Professor Malcolm Sparrow (2000) argues:
"Regulators, under unprecedented pressure, face a range of demands, often contradictory in nature: be less intrusive – but be more effective; be kinder and gentler – but don't let the bastards get away with anything; focus your efforts – but be consistent; process things quicker – and be more careful next time; deal with important issues – but do not stray outside your statutory authority; be more responsive to the regulated community – but do not get captured by industry"

This document is intended to facilitate better institutional arrangements, and consequently it complements documents such as the OECD's Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA) (2008), which guides the development of better rules and regulations, and the OECD's Recommendation of the Council on Regulatory Policy and Governance (2012). Both documents support the work underway across member countries' governments to improve the operational processes and practices within regulators and to support regulators' efforts to attract and develop the best people

How a regulator is set up, directed, controlled, resourced and held to account — including the nature of the relationships between the regulatory decision-maker, political actors, the legislature, the executive administration , judicial processes and regulated entities — builds trust in the regulator and is crucial to the overall effectiveness of regulation. Improving governance arrangements can benefit the community by enhancing the effectiveness of regulators and, ultimately, the achievement of important public policy goals.

Achieving good regulatory outcomes is almost always a cooperative effort: by the regulator and other regulators, the regulated, and often the broader community. Governance arrangements for regulators can be important to foster such cooperative efforts and build the legitimacy of any necessary, strong enforcement action. For these reasons, governance arrangements require careful consideration to ensure they promote, rather than hinder, the efficient achievement of policy objectives and public confidence in the operations of regulatory agencies.

This document aims to develop a framework for achieving good governance through outlining general principles that might apply to all regulators. The framework is intended to provide:

- principles for assessing existing governance arrangements and undertaking reviews of regulators and their administration; and
- a guide to the development of governance arrangements for any proposed new regulators

This document sets out principles within seven areas which need to be considered to support good governance of regulators:

-Role clarity
-Preventing undue influence and maintaining trust
-Decision-making and governing body structure for independent regulators
-Accountabilityand transparency
-Engagement
-Funding
-Performance Evaluation

Providing comments, information and responding to this paper:
Each section provides a brief explanation of how these mesh with the principles of good regulation and discusses the implications of applying the governance principles to regulators within government. Each section ends with a series of questions to guide those seeking to apply the principles to specific cases, either to review existing regulators or in the establishment of new regulatory bodies.

The OECD is also calling for information to provide country examples to support the application of the principles in countries. Further details can be found in Annex 1 of some specific examples that are sought. However the OECD welcomes other submissions of country examples as well that can be used to populate the final version of this paper that will bring to life the variety of international experience in the governance arrangements of regulators.

The OECD welcomes comments and input on all aspects of this paper. The paper primarily makes use of English-language sources from North American and European authors. In responding to the discussion questions, specific references to documents where further information is available would be of great use to broaden the base of literature the paper is based on.

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.

Evaluating the effectiveness of pharmaceutical legislation and accompanying regulations is not always easy.The process of evaluation depends on the types of performance indicators and criteria used and on the availadility of adequate data.

The important factor in the effectiveness of pharmaceutical laws and regulations is the extent to which the legislative framework is in tune with national policy and the existing situation .Changes in policy needed to be reflected in the legislation and in its implementation.

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