swissmedic
Swiss Agency for Therapeutic Products



The Way to the Cannabis Medication

Conference of the Swiss Task Force for Cannabinoids in Medicine (STCM)

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Introduction / Status

- **Switzerland:**
  - currently no authorised medicinal product (by Swissmedic) containing „cannabis“
- **other countries:**
  - authorised medicinal products with Dronabinol ([-]-trans-Δ^9-THC)
  - authorised medicinal products with cannabis-extracts (from leaves and flowers of *cannabis sativa* L.)
- **in general**
  - authorisation of medicinal products containing „cannabis“ is possible in Switzerland

authorised medicines abroad
e.g. Marinol®

US labeling excerpt

- **active ingredient**
  - synthetic delta-9-tetrahydrocannabinol
- **dosage form**
  - capsules for oral administration
- **indication**
  - anorexia associated with weight loss in patients with AIDS
  - nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments
- **dosage**
  - dosage individualization is critical, due to considerable interpatient variability.

authorised medicines abroad
e.g. Sativex®

UK labeling excerpt

- **active ingredients**
  - two soft extracts from Cannabis sativa leaf and flower corresp. to 61-71% delta-9-tetrahydrocannabinol and 60-71% cannabidiol.
- **dosage form**
  - Oromucosal spray
- **indication**
  - symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy
- **dosage**
  - titration period is required to reach optimal dose

Switzerland: Legal Situation I

enacted by swiss government / commencement date: July 1st 2011

Ordinance on the Control of Narcotics of May 25th 2011

Verordnung über die Betäubungsmittelkontrolle vom 25. Mai 2011 (Betäubungsmittelkontrollverordnung, BetmKV)

⇨ **application for marketing authorisation for a medicinal product containing preparations made of *Cannabis sativa* L. is possible**

Switzerland: Legal Situation II

Federal Act on Medicinal Products and Medical Devices (TPA)

- **according to Art. 10: any person applying for a marketing authorisation for a medicinal product or procedure must**
  - prove that the medicinal product or procedure is of high quality and is safe and effective;
  - be a holder of an authorisation to manufacture, import or conduct wholesale trade issued by the competent authority;
  - have a registered address, registered office or a branch office in Switzerland.
- **according to Art 9: exempt from authorisation are**
  - medicinal products prepared according to a doctor's prescription by a public pharmacy or a hospital pharmacy, or under mandate to the latter by another establishment holding a manufacturing authorisation, and for a given person or group of persons (magistral formula)

Switzerland: Legal Situation III

Ordinance on Medicinal Products (VAM)

- **according to Art. 22:**
  - Swissmedic classifies the medicinal product into a supply category

Ordinance of the Swiss Agency for Therapeutic Products on the Authorisation of Medicinal Products (AMZV)

- **according to Art 2:**
  - The application for authorisation must contain a complete documentation, which is in accordance with the current state of the art and proves the quality, safety and efficacy of the medicinal product.

Switzerland: Legal Situation IV

Ordinance of the Swiss Agency for Therapeutic Products on the simplified Authorisation of Complementary and Herbal Medicinal Products (KPAV)

- **according to Art. 4: Herbal medicinal products**
  - are medicinal products that contain exclusively one or more herbal substances or preparations as active substances and that
  - cannot be classified within specially oriented therapies such as homeopathy or anthroposophic medicine

- **according to Art. 5:**
  - herbal medicinal products may be authorised by means of a simplified authorisation procedure or on the basis of an application procedure, as long as the conditions of the present ordinance are fulfilled.

Switzerland: Legal Situation V

Administrative ordinance:

Instruction for the Submission of Authorisation Applications for Herbal Medicines for Human Use (Phyto-Anleitung)

- **Herbal medicinal products are medicinal products that contain exclusively herbal active substances, exempt from**
  - medicinal products with pure compounds, isolated out of plants (e.g. atropine, digoxin);
  - medicinal products with synthesised or semisynthesised active substances (even if synthesised out of herbal raw material), e.g. codeine, troxerutin
  - medicinal products of specially oriented therapies, manufactured according to specific production methods (e.g. homeopathic or anthroposophic medicinal products)

Authorisation Procedure I

- **any person applying for a marketing authorisation for a medicinal product must**
  - have a registered address, registered office or a branch office, in Switzerland;
  - be a holder of an authorisation to manufacture, import or conduct wholesale trade issued by the competent authority
    - in case of a product containing cannabis, an establishment license for narcotics is necessary prior to the application for authorisation;
  - prove that the medicinal product is of high quality and is safe and effective
    - documentation according to the Ordinance on the Authorisation of Medicinal Products (AMZV) Art. 3 – 6

see following slides

Documentation I

- **about analytical, chemical and pharmaceutical trials, in particular details and documents about**
  - qualitative and quantitative description of all constituents
  - production methods
  - control of raw material
  - control of intermediate products
  - control of finished product
  - tests on shelf life / stability testing
- **about pharmacological and toxicological trials, in particular details and documents about**
  - pharmacodynamics
  - pharmacokinetics
  - toxicology
  - environmental toxicity

Documentation II

- **about clinical trials, in particular**
  - GCP
  - prophylactic or therapeutic effects, clinical tolerance, nature of the effects, adverse reactions
- **details and documents about**
  - clinical pharmacology
  - pharmacokinetic and pharmacodynamic interactions

Swissmedic may ask for further information

Documentation III

Herbal medicinal products:

- **trials on therapeutic efficacy and safety may be replaced by:**
  - proof of the therapeutic equivalence between the medicinal product in question and a medicinal product that has already been authorised;
  - proof of the pharmaceutical equivalence between the medicinal product in question and a medicinal product that has already been authorised;
  - observational studies;
  - bibliographical documentation, as long as published scientific literature provides sufficient proof and as the results apply analogously to the medicinal product in question.

Swissmedic decides on a case by case basis which documents among those cited above are relevant.

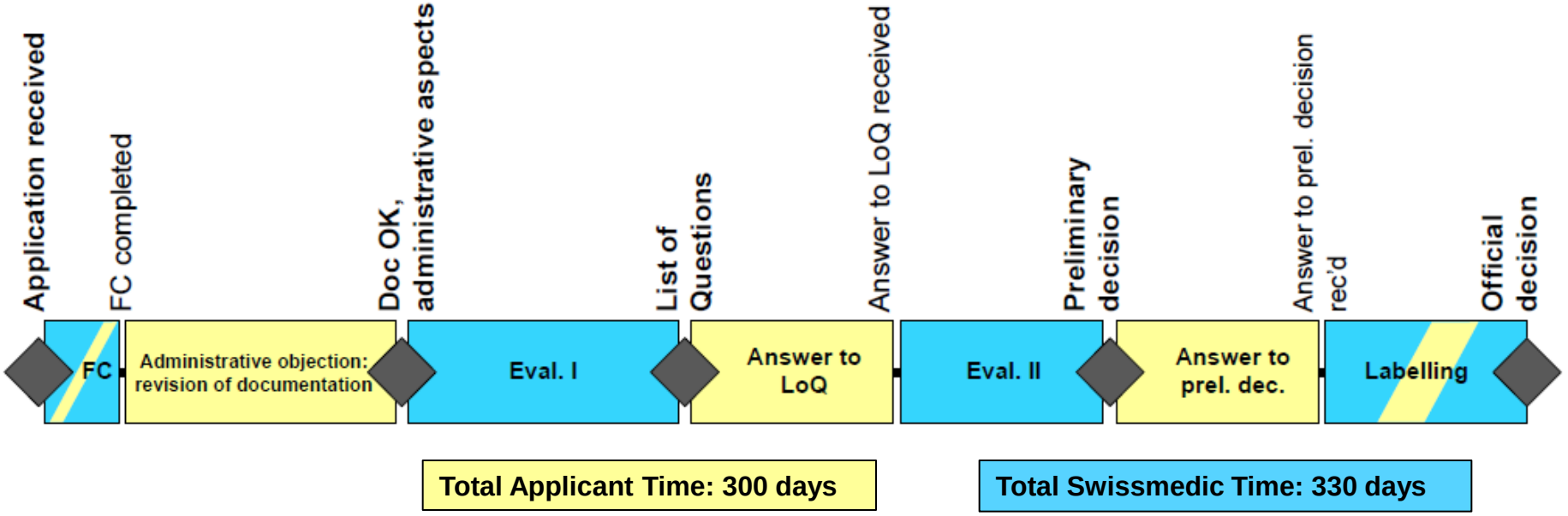
Authorisation Procedure II

- **Procedure „New active pharmaceutical ingredients (New API)“**
  - Neither Dronabinol nor Cannabis-extracts have been included to date in any medicinal product that is or has been authorised by Swissmedic.
- **Evaluation of**
  - information for healthcare professionals and patient information as well as packaging
  - applied supply category (indication, dosage, etc. are also taken into account)
- **Fees**
  - according to the Ordinance on Fees for Therapeutic Products (HGebV)
- **Time**
  - Swissmedic Processing Time: approx. 330 days.
  - Applicant Time for submitting answers, additional documentation

Authorisation Procedure - Overview

- **Documentation (Quality, Preclinical, Clinical)**
- **Establishment licences, esp. for narcotics, granted by Swissmedic**

⇨ **Application**



Conclusion

- **Medicinal Product with a Cannabis-extract as active substance**
  - Herbal Medicinal Product
  - Evaluation according to „*Instruction for Herbal Medicines*“
  - Fee: CHF 6‘000.-
- **Medicinal Product with Dronabinol ([-]-trans-Δ^9-THC) as active substance**
  - Synthetic Medicinal Product
  - Evaluation according to „*Instructions for new active pharmaceutical ingredients*”
  - Fee: CHF 60’000.-
- **Indication, supply category, etc. will be decided on after evaluation of the submitted documentation**

⇨ **Competent Authority for Reimbursement: Federal Office of Public Health (FOPH) (BAG) („List of pharmaceutical specialties “)**

Swissmedic / Swiss Agency for Therapeutic Products

Thank you for your attention

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