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Review

Current Trends In Regulatory Actions Against Misbrandind And Adulteration

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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 anufacturer, 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

INTRODUCTION

Introduction to regulatory affairs in pharmaceutical industry

Introduction to regulatory affairs

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents.

This department is responsible for knowing the regulatory requirements for getting new Products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified.

Importance of regulatory affairs

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

Inadequate reporting of data may prevent a timely positive evaluation of marketing application. A new drug may have cost many millions of pounds, Euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse1 failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavor with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources.

The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company for better, or worse Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent.

The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.

Responsibility of Regulatory Affairs Professional's

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

It may take anything up to 15 years to develop and launch a new pharmaceutical product and problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, in appropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labeling or in advertising.

Need of regulatory affairs in the pharmaceutical industry

Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

Misbranding

Misbranding is one of the unethical trade practices the Indian pharmaceutical industry has been indulging in for some time now. There has been hardly any action against such practices from the regulatory authorities until recently.

Misbranding is a dubious way of exploiting a well-established brand name for a totally different product. The temptation is because of the massive build up of goodwill a brand attains over a long period of time. Two recent cases of misbranding are that of Disprin Plus of Reckitt Benckiser and Aspro Plus of Nicholas Piramal. Both Disprin and Aspro are old and well-established aspirin brands in Indian Pharmaceutical market. With a sharp cut in the price of aspirin early this year by NPPA, returns from these two aspirin brands may have become totally unattractive to these manufacturers.

They have, therefore, decided to discontinue these products shortly after the price cut. But at the same time they did not want to just give up such highly popular brand names. The reason to launch Disprin Plus and Aspro Plus with paracetamol as the ingredients by these companies is with the intention of exploiting the brand equity of Dispirin and Aspro. Such actions may be commercially justifiable but certainly are not ethical.

In such blatant cases of misbranding what these companies have done is putting the lives of several patients at risk, as most of them could not comprehend the total change of ingredient in the product. Such unpublicised change of the main ingredient in a brand also creates a lot of confusion among the retail chemists.

There are over 100 such cases of misbranding detected by the office of the Drug Controller General of India (DCGI) in pharma industry so far. And this tendency can only grow to dangerous levels considering the intense competition existing in the formulation sector.

The government's decision to incorporate suitable provisions in the Drugs and Cosmetics Act to curb this practice of misbranding is therefore a laudable move. D&C Act in its present form is not competent enough to curb the practice of misbranding.

A set of mandatory guidelines, therefore, needs to be in place. The Drug Consultative Committee attached to the ministry of chemicals and fertilizers has also seized of the matter and has taken it up as the main agenda for its next meeting.

There could be resistance to the proposed provisions from the powerful companies as some of them are already offenders. But the DCGI needs to be firm and clear while framing, adopting and implementing these provisions. Stringent punitive clauses need to be included in the Act to deter such temptations.

Adulteration of Food

Adulteration of Food. "Adulteration" is a legal term meaning that a food product fails to meet federal or state standards. Adulteration usually refers to noncompliance with health or safety standards as determined, in the United States, by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

Definition of Adulterated Food

The Federal Food, Drug, and Cosmetic (FD&C) Act (1938) provides that food is "adulterated" if it meets any one of the following criteria:

a. it bears or contains any "poisonous or deleterious substance" which may render it injurious to health;
b. it bears or contains any added poisonous or added deleterious substance (other than a pesticide residue, food additive, color additive, or new animal drug, which are covered by separate provisions) that is unsafe;
c. its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
d. it bears or contains a pesticide chemical residue that is unsafe. (Note: The Environmental Protection Agency [EPA] establishes tolerances for pesticide residues in foods, which are enforced by the FDA.)
e. it is, or it bears or contains, an unsafe food additive;
f. it is, or it bears or contains, an unsafe new animal drug;
g. it is, or it bears or contains, an unsafe color additive;
h. it consists, in whole or in part, of "any filthy, putrid, or decomposed substance" or is otherwise unfit for food;
i. it has been prepared, packed, or held under unsanitary conditions (insect, rodent, or bird infestation) whereby it may have become contaminated with filth or rendered injurious to health.
j. it has been irradiated and the irradiation processing was not done in conformity with a regulation permitting irradiation of the food in question (Note: FDA has approved irradiation of a number of foods, including refrigerated or frozen uncooked meat, fresh or frozen uncooked poultry, and seeds for sprouting [21 C.F.R. Part 179].);
k. it contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended in labeling (for example, foods or dietary supplements containing aristolochic acids, which have been linked to kidney failure, have been banned.);

l. a valuable constituent has been omitted in whole or in part or replaced with another substance; damage or inferiority has been concealed in any manner; or a substance has been added to increase the product's bulk or weight, reduce its quality or strength, or make it appear of greater value than it is (this is "economic adulteration");
m. it is offered for import into the United States and is a food that has previously been refused admission, unless the person reoffering the food establishes that it is in compliance with U.S. law.

Enforcement Actions against Adulterated Food

If a food is adulterated, FDA and FSIS have a broad array of enforcement tools. These include seizing and condemning the product, detaining imported product, enjoining persons from manufacturing or distributing the product, or requesting a recall of the product. Enforcement action is usually preceded by a Warning Letter from FDA to the manufacturer or distributor of the adulterated product. In the case of an adulterated meat or poultry product, FSIS has certain additional powers. FSIS may suspend or withdraw federal inspection of an official establishment. Without federal inspection, an establishment may not produce or process meat or poultry products, and therefore must cease operations. With the exception of infant formula, neither FDA nor FSIS has the authority to require a company to recall an adulterated food product. However, the ability to generate negative publicity gives them considerable powers of persuasion.

Food, Drug and Cosmetic Act, 1938:

I. Short Title
II. Definitions
  a) 201(f) is the definition for a food, which explicitly includes chewing gum
  b) 201(g) is the definition for a drug
  c) 201(h) is the definition for a medical device
  d) 201(s) is the definition of a food additive
  e) 201(ff) is the definition of a dietary supplement
III. Prohibited Acts and Penalties

This section contains both civil law and criminal law clauses. Most violations under the act are civil, though repeated, intentional, and fraudulent violations are covered as criminal law. All violations of the FD&C Act require interstate commerce because of the commerce clause, but this is often interpreted broadly and few products other than raw produce are considered outside of the scope of the act.

Notably, the FD&C Act uses strict liability due to the Dotterweich and Park Supreme Court cases. It is one of a very small number of criminal statutes that does.

IV. Food

There is a distinction in food adulteration between those that are added and those that are naturally present. Substances that are added are held to a stricter "may render (it) injurious to health" standard, whereas substances that are naturally present need only be at a level that "does not ordinarily render it injurious to health"[8]

V. Drugs and Devices
  a) 505 is the description of the drug approval process
  b) 510(k) is the section that allows for clearance of class II medical devices
  c) 515 is the description of the (class III) device approval process
VI. Cosmetics
VII. General Authority
  a) 704 allow inspections of regulated entities. Inspection results are reported on Form 483.
VIII. Imports and Exports
IX. Tobacco Products
X. Miscellaneous

The Prevention of Food Adulteration Rules, 1955;

PART I—PRELIMINARY

Short title, extent and commencement

(1) These Rules may be called the Prevention of Food Adulteration Rules, 1955.
(2) They extend to the whole of India.
(3) The rules other than those contained in Part III. Appendix 'B', Item A. 12- Margarine, Part VI and Part VII shall come into force on the date of their publication in the Official Gazette, the rules contained in Part III, Appendix 'B' Item A.12- Margarine shall come into force on the first day of June, 1956 and the rules contained in Part VI and Part VII shall come into force on the first day of December, 1956.

Definition -- In these rules, unless the context otherwise requires

(a) "Act" means the Prevention of Food Adulteration Act, 1954(37 of 1954);
(b) "Director" means the Director of the Laboratory;
(c) "Laboratory" means a Central Food Laboratory;
(d) "Form" means a Form set forth in Appendix A to these rules;

- "infant" means a child not more than twelve months of age;
- "infant food" means any food (by whatever name called) being marketed or otherwise represented as a complement of mother's milk to meet the growing nutritional needs of infant after the age of four months;
- "infant milk substitute" means any food being marketed or otherwise represented as partial or total replacement for mother's milk, whether or not it is suitable for such replacement';

(e) "Local Authority" means

(i) in the case of sea ports, the Health Officer as defined in the Indian Port Health Rules, 1955, in respect of that portion of local area falling within the jurisdiction of the ports;
(ii) in the case of airports, the Health Officer as defined in the Indian Aircraft (Public Health) Rules, 1954, in respect of that portion of the local area falling within the jurisdiction of the airport;
(iii) in the case of all railway stations or groups of railway stations (including any railway colony, office, yard, goods-shed, transshipment shed, workshop and other works owned and maintained by the Railway Administration for the purpose or in connection with Railways) the Medical Superintendent/ Divisional Medical Officer of the Railways in respect of that portion of the local area falling within the jurisdiction of the said railway station or group of railway stations.
(iv) In case of an ordnance factory or equipment factory, the General Manager of such factory or equipment factory or both.

PART II – THE CENTRAL FOOD LABORATORY

Functions: (1) In addition to the functions entrusted to the Laboratory by the Act, the Laboratory shall carry out the following functions, namely

(a) analysis of samples of food sent by any officer or authority authorized by the Central Government for the purpose and submission of the certificate of analysis to the authorities concerned;
(b) investigation for the purpose of fixation of standard of any article of food;
(c) investigation, in collaboration with the laboratories of Public Analysis in the various States and such other laboratories and institutes which the Central Government may approve in this behalf for the purpose of standardizing methods of analysis.

Analysis of Food Samples

(1) (a) Sample of food for analysis under sub section (2) of section 13 of the Act shall be sent either through a Messenger or by registered post in a sealed packet, enclosed together with a memorandum in Form I in an outer cover addressed to the Director.

(b) Samples of food for analysis under sub-section (2) of section of the Act or under clause (a) of Rule 3 shall be sent either through a Messenger or by registered post in a sealed packet enclosed together with a memorandum in Form I-A in an outer cover addressed to the Director.

(2) The container as well as the outer covering of the packet shall be marked with a distinguishing number.
(3) A copy of the memorandum and a specimen impression of the seal used to seal the container and the cover shall be sent separately by registered post to the Director.
(4) On receipt of a package containing a sample for analysis, the Director or on officer authorised by him, shall compare the seals on the container and the outer cover with specimen impression received separately and shall note the condition of the seals thereon.
(5) The fees payable in respect of such a certificate shall be Rs.1000 per sample of food analyzed.
(6) Certificates issued under these rules by the Laboratory shall be signed by the Director.
(7) The fee payable in respect of analysis of samples of imported food analysed in any designed laboratory shall be Rs. 3000/- per sample payable by the importer.

PART III – DEFINITIONS AND STANDARDS OF QUALITY

Standards of quality of the various articles of food specified in Appendix B to these rules are as defined in that unless he:

PART IV – PUBLIC ANALYSTS AND FOOD INSPECTORS

Qualification of Public Analyst—A person shall not be qualified for appointment as a public analyst unless he:

hold a Master's Degree in Chemistry or Bio-Chemistry Food Technology or Microbiology or Food and Drugs from a University established in India by Law or is an Associate of the Institution of Chemists (India) by examination in the section of Food Analyst conducted by the Institution of Chemists (India) or has an equivalent

qualification recognised and notified by the Central Government for such purposes and has not less then three years' experience in the analysis of food;

(1) has been declared qualified for appointment as a public analyst by a Board appointed and notified by the Central Government for such purposed.

Provided that a person who is a public analyst on the date of commencement (24.8.1995) of these Prevention of Food Adulteration (Amendment) Rules, 1995 or who has worked as a public analyst for a period of three years before such commencement may hold office as such, subject to the terms and conditions of service applicable to him even though he does not fulfil the qualifications laid down in clauses (1) and (2).

Provided further that a person who:-

(i) holds a degree in science with chemistry or Bio- chemistry or Food Technology or Food and Drugs from a University establishment in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose and has not less than five years of experience after graduation in the analysis of food, and

(ii) (a) has been declared qualified for appointment as a public analyst by a Board appointed and notified under clause (2) of this rule, prior to commencement of the Prevention of Food Adulteration (Amendment) Rules, 1955 or

(b) Shall be declared qualified for appointment as a public analyst by a Board appointed and notified under clause (2) of this rule upto the period of 31st March, 1999.

Duties of public analyst

(1) On receipt of a package containing a sample for analysis from a Food Inspector or any other person the Public Analyst or an officer authorised by him shall compare the seals on the container and the outer cover with specimen impression received separately and shall note the condition of the seals thereon.
Provided that in case sample container received by the public analyst is found to be is broken condition or unfit for analysis he shall within a period of seven days from the date of receipt of such sample inform the Local (Health) Authority about the same and send requisition to him for sending second part of the sample.

(2) The public analyst shall cause to be analyst such samples of article of food as may be sent to him by Food Inspector or by any other person under the Act.

(3) The public analyst shall, within a period of forty days from the date of receipt of any sample for analysis, send by registered post or by hand to the Local (Health) Authority a report of the result of such analysis in Form III.

Provided that where any such sample does not conform to the provisions of the Act or these rules, the public analyst shall send by registered post or by hand four copies of such report to the said Authority.

Note: In case of sample received under the proviso of Rule 7(1) or Rule 9A, the period of forty days shall be counted from the date of receipt of the second part of the sample.

Qualifications for Food Inspector- A person shall not be qualified for appointment as Food Inspector unless he—

(a) is a medical officer in charge of health administration of a local area; or

(b) is a graduate in medicine and has received at least one month's training in food inspection and sampling work approved for the purpose by the Central Government or a State Government or

(c) is a graduate in Science with Chemistry as one of the subjects or is a graduate in Agriculture or Public Health or Pharmacy or in Veterinary Science or a graduate in Food Technology or Dairy Technology or is a diploma holder in Food Technology or Dairy Technology from a University or Institution established in India by law or has equivalent qualifications recognised and notified by the Central Government for the purpose and has received three month's satisfactory training in food inspection and sampling work under a Food (Health) Authority or in an institution approved for the purpose by the Central Government.

Provided that the training in Food inspection and sampling work obtained prior to the commencement of Rule 3 of Prevention of Food Adulteration (Fourth Amendment) Rules, 1976 in any of the laboratories under the control of –

(i) a public analyst appointed under the Act, or

(ii) a fellow of the Royal Institution of Chemistry of Great Britain (Branch E); or

(iii) any Director , Central Food Laboratory; or

the training obtained under a Food (Health) Authority, prior to the commencement (1.3.1980) of the Prevention of Food Adulteration (Amend-ment) Rules 1980, shall be considered to be equivalent for the purpose of the requisite training under these rules.

Provided further that a person who is a qualified Sanitary Inspector having experience as such for a minimum period of one year and has received at least three months training in whole or in parts in food inspection and sampling work, may be eligible for appointment as food inspector, upto the period ending on the 31st March

, 1985 and may continue as such if so appointed even though he does not fulfil the qualifications laid down in clauses (a) to (c).

Provided also that nothing in this rule shall be construed to disqualify any person who is a food inspector on the commencement (1.3.1980) of the Prevention of Food Adulteration (Amendment) Rules, 1980 from continuing as such after such commencement.

Duties of Food Inspector:- It shall be the duty of the food inspector--

(a) to inspect as frequently as may be prescribed by the Food (Health) Authority all establishments licensed for the manufacture, storage or sale of an article of food within the area assigned to him;
(b) to satisfy himself that the conditions of the licences are being observed;
(c) to procure and send for analysis; of necessary, samples of any articles of food which he has reason of suspect are being manufactured, stocked or sold or exhibited for sale in contravention of the provisions of the Act or rules thereunder;
(d) to investigate any complaint which may be made to him in writing in respect of any contravention of the provisions of the Act, or rules framed thereunder;
(e) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of sample and the seizure of stocks, and to submit copies of such record to the health officer or the Food (Health) Authority as directed in this behalf.
(f) To make such enquiries and inspections as may be necessary to detect the manufacture, storage or sale of articles of food in contra-vention of the Act or rules framed thereunder;
(g) To stop any vehicle suspected to contain any food intended for sale or delivery for human consumption;
(h) When so authorised by the health officer, having jurisdiction in the local area concerned or the Food (Health) Authority, to detain imported packages which he has reasons to suspect contain food, the import or sale of which is prohibited.

(i) To person such other duties as may be entrusted to him by the health officer having jurisdiction in the local area concerned or Local (Health) Authority or the Food (Health) Authority;

Sending of sample by Local Health Authority-- (a) Local (Health) Authority shall within a period of seven days of seven days of receipt of requisition for second part of the sample from Public Analyst under the proviso of Rule 7(1), send such sample of the Public Analyst.

(b) Local (Health) Authority, while sending second part of the sample under the provision of sub-section (2E) of section 13 of the Act, shall do so within a period of 20 days from the date of receipt of the report from the first public analyst.

Local (Health) Authority to send report to person concerned-- The Local (Health) Authority shall within a period of ten days after the institution of prosecution forward a copy of the report of the result of analysis is Form III delivered to him under sub-rule(3) of Rule-7, by registered post or by hand, as may be appropriate, to the person from whom the sample of the article was taken by the Food Inspector, and simultaneously also to the person, if any, whose name, address and other particulars have been disclosed under section 14A of the Act.

Provided that where the sample conforms to the provisions of the Act or the rules made thereunder, and no prosecution is intended under sub-section (2), or no action is intended under sub-section (2E) of section 13 of the Act, the Local (Health) Authority shall intimate the result to the vendor from whom the sample has been taken and also to the person, whose name, address and other particulars disclosed under section 14A of the Act, within 10 days from the receipt of the report from the public analyst.

Forms of order not to dispose of stock and of bond- Where the food inspector keeps any article of food in the safe custody of the vendor under sub-section (4) of section 10—

(a) he shall, after sealing such article of food, make an order to the Vendor in Form IV and the vendor shall comply with such an order, and
(b) He may require the vendor to execute a bond in Form IV A.

Form of receipt for food seized by a food inspector

For every articles of food seized and carried away by food inspector under sub-section (4) of section 10 of the Act, a receipt in Form V shall be given by the food inspector to the person from whom the article was seized.

Notice of intention to take sample for analysis

When a Food Inspector takes a sample of an article for the purpose of analysis, he shall give notice of his intention to do so in writing in Form VI, then and there, to the person from whom he takes the sample and

simultaneously, by appropriate means, also to the persons, if any, whose name, address and other particulars have been disclosed under section 14A of the Act.

Provided that in case where a food inspector draws a sample from an open container, he shall also draw a sample from the container in original condition of the same article bearing the same declaration, if such container is available, and intimate this fact to the Public Analyst.

Warranty—Every manufacturer, distributor or dealer selling an article of food to a vendor shall give either separately or in the bill, cash memo or a label a warranty in Form VIA.

Form of nomination of Director or Manager and his content, under section 17-- (1) A company may inform the Local (Health) Authority of the concerned local area, by notice in duplicate, in Form VIII containing the name and address of the Director or Manager, who has been nominated by it under sub section (2) of section 17 of the Act to be in charge of, and responsible to the company for the conduct of the business of the company or any establishment, branch or unit thereof.

Provided that no such nomination shall be valid unless the Director or Manager who has been so nominated, gives his consent in writing and has affixed his signature, in Form VIII in duplicate in token of such consent.

(2) The Local (Health) Authority shall sign and return one copy of the notice in Form VIII to the company to signify the receipt of the nomination and retain the second copy in his office for record.

Vendor to disclose name and address of Director/Manager in certain circumstances—Every vendor of an article of food shall disclose the name and address of the Director or Manager, as the case may be , nominated in Form VIII under Rule-12B to a purchase who informs such vendor of his intention of purchasing any such article him for analysis by a public analyst under section 12 of the Act.

Power of food inspector to deal with carriers of disease handling food—

(1) Where the food inspector is of the opinion that any person engaged in selling or manufacturing any article of food is suffering from or harbouring the germs of any infectious disease, he may examine or cause to be examined such person.

Provided that where such person is a female above the age of eight years she shall be examined by a woman duly authorised by the food inspector.

(2) If on such examination the food inspector finds that such person is suffering from any such disease, he may by order in writing direct such person not to take part in selling or manufacturing any article of food.

Part v - sealing, fastening and dispatch of samples

Manner of Sending of sample for analysis: Sample of food for the purpose of analysis shall be taken in clean and dry bottles or jars or in other suitable containers which shall be closed sufficiently tight to prevent leakage, evaporation or in the case of dry substance entrance of moisture and shall be carefully sealed.

Bottles or containers to be labelled and addressed- All bottles or jars or other containers containing samples for analysis shall be properly labelled and the parcels shall be properly addressed. The label on any sample of food sent for analysis shall bear:-

(a) code number and Serial number of the Local(Health) Authority
(b) Name of the sender with official designation, if any
(d)Date and Place of collection;
(e)Nature of article submitted for analysis;
(f)Nature and quantity of preservative if any, added to the sample;

Provided that in the case of a sample of food which has been taken from Agmark sealed container, the label shall bear the following additional information:-

(a) Grade;
(b) Agmark label no/Batch No;
(c) Name of packing station.

Manner of Packing and sealing the samples - All samples of food sent for analysis shall be packed , fastened and sealed in the following manner, namely :-

a) The stopper shall first be securely fastened so as to prevent leakage of the content in transit;
b) The bottle, jar or other container shall then be completely wrapped in fairly strong thick paper, The ends of the paper shall be neatly folded in and affixed by means of gum or other adhesive;
c) a paper slip of the size that goes round completely from the bottom to top of the container, bearing the signature and code and serial number of the Local (Health) Authority, shall be pasted on the wrapper ,the

signature or the thumb impression of the person from whom the sample has been taken being affixed in such a manner that the paper slip and the wrapper both carry a part of the signature or thumb impression:
Provided that in case, the person from whom the sample has been taken refuses to affix his signature or thumb impression, the signature or thumb impression of the witness shall be taken in the same manner.

d) The paper cover shall be further secured by means of strong twine or thread both above and across the bottle, jar or other container, and the twine or thread shall then be fastened on the paper cover by means of sealing wax on which there shall be at least four distinct and clear impressions of the seal of the sender, of which one shall be at top of the packet, one at the bottom and the other two on the body of the packet. The knots of the twine or thread shall be covered by means of sealing wax bearing the impression of the seal of the sender.

Manner of despatching of containers of samples :- The containers of the sample shall be despatched in the following manner, namely:-

a) The sealed container of one part of the sample for analysis and a memorandum in Form VII shall be sent in a sealed packet to the public analyst immediately but not later than the succeeding working day by any suitable means:
b) The sealed containers of the remaining two parts of the sample and tow copies of the memorandum in Form VII shall be sent in a sealed packet to the Local (Health) Authority immediately but not later than the succeeding working day by any suitable means:
c) The sealed container of one of the remaining two parts of the sample and a copy of the memorandum in Form VII kept with the local (Health) Authority shall within a period of 7 days be sent to the Public Analyst on requisition made by him to it by any suitable means.

Provided that in the case of food which has been taken from container bearing Agmark seal, the memorandum in Form VII shall contain the following additional information, namely:-

a) Grade;
b) Agmark label No /Batch No:
c) Name of packing station

Memorandum and impression of seal to be sent separately:-

A copy of the memorandum and specimen impression of the seal used to seal the packet shall be sent, in a sealed packet separately to the Public Analyst by any suitable means immediately but not later than the succeeding working day.

Addition of preservatives to sample

Any person taking a sample of any food for the purpose of analysis under the Act may add a preservative as may be prescribed from time to time to the sample for the purpose of maintaining it in a condition suitable for analysis.

Preservative in respect of milk, cream, dahi, khoa or khoa based and paneer based sweets, such as Kalakand and Burfi, Chutney and prepared foods Gur, Coffee and Tea -- The preservative used in the case of samples of any milk including toned, separated and skimmed milk , standardised milk chhanna, skimmed milk chhanna , cream , ice candy, dahi khoa or khoa based and Paneer based sweets, such as Kalakand and Burfi, Chutney and prepared foods Gur, Coffee and Tea in liquid of semi-liquid form shall be the liquid commonly known as "formalin" that is to say, a liquid containing about 40 per cent of formaldehyde in aqueous solution in the proportion of 0.1ml. (two drops) for 25ml. Or 25 grams.

Provided that in case of samples of ice cream and mixed ice cream, the preservative used shall be the liquid commonly known as formalin, that is to say a liquid containing about 40 per cent of formaldehyde in aqueous solution in the proportion of 0.6ml.for 100ml. or 100 grams.

Nature and quantity of the preservative to be noted on the label—Whenever any preservative is added to a sample, the nature and quantity of the preservative is added shall be clearly noted on the label to be affixed to the container.

Part vi – colouring matter

Unauthorised addition of colouring matter prohibited

The addition of a colouring matter to any article of food except as specifically permitted by these rules, is prohibited.

Extraneous addition of colouring matter to be mentioned on the label
Where an extraneous colouring matter has been added to an article of food, there shall be displayed one of the following statements in capital letters, just beneath the list of ingredients on the label attached to any package of food so coloured.

Part vii - packaging and labelling of foods
Package of food to carry a label - Every package of food shall carry label and unless otherwise provided in these rules, there shall be specified every label:-

(a) the name trade name or description of food contained in the package, Provided that the name, trade name or the description of food given on the package of food shall not include the name of any food or ingredient prefixed or suffixed to it, if such food ingredient is not the main ingredient of the final food product.
(b) The names of ingredients used in the product in descending order their composition by weight or volume as the case may be.

Provided that in the case of artificial flavouring substances, the label may not declare the chemical names of the flavours, but in the case of natural flavouring substances or nature-identical falvouring substances, the common name of flavours shall be mentioned on the label.
Provided also that whenever Gelatine is used as an ingredient, a declaration to this effect shall be made on the label by inserting the word " Gelatine-Animal Origin."

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.

The present medical armamentarium consists of large number of botanicals, drugs, foods, cosmetics and devices and volumes of complex and variety of these products are being added to the market every day. With the advent of more complex chemical and biological entities, coupled with more sophisticated biological entities, the potential for adulteration increases. The primary means of controlling the incidence of adulteration is stringent quality control through strict adherence to Current Good Manufacturing Practices. An important component of Current Good Manufacturing Practice relating directly to the prevention of distribution of adulterated products involves the development of appropriate specifications. These specifications are the cornerstone for effectively testing finished dosage forms to assure that they are safe and meet the strength, quality, purity and identity characteristics they purport to posses.

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