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Briefing
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Amendment to the Drugs Act 2035 (1978 AD)

Introduction

The Government of Nepal ("GON") recently amended Drugs Act 2035 (1978 AD) ("Drugs Act") through Drugs (Third Amendment) Ordinance 2077 (2020 AD) ("Amendment"). The Amendment authorizes the Department of Drugs Administration ("Department") – the regulatory authority for drugs and pharmaceutical products, to register drugs and vaccines for their emergency usage and to mandate approval requirements from the Department before conducting clinical trials of a new drug or vaccine.

Provisions introduced by the Amendment, in detail, are discussed below:

Registration of Drugs or Vaccines for Emergency Usages

Section 9(A) authorizes the Department, at the recommendation of the Drugs Advisory Committee, to register a drug or vaccine for its emergency use in Nepal in order to prevent, control, or mitigate communicable disease leading to an epidemic. Such drug or vaccine must be listed with the World Health Organization ("WHO") or registered with or granted approval for emergency use by the regulatory authority of the relevant jurisdiction.

The Department shall provide recommendations for import of drugs or vaccines registered for emergency use in Nepal. The quantity of import of a registered drug or vaccine or other conditions relating to its usage, sale or distribution shall be as specified by the Department.

In the event, drug or vaccine imported, used or sold in Nepal in accordance to Section 9 (A) causes any adverse effect to users, or its use has been prevented by WHO or by the country where it is registered or approved for emergency usage, the Department has the authority to cancel the registration of such drug or vaccine.

A drug must be registered with the Department prior to its sale or distribution in Nepal. It applies to all drugs manufactured by an industry licensed in Nepal and those manufactured by a foreign manufacturer which are imported into Nepal. Vaccine Act 2072 (2016 AD) ("Vaccine Act") and Vaccine Regulation 2074 (2018 AD) ("Vaccine Regulations"), which regulate administration of vaccines, do not prescribe registration requirements for a vaccine. Nonetheless, a vaccine must fulfill the standard provided by Vaccine Act and Vaccine Regulations such as, prequalification from WHO, prior use in the country of manufacture or in other countries, presence of vaccine vial monitor, etc.

Registration of drugs at the Department is a lengthy procedure requiring an applicant to submit various documents such as product specification, lab report, certification from the regulatory body of relevant jurisdiction (if applicable), pharmacopeia standards, etc. The Amendment, promulgated at the time of current Coronavirus pandemic, seeks to eliminate the conventional lengthy registration requirements during the epidemic.

Provisions Regarding Clinical Trial

Section 31 of Drugs Act prescribes requirements for obtaining prior approval from the Department in order to conduct clinical trials of a new drug or vaccine. A 'clinical trial' is defined as a process of examining a new drug or vaccine by administering it to patients at approved hospitals or to other persons with their consent in order to determine whether or not such drug or vaccine is safe for its general use.

GON has the discretion to permit clinical trials of a vaccine which has been approved for clinical trials in foreign countries in the event its manufacturer wishes to conduct clinical trials in Nepal as well. GON may prescribe other provision relating to clinical trials.

Prior to the Amendment, Drugs Act prescribed clinical trials of drugs only. The Amendment, however, requires approval for clinical trials for both vaccines and drugs.

Nepal Health Research Council ("NHRC") is the apical body responsible for ensuring ethical standards and quality in health research. At present, National Guidelines on Clinical Trials with the Use of Pharmaceutical Products 2005 and the National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedures 2011, issued by NHRC, governs the aspect of clinical trials in Nepal.

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