SCHEDULES

SCHEDULE 10

National homoeopathic products

Requirement to submit safety data

3.—(1) The applicant must submit data as to the safety of the product unless paragraph 4 applies.

(2) The data must include information about the following aspects of the safety of the product—

(a) pharmacology;

(b) pharmacokinetics; and

(c) toxicology, including its toxicity, genotoxicity, reproductive and developmental toxicity and local tolerance.

(3) The data must be scientific data unless sub-paragraph (5) applies.

(4) For this purpose "scientific data" means—

(a) study reports in relation to the product;

(b) published scientific data; or

(c) a combination of data within paragraph (a) and data within paragraph (b).

(5) The applicant may submit other data in relation to an aspect of the safety of the product if having made reasonable attempts to obtain scientific data in relation to that aspect—

(a) the applicant is satisfied that no such scientific data is available; or

(b) the applicant thinks that such scientific data as is available may be inadequate to demonstrate an acceptable level of safety in relation to that aspect.

(6) The applicant must include with the data—

(a) a table of contents; and

(b) an evaluation of the scientific data, including an explanation of how it demonstrates an acceptable level of safety.

(7) If the applicant submits data other than scientific data, the applicant must include—

(a) a statement that sub-paragraph (5) applies; and

(b) an explanation of why an acceptable level of safety can be demonstrated despite the lack of scientific data.

Status:
Point in time view as at 31/03/2014.

Changes to legislation:
The Human Medicines Regulations 2012, Paragraph 3 is up to date with all changes known to be in force on or before 18 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.