Fmhaca Guidelines

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Food, Medicine and Healthcare Administration and Control ...
Authority of Ethiopia (FMHACA) Guidelines for Registration of Biotherapeutic Protein Products Prepared by Recombinant DNA Technology February 2018 Addis Ababa, Ethiopia 2 This guideline is adapted from Guidelines on the quality, safety and efficacy of biotherapeutic
Food, Medicine and Healthcare Administration and Control ...
Authority of Ethiopia (FMHACA) Guidelines for Registration of Vaccines February, 2018 Addis Ababa, Ethiopia 1 This guideline is adapted from Guidance Document Harmonized Requirements for the Licensing of Vaccines and Guidelines for the Preparation of an Application, Health Canada, 2016 2
Food, Medicine and Healthcare Administration and Control ...
Authority of Ethiopia (FMHACA) Guidelines for Registration of Similar Biotherapeutic Products (SBPs) February 2018 Addis Ababa, Ethiopia i This guideline is adapted from Guidelines on evaluation of similar biotherapeutic products (SBPs), Annex 2, WHO Technical Report Series No …
Ethiopia Food and Agricultural Import Regulations and ...
GUIDELINES FOR IMPORT AND EXPORT OF ANIMAL AND ANIMAL GENETIC MATERIALpdf In coordination with FMHACA and MoALR, the Ethiopian Standards Agency (ESA) develops the national food safety standards, some of which are mandatory while others are voluntary FMHACA and
GUIDELINE FOR REGISTRATION OF MEDICAL DEVICES
Guideline for Registration of Medical Devices 1 INTRODUCTION The Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia was established to safeguard the health and safety of patients, users, and other persons
Food, Medicine and Healthcare Administration and Control ...
Food, Medicine and Healthcare Administration and Control Authority of Ethiopia Third Edition, 2014 Standard Treatment Guidelines for Primary

Hospital Good Prescribing & Dispensing Practices for Better Health Outcomes Diseases Clinical features Investigations Treatment Referrals

GUIDELINE FOR REGISTRATION OF MEDICINES

Guideline for Registration of Medicines iii ACKNOWLEDGEMENT The Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA) would like to acknowledge and express its appreciation of the United States Agency for International Development (USAID) and the U S Pharmacopeial Convention

Ethiopia

Guidelines (Sept 2014), p 34-38 Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data

Food Standards, Food Law and Regulation System in Ethiopia ...

Food Standards, Food Law and Regulation System in Ethiopia: A Review guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose Product standards (FMHACA, 2009) As a result, giving attention to ensure quality and safety does not plays a significant

Guideline for Registration of Medical Devices

Guidelines for Registration of Medical Devices (revised April 12, 2006) Chapter 1 General Principles Article 1 These Guidelines are formulated in accordance with the regulations of Article 40, Paragraph 3 of the Pharmaceutical Affairs Act (herein referred to as this Act)

Initiatives ü CHAPTER 3 ü - Food Fortification Initiative

FMHACA Draft Fortified oil manufacturer, importer, exporter and wholesaler directive FMHACA Draft Fortified oil standard FMHACA Draft Fortified flour standard FMHACA Draft Infant formula directive FMHACA Draft Food supplement directive FMHACA Draft Food, Medicine and Health Care Administration and Control Proclamation Government of Ethiopia 2009

Ethiopia’s Food, Medicine and Health Care Administration ...

FMHACA Director General Ethiopia’s Food, Medicine and Health Care Administration and Control Authority: Protecting the Public Health Hailu Tadeg The absence of regulatory systems to monitor the quality, safety, and efficacy of medicines can compromise the overall effectiveness of health care services and endanger the public health

Good Manufacturing Practices (GMP) for Medicinal Products

3 Good Manufacturing Practices (GMP) guidelines GMP is a production and testing practice that helps to ensure a quality product Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures, and have created their own GM P guidelines that correspond with their legislation

ETHIOPIAN HOSPITAL SERVICES TRANSFORMATION ...

Guidelines (EHRIG), which built on both the Business Process Reengineering (BPR) and Hospital Blueprint efforts, as well as the Masters in Hospital and Healthcare Administration (MHA) degree program Subsequently the , country FMHACA Food, Medicine and …

Guidelines for Compounding Practices

Guidelines for Compounding Practices 3 Regulatory Framework In general, professions such as medicine and pharmacy are established as legal entities within a state by the professional practice acts of each state that are enacted by the state lawmakers (legislature) Once a profession is established, the state legislatures make laws to govern its

MEDICO-LEGAL GUIDELINES

Guidelines to incorporate HIPAA privacy regulations and update other cited authorities In 2008, Medico-Legal Guidelines were revised to include information concerning appropriate handling of mental health, substance abuse, and psychotherapy records In 2014, the Medico-Legal Guidelines were revised again to reflect changes in ap-

Ethiopia

Nomenclature system name: — Web site: wwwfmhacagovet Medical device incorporation procurement Policy or guideline: Yes Web site: wwwfmohgovet National level procurement: Yes Web site: — Donations Policy or guideline: Yes Web site:wwwfmhacagovet technical specifications Technical specifications to support procurement or donations: Yes,

Establishment of Medicines Waste Management and Disposal ...

Establishment of Medicines Waste Management and Disposal System in Ethiopia: a Report on Progresses and Achievements vi The stakeholders who participated in all events pointed out that the issuance of the directive is timely, given the existing challenges and promised to contribute towards its proper execution

International Ethical Guidelines for Health-related ...

1982 Guidelines, and CIOMS, with the collaboration of WHO and its Global Programme on AIDS, undertook the task The outcome was the issue of two sets of guidelines: International Guidelines for Ethical Review of Epidemiological Studies in 1991, and International Ethical Guidelines for Biomedical Research Involving Human Subjects in 1993

ETHIOPIAN ES 3611:2012 Secretariat STANDARD

(FMHACA) A Health center shall provide services in accordance with this standard and shall The latest editions of the following laws, regulations, directives and guidelines shall be taken as part and parcel of this Ethiopian Standard 21 Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No 661/2009 22