15 DECEMBER 2015

PROPOSED HEALTH PRODUCTS (CLINICAL TRIALS) REGULATIONS 2015

CONSULTATION PERIOD: 15 December 2015 to 15 January 2016

INTRODUCTION

1. HSA currently regulates the conduct of clinical trials on medicinal products, primarily through the granting of clinical trial certificates, monitoring of adverse events and conducting Good Clinical Practice (GCP)[1] inspections.

2. The primary purpose of the regulations is to put in place the requirement to conduct all clinical trials in accordance with internationally recognised principles of GCP. This is to ensure that participants' safety, rights and interests are adequately protected.

3. A review of the clinical trials regulatory framework was undertaken in conjunction with the initiative to consolidate the existing controls for regulating western pharmaceuticals (to be re-defined as therapeutic products) into the Health Products Act.

4. The proposed regulatory controls for clinical trials on therapeutic products remain largely similar to the current controls under the Medicines Act and regulations, which are fundamentally aligned to internationally-accepted standards and best practices. The existing regulations under the Medicines Act will also be updated as it will continue to be used for clinical trials on medicinal products other than western pharmaceuticals.

[1] *Good Clinical Practice (GCP) is an internationally-accepted ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, and that clinical trial data are credible.*

5. The proposed changes are a result of judicious consideration of international trends and developments spearheaded by regulatory counterparts in other developed countries, as well as major international bodies[2]. These changes aim to enhance transparency of clinical research and to support more efficient global clinical development without compromising on health and safety of research subjects.

6. The regulations have also been updated to strengthen existing legal provisions to reflect current practice in accordance to GCP, enhance trial coordination and communication, and streamline administrative requirements. In the course of formulating these proposed changes, feedback has been obtained from the pharmaceutical and clinical research industry, local healthcare professionals, and hospital's institutional review boards.

SUMMARY OF CHANGES

7. The key changes to the clinical trials regulation include the following:

a) <u>Introduction of a Risk-based Regulatory Framework</u>

A risk-based approach to clinical trial regulation has been proposed to improve overall resource efficiency while continuing to ensure participants' safety.

This will involve the introduction of a dual-submission-track Clinical Trial Authorisation (CTA) – Clinical Trial Notification (CTN) system, in which the extent of pre-trial regulatory review will be stratified according to the local registration status of the investigational therapeutic product used in the clinical trial. The CTA will be similar to the existing CTC system in regard to the regulatory review process. On the other hand, the CTN system is intended for trials using an approved drug in accordance with

[2] *This includes the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), the United Kingdom Medicines and Healthcare Products Regulatory Agency (MRHA), the World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).*

its approved label. As the product would already have been reviewed by HSA prior to its marketing approval, the use of the registered drug in the clinical trial is therefore deemed to be of no greater risk than when used in standard medical practice.

Additionally, observational clinical trials will be excluded from the new regulatory controls as the treatment prescribed in these studies is expected to be in accordance with standard medical practice.

b) Strengthening of Legal Obligations on Sponsors and Clarification of Legal Responsibilities of Investigators

The current regulations focus on the role and responsibilities of the principal investigator, and indirectly advocate compliance with GCP by investigators and sponsors.

The revised regulations will be strengthened with the direct incorporation of the principles of GCP into regulations. In addition, the role and responsibilities of sponsors will be more clearly prescribed in the regulations to reflect both sponsor and principal investigator responsibilities in accordance with GCP.

c) Clarification of Safeguards and Consent Requirements for Vulnerable Populations

The safeguards and consent requirements for this vulnerable subject population remain largely unchanged, except for clarifications to reflect the definition of legal representative defined under other applicable local legislation such as the Mental Capacity Act (MCA), and for such clinical trials to be conducted in accordance to conditions specified in other international regulatory positions and ethical standards including the Declaration of Helsinki and GCP.

d) Clinical Trials Register

Whilst information about local clinical trials is already accessible in publicly-accessible register on the HSA website, a new provision has been proposed to prescribe the publication of more detailed information on clinical trials.

This initiative is in line with the current global approach to improve public availability of information about clinical trials, which will enhance transparency and may facilitate patient enrolment.

e) Refinement of Labelling Requirements

In consideration of stakeholders' feedback, technological advances in the management of investigational products, and to facilitate multi-regional clinical trials, labelling elements have been refined to align with international requirements. There will also be a measured degree of flexibility in allowing for alternative approaches to traditional labelling requirements, provided key principles of labelling are not compromised.

HEALTH SCIENCES AUTHORITY