REGISTRATION OF MEDICINAL PRODUCTS IN SINGAPORE: NEW TECHNICAL REQUIREMENTS FROM 1 APRIL 2004

Since the formation of the Health Sciences Authority (HSA) in April 2001, HSA has been actively reviewing Singapore's regulatory processes and technical requirements for registration of medicinal products in Singapore. This is to ensure that our requirements are scientifically robust and in line with international best practices. At the same time, refinements are appropriately adapted to ensure that the requirements are not unnecessarily onerous and are scientifically justified.

With effect from 1 April 2004, medicinal product applications submitted to HSA are required to comply with the following new requirements to enhance the quality, safety and efficacy of medicinal products approved for sale in Singapore.

(1) Requirement for Bioequivalence Study Data

Applications to register generic prescription medicines in solid oral dosage forms are required to be supported by Bioequivalence Study Data to demonstrate that the products are therapeutically equivalent to the reference product. The bioequivalence studies must be conducted in accordance with internationally acceptable guidelines. Other types of data, such as Dissolution Test Data, may be submitted for HSA's consideration if the data has been scientifically proven to be an acceptable substitute for Bioequivalence Study Data.

(2) Requirement for On-site GMP Audit of Overseas Manufacturers

This requirement is applicable to new overseas manufacturers that have not been previously audited by the competent authorities of the US, Japan and member authorities of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S). Member authorities of the PIC/S include major countries in the European Union, Switzerland, Canada, Australia, Malaysia and Singapore.

This new requirement will ensure that all medicinal products registered in Singapore have been manufactured in accordance with the appropriate standards of Good Manufacturing Practice (GMP).

(3) Requirement for Additional Information on Active Ingredients and Excipients

In line with the requirements contained in the International Conference for Harmonization (ICH) Technical Document and the ASEAN Common Technical Document (ACTD), additional information related to the quality of active ingredient(s) and the control of excipients are now required to be submitted. The core information required would include the source and stability data of the active ingredient(s); specifications and analytical procedures for all ingredients used.

The above new requirements are presently being implemented for new product applications submitted to HSA from 1 April 2004. For the existing approved products, these requirements will be imposed on a case-by-case basis, when there are reasons for HSA to be concerned about the standards of safety, efficacy and quality of the product.

The pharmaceutical companies have been kept abreast of the additional requirements prior to its implementation.

For further information or inputs and suggestions, kindly contact the following officers from CDA's Drug Registration Branch:
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