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Complementary medicinal products: Requirements for bibliographical evidence in connection with simplified authorisation procedures

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Complementary medicinal products with or without indication

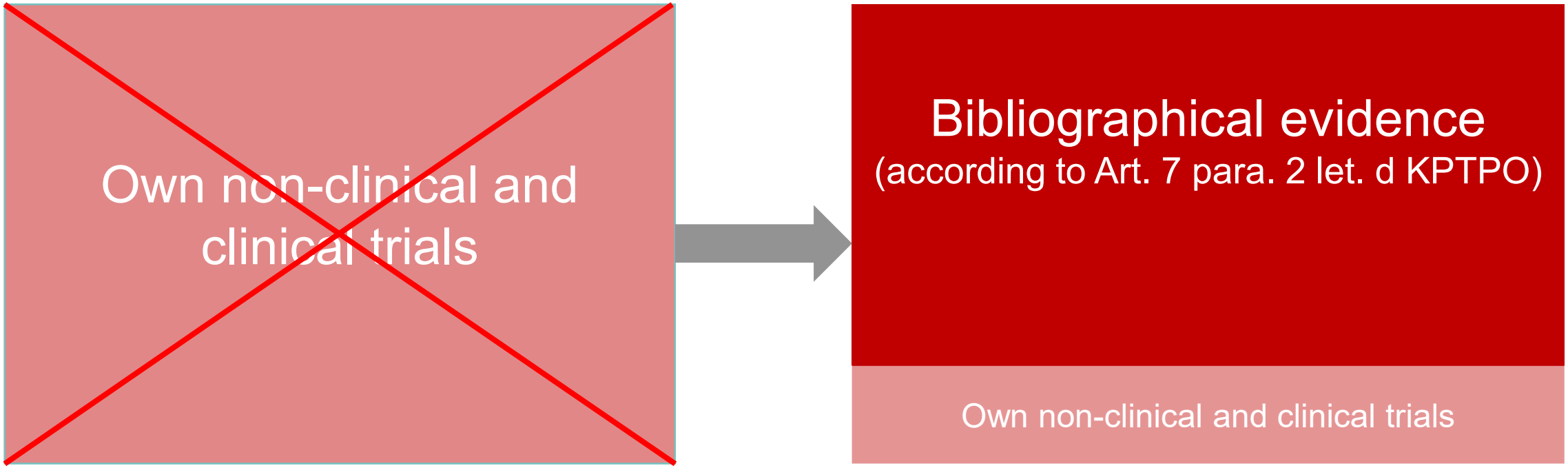
Chapter 4 KPTPO
Homeopathic medicinal products
Homeopathic spagyric medicinal products
Spagyric medicinal products
Anthroposophic medicinal products
Medicinal products for Schüssler therapy

Chapter 5 KPTPO
Chinese medicinal products (TCM)
Tibetan medicinal products
Ayurvedic medicinal products

Chapter 6 KPTPO
Medicinal products for gemmotherapy

Active substances, compositions, dosage forms, indications and dosage recommendations are derived from the **approach or therapeutic principle of the corresponding treatment**

Simplified authorisation procedure according to Art. 14 para. 1 let. b TPA



Requirements

- Reference to **published, independent** specialist literature such as pharmacopoeias, reference books or articles in specialist journals **covering the treatment in question**.
- The evidential value of this empirical documentation is dependent on the **quality, scope** and **transferability** of the information and the consistency of the statements that can be derived.
- Safety, harmlessness and tolerability aspects are in accordance with the current state of science and technology.

Requirements

- **Scientifically prepared documentation:** The overviews (Module 2.4 and 2.5) are structured, referenced and comprehensible. The conclusions drawn have been explored, discussed and evaluated in full.
- **Transferability:** Only references relating to the medicinal product to be authorised should be cited and submitted. The evidence must be transferable to the medicinal product to be authorised! Deviations must also be discussed and evaluated.
- **Scope:** Cite and submit references that contribute to the consistency of the available data. For example, if the same information is explained by different authors. Any inconsistencies must also be discussed and evaluated.

Further information

- https://www.swissmedic.ch/swissmedic/en/home/kpa.html

- ZL101_00_016e_WL Guidance document Authorisation of homeopathics, anthroposophics and other complementary medicinal products HMV4 (PDF, 431 kB, 01.05.2021)

- ZL101_00_009e_WL Guidance document Authorisation of Asian medicinal products HMV4 (PDF, 633 kB, 01.10.2021)