Proposed Rules for Minister's consent by Verification made pursuant to section 22E of the Medicines Act 1981 – draft for consultation

Pursuant to section 22E of the Medicines Act 1981 (the Act), the Minister of Health has made the following rules in relation to applications to the Director-General of Health for the Minister's consent by verification under section 22C of the Act.

The Rules are administered by the Ministry of Health.

The Rules are secondary legislation for the purposes of the Legislation Act 2019.

Dated this [date].

The Rules commence on [date]

Definitions:

Primary marketing authorisation: the authorisation, approval, or consent of a medicine from one recognised regulatory authority for the purposes of section 22D(b)(i) of the Act. The primary marketing authorisation is relied on for all dossier information.

Secondary marketing authorisation: the authorisation, approval, or consent of a medicine from one recognised regulatory authority for the purposes of section 22D(1)(b)(i) of the Act.

Primary recognised regulatory authority: the recognised regulatory authority, (section 22B of the Act) that issued the primary marketing authorisation.

Secondary recognised regulatory authority: the recognised regulatory authority, (section 22B of the Act) that issued the secondary marketing authorisation.

Rules

1. For the purposes of section 22C(2) of the Act, the Director-General must decide within a period of 10 working days following receipt of the application and payment of the application validation fee whether the application for consent by verification complies with section 21(2) and these rules.

2. For the purposes of section 22D(4) of the Act, the Minister must make a decision on the application within 30 working days, which begins on the date the fee payable in respect of the application is paid.

3. For the purposes of section 22D(b)(i) and (ii) of the Act, the applicant must provide evidence of a marketing authorisations granted by two recognised regulatory authorities. The applicant must nominate one authorisation as the primary marketing authorisation. The recognised regulatory authority that issued the primary marketing authorisation will be considered the primary regulatory authority.

4. An application for consent by verification must contain, for each marketing authorisation:

    a. Appropriate evidence of each marketing authorisation, including any associated attachments, issued by the corresponding recognised regulatory authorities.
    b. Full assessment reports completed for each of the marketing authorisations by the corresponding recognised regulatory authority. These must include assessment reports for each dossier module and reports for each stage of evaluation for the marketing authorisations. All reports issued by the primary regulatory authority must be complete and unredacted.
    c. The full consolidated technical dossier as it was provided to and approved by the primary regulatory authority, in Common Technical Dossier (CTD) format.
    d. The full consolidated technical dossier as it was provided to and approved by the secondary regulatory authority, in CTD format, must be available on request.
    e. A list of all events and correspondence that occurred during the initial marketing authorisation application and any variations to each marketing authorisation since each marketing authorisation was first granted (a table of regulatory history).
    f. Appropriate evidence of approval of each variation to the marketing authorisation, listed in (e), issued by the primary recognised regulatory authority.
    g. Risk assessments conducted or completed after approval granted by the recognised regulatory authorities, and risk assessments that were not reviewed by those recognised regulatory authorities at the time of granting the marketing authorisation.
    h. Appropriate evidence of acceptable Good Manufacturing Practice for all manufacturing and testing sites.
    i. Information relevant to the medicine's suitability for supply in New Zealand, supplied in module 1 of a technical dossier in Common Technical Document (CTD) format.

5. For the purpose of section 22D(1)(b)(i) of the Act, the application must be made on the basis of marketing authorisations granted by each recognised authority no longer than [to be consulted on] before the date of application for consent by verification.

6. For the purpose of section 22D(5) of the Act, the applicant must respond to requests for information within 20 working days of the request being made.

7. For the purpose of 22D(1)(b)(v) of the Act, medicines that *require independent assessment by the Director-General to contextualise the benefit-risk profile of the medicine due to local disease epidemiology, public health considerations, or New Zealand specific health risks* include, but are not limited to:

    a. Fractionated plasma products and other medicines derived from blood.
    b. Medicines specifically indicated for use in children or pregnant people.
    c. Gene therapy medicines, including medicines using a genetic technology to create the dose form (e.g. viral vector), or where the mode of action involves modification of genetics or epigenetics.
    d. Personalised medicines that share the same manufacturing process but result in unique medicines designed for specific patients.

8. If the medicine is a generic or biosimilar prescription medicine, and any supporting bioequivalence or clinical studies use a reference product sourced from outside New Zealand, the application must include data that demonstrates the overseas reference product is identical to the respective New Zealand innovative medicine.

9. The application must include the therapeutic purpose(s) for which the medicine is intended, which must be identical to that of the medicine approved by both recognised regulatory authorities.