DRUG REGULATORY AGENCIES IN USA:

MAIN BODIES:

- The Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Centres for Disease Control and Prevention (CDC)
- Department of Health and Human Services (DHHS)
- National Centre for Complementary and Alternative Medicine (NCCAM)
- National Centre for Infectious Diseases (NCID)
- National Library of Medicine National Science Foundation Office of Disease Prevention (NLM).

USFDA

- The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services.
- It consists of six product centres, one research centre, and two offices.
- FDA's responsibilities extend to the 50 United States

FDA Organizational chart:

states that the FDA has 4roles:

a) To promote health by reviewing research and approving new products.
b) To ensure foods and drugs are safe and properly labelled.
c) To work with other nations to "reduce the burden of regulation".
d) To cooperate with scientific experts and consumers to effectively carry out these obligations.

FDA Organizational chart:

Department of Health and Services

- ❑ Office of the Commissioner
- ❑ Office of Operations
  - Office of the Equal Employment Opportunity
  - Office of Human Resources
  - Office of Finance, Budget and Acquisition
  - Office of Information Management and Technology
  - Office of Security Operations
  - Office of Facilities Engineering and Mission Support Services
- ❑ Office of Planning, Legistration and Analysis
- ❑ Office of Medical Products and Tobacco

- Center for Biologics Evaluation and Research(CBER)
- Center for Devices and Radiological Health(CDRH)
- Center for Drug Evaluation and Research(CDER)
- Oncology Center of Excellence(OCE)
- Center for Tobacco Products(CTP)
- Center of Veterinary Medicine(CVM)
- Center for Food Safety and Applied Nutrition(CFSAN)
- Office of Global Regulatory Operations and Policy
- National Center for Toxicological Research(NCTR)

CBER:

- Center for Devices and Radiological Health is responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance, and safety of these devices.
- The CDRH also oversees the radiation safety performance of non-medical devices which emit certain types of electromagnetic radiation such as cellular phones and microwave ovens.

CDER:

- Center for Drug Evaluation and Research will monitors most drugs in the Food, Drug and Cosmetic Act.
- Some biological products are also legally considered drugs but they are covered by the CBER.

CTP:

- Center for Tobacco Products.
- It is the FDA center is responsible for the implementation of the Family Smoking Prevention and Tobacco Control Act.

CVM:

- Center of Veterinary Medicine.
- It regulates the manufacture and distribution of food, food additives and drugs that will be given to animals.

CFSAN:

- It regulates the Food, Dietary supplements and Cosmetics.
- Center for Food Safety and Applied Nutrition.

RESPONSIBILITES:

- The FDA is led by the Commissioner of Food and Drugs, who is appointed by the President and confirmed by the Senate.
- FDA is responsible for Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labelled; Assuring human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labelled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated

DRUG REGULATORY AGENCIES IN EUROPE:

1.EDQM:

- (EUROPIAN DIRECTORATE FOR THE QUALITY OF MEDICINES AND HEALTHCARE). It is established in 1996.
- But the base of EDQM is established in 1964 with the convection on the elaboration of European pharmacopoeia signed by 8 member states.
- It involves,
  - Harmonization and co-ordination of standardization,
  - regulation and quality control of medicines (1991-1992).
  - Blood transfusion and organ transplantation activities (2006)

  Pharmaceuticals and pharmaceutical care (2008)

  At present, in 2011, ISO 9001:2008 certificate was extended to:

• The market surveillance of finished medicinal products.
Issuance of guidelines for the release of human immunological and blood derivative medicinal products.

2.EMEA:

- (EUROPEAN MEDICINES EVALUATION AGENCIES)
- It is established in 1995 at London.
- It was formed to co-ordinate the processing of European Union (EU) license application.
- It is a part of EU commission and co-ordinates scientific resources of the member state for evaluation, supervision and pharmacovigilance of medicinal products for both human and veterinary throughout the EU.

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EMA (EUROPEAN MEDICINES AGENCIES)

- EMA is a European agency for the evaluation of medicinal product. EMA was set up in 1995.
- From 1995 to 2004, EMA was known as European agency for the evaluation of medicinal product.
- The European Medicines Agency (EMA) is a decentralized body of the European Union, located in London Mission: to foster scientific excellence in evaluation and supervision of medicines

ACTIVITIES OF EMA:

- Science-based recommendations on the quality.
- Safety and efficacy of medicines.
- Applies efficient and transparent evaluation procedures to help bring new medicines to the market.
- Implements measures for continuously supervising the quality, safety and efficacy of authorised medicines.
- Provides scientific advice to stimulate the development and improve the availability of innovative new medicines.
- Recommend safe limits for residues of veterinary medicines used in food-producing animals.

- Publishes impartial and comprehensible information about medicines and their use.
- Develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level European Directorate for the Quality of Medicines & Health Care the EDQM (Council of Europe) is a key European Organisation involved in Harmonisation & Co-ordination of Standardisation. Regulation & Quality Control of Medicines.
- Blood Transfusion.
- Organ Transplantation.
- Pharmaceuticals and Pharmaceutical Care.

DRUG REGULATORY AGENCIES IN JAPAN:

MHLW:

- The Ministry of Health, Labour, and Welfare (MHLW) was established by a merger of the Ministry of Health and Welfare (MHW) and the Ministry of Labour, on January 6, 2001.
- The MHLW, which was originally established in 1938, has been in charge of the improvement and promotion of social welfare, social security and public health and the new organization has the same tasks.
- It consists of the ministry proper, affiliated institutions, councils, local branches, and an external organization.
- MHLW Social insurance agency Ministry proper Minister's secretariat Heath policy bureau Heath service bureau PFSB Social welfare & war victim's relief bureau Health and welfare bureau for elderly Equal employment children & family bureau Insurance bureau Pension bureau Director general for policy planning

ORGANIZATION:

Ministry proper
- Minister's Secretariat
- 11 bureaus
- Director General for Policy Planning and Evaluation.

Councils
- Social Insurance Council
- Pharmaceutical Affairs
- Food Sanitation Council(PAFSC)

Affiliated Institution
- National hospitals
- The National Institute of Health Sciences.

Local Branches
- Regional Bureaus of health
- Welfare and prefectural labour bureaus.

External organization
- Social Insurance Agency
- The Central Labour Relations Commission

FUNCTIONS OF MHLW:

PUBLIC HYGIENE

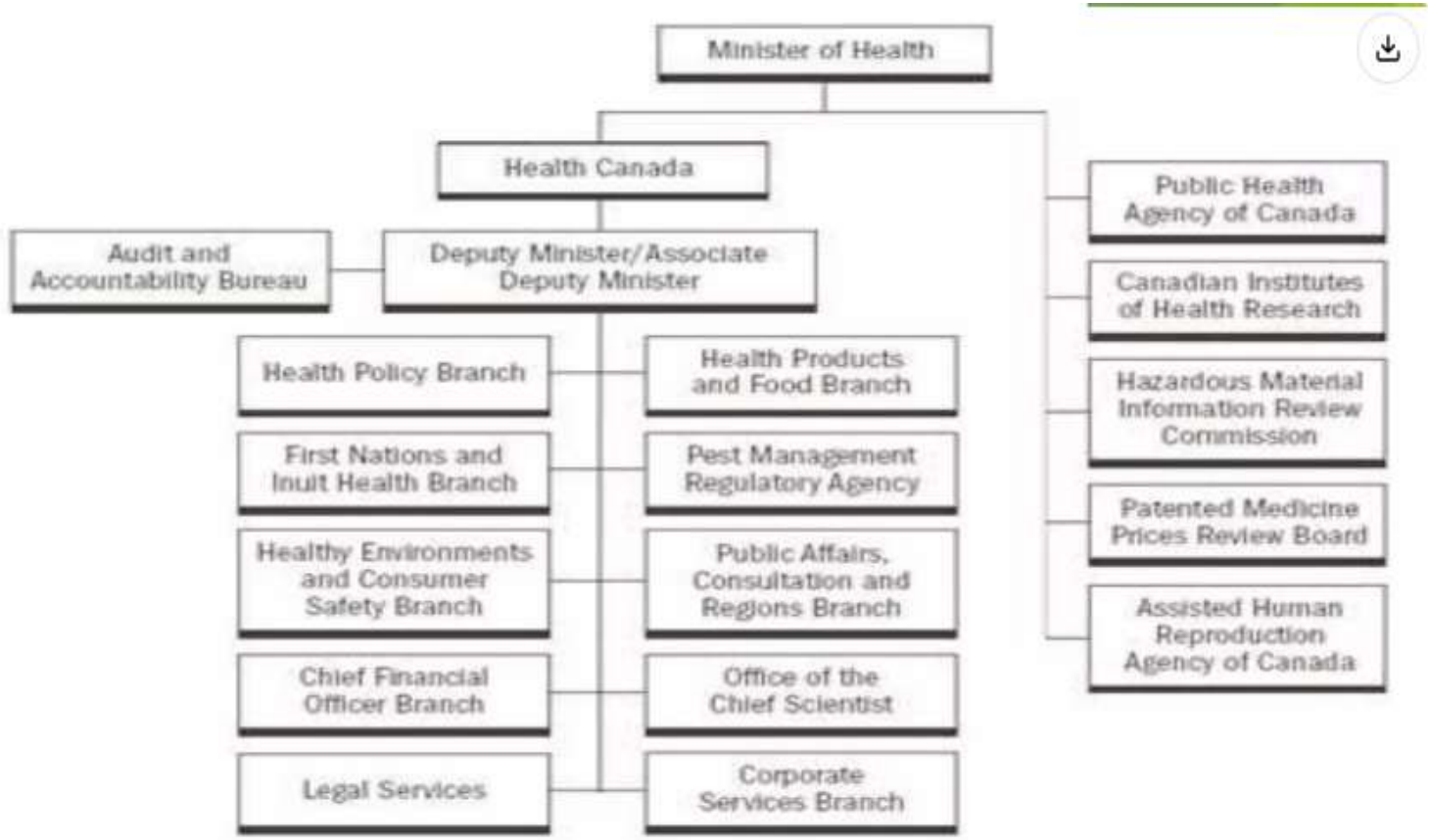
- Appropriate medical services for diseases & injuries ensuring the safety of food, Water and medical supplies.
- Research into health science in order to make technological Advances Maternal and child health

JOB SECURITY

- Services for persons with disabilities Social Security.
- Pension systems.
- Long term insurance to provide nursing care services.
- Public assistance systems that guarantee minimum standards.
- Management of the employment.
- Insurance system in Human Resources Development:
- Promotion of human resources development that reacts to changes in the industrial system.
- Encouragement of worker's skill development under their own initiative.
- Development of skilled human resources that support industrial progress.

HEALTH CANADA (HPFB)

- Drugs are authorized for sale in Canada once they have successfully gone through the drug review process. This process is the means by which a drug application is reviewed by scientists in the health products and food branch (HPFB) of Health Canada, and on occasion, outside experts, to assess the safety , efficacy, and quality of a drug.
- Throughout this process, the safety and well-being of Canadians is the paramount concern.
- Health Canada's HPFB is the national authority that regulates, evaluates, and monitors the safety, efficacy and quality of therapeutic and diagnostic products available to Canadians. These products include drugs, disinfectants and sanitizers with disinfectant claims.
- Head quarters of this Health Canada is at Ottawa, Ontario, Canada.



Health Canada also contributes grants and contributions to several health organizations such as Infoway, Canadian Institute for Health Information and Canadian Health Services Research Foundations.

Regulatory process for drug in Canada

- The exhibit shows the steps in the regulatory process for drugs in Canada, from pre market to post market. The pre-market part of the process starts with pre-clinical studies. The steps are:
- Pre-clinical studies.
- Clinical trails.
- Regulatory product submission.
- Submission review.
- Market authorization decision.
- Public access.
- Surveillance, inspection, and investigation.
- The post-market part of the process begins with the surveillance, inspection, and investigation when a drug has been made accessible to public.