Press Release

Brussels (Belgium), 4 November 2021

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of a new International Pharmaceutical Excipient Council Safety Guide for Pharmaceutical Excipients. This guide is applicable globally.

Building off of articles published by both IPEC-Americas (A New Approach to the Safety Assessment of Pharmaceutical Excipients) and IPEC Europe (The Proposed Guidelines for the Safety Evaluation of New Excipients) in 1996 and 1997, respectively, the IPEC Safety Guide has been designed to give an overview on recommended toxicological studies for different therapeutic applications, routes of administration and treatment periods. Toxicological safety studies described in this guide are intended for consideration by excipient manufacturers who market excipients for use in drug formulations and excipient users who conduct toxicology studies required for the initial approval of a novel excipient in a drug formulation. Excipient users formulating an excipient beyond its approved, prior use are responsible for conducting the appropriate safety studies.

Proposals to test or market new drug products should adequately address the safety of the proposed exposure to the excipients in those products. The specific safety data can vary depending on the clinical situation, including such factors as the duration, level and route of exposure. In addition, considerations should take into account acute, repeat-dose, reproductive and genetic toxicity data, carcinogenicity data and specialized toxicology information such as sensitization or local irritation data. Although many regional and ICH Guidances currently exist to aid in the development of pharmaceuticals, with the exception of the US FDA Guidance Document Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients (May 2005), guidance documents defining development of safety profiles to support use of novel excipients as components of drug or biological products are limited.

At the time of publication of this guide, with the exception of a pilot program for novel excipients review recently introduced by the US FDA, there is no independent review of novel excipients and this guide is intended to provide information to assist in determining the level of safety information necessary to support the use of a novel excipient, taking into account that depending on the type of novel excipient, different levels of safety information may be required.

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium
W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org
VAT: BE 08239313 61 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region

The Guide includes several clinical therapeutic areas for novel excipients based on intended use in special patient populations when specific considerations are required to assess potential excipient safety concerns such as: pediatric safety, endocrine activity, nano character and biological occurrence. In addition, several recent New Approach Methods (NAMs) are discussed to introduce the global emergence of alternative in silico and in vitro methods to complement traditional in vivo approaches. These approaches are being used to employ a Weight-of-Evidence (WoE) approach to demonstrate the safety of novel excipients consistent with the growing regulatory commitment to reduce animal testing in safety assessments.

The guide will be available, initially exclusively to IPEC members for a three-month period, on the IPEC Federation and national/regional members' websites. Thereafter, the guide will be made available to the general public.

For further information contact the IPEC Federation Secretariat at:

+32 2 213 74 40 / info@ipec-federation.org

IPEC Federation asbl
The Federation of the International Pharmaceutical Excipients Council
Rue Marie de Bourgogne 52 – 1000 Brussels
T: +32 2 213 74 40