Regulation of herbal medicines in Switzerland

Dr. Karoline Mathys Badertscher
Head Market Surveillance
Swissmedic
Herbal medicines

Conventional medicine

Complementary medicine
Herbal medicines

✓ Recognized and authorized as medicines for over 100 years
✓ Authorized for specific indications
✓ Established as medicines in Europe (but no harmonization regarding authorization requirements prior to 2004)
✓ International pharmacopoeia quality monographs (Ph. Eur)
✓ Many international monographs on efficacy and safety of certain plants and plant preparations (ESCOP, WHO, HMPC)
✓ Many international guidelines concerning quality, efficacy and security requirements (e.g. GMP-, ICH-Guidelines)
Herbal medicines

✓ Proof of quality, efficacy and safety

Simplification of authorization upon proof of efficacy and safety
(Reference to already authorized medicines and bibliographical documentation on pharmacological, toxicological and clinical trials)

⇒ No facilitation / compromises regarding quality
Pre-clinical requirements for herbal medicines

✓ Documentation on pharmacological and toxicological studies

The applicant may submit bibliographical documentation. Additional studies are required if published data are not sufficient
Proof of efficacy and safety of herbal medicines

✓ Documentation on clinical trials

As long as the composition of the medicine, its innocuousness, therapeutic effect and scope, method of administration, indication, and duration of treatment justify and permit it, the therapeutic efficacy and safety can be established by means of:

✓ proof of therapeutic equivalence
✓ treatment records
✓ bibliographical documentation:
  ⇨ sufficient published documentation available
  ⇨ results applicable by analogy

✓ Proof of tolerance should be provided
Asian medicines – TCM market in Switzerland

- Considerable increase in the use of traditional Chinese medicines (TCM) in Switzerland over the last twelve years
- Ca. 25 hospitals specialized in TCM
- Ca. 700 physicians with specific training in acupuncture and TCM
- Ca. 1400 TCM - therapists (acupunctur, herbalists, masseures, etc.)
- The basic range of medicines comprises around 500 substances (single drugs, “traditional” formulae, “modern” combinations)
- Medicines contain substances of plant, mineral or animal origin
- Substances used mostly not known in Europe
- Medicines are mainly manufactured in Japan, China or Taiwan

=> The Swiss market for TCM medicines is quite important
=> Control of Quality, Safety and Efficacy is a big challenge
Law on Therapeutic Products (LTP) of 1 January 2002

Mandatory authorization for all “ready-to-use” medicines

Art. 95 LTP Transitional provisions

³ For medicinal products for which no authorization was previously required, but which must be authorized under the LTP requests for marketing authorization must be submitted within one year of entry into force of the LTP. The products may continue to be placed on the market until the Agency has reached a decision.

➢ Till 31 December 2002 ca. 5500 requests for Asian (herbal) medicines have been submitted (including more than 5000 for TCM medicines)
Different categories of Asian products

- Medicines with (western) indications sold in pharmacies and drogueries by and to persons without TCM knowledge ("western" used TCM medicines)
  - Marketing authorization requirements as for western (herbal) medicinal products (exempt for the justification of the combination)

- TCM medicines used by TCM doctors or TCM therapists ("traditionally" used TCM medicines)
  - Elaboration of special marketing authorization requirements for TCM products for individual treatment
Definition of the authorization requirements for Asian medicines

  - Representatives of the UNION of Associations of Swiss Physicians for Complementary Medicine; of the Swiss Association for Therapeutic Products from Complementary Medicines (ASMC); other experts

- Objective
  - Definition of the requirements for the authorization of Asian medicines, in order to guarantee that only medicines of high quality, with sufficient data concerning their safe and efficacious use by appropriate experts are authorized and marketed

- Most important aspect is the quality and safety of these medicines
Asian medicines

- Medicines with indication
  Proof of quality, safety and efficacy as for all other medicines
  ⇒ when assessing the composition, the specific therapeutic principles are taken into account

- Medicines without indication, for personalized therapy
  Proof that the medicines are traditionally used and documentation on quality and safety (esp. substances of animal origin)
  or
  mandatory notification based on TAS list (Traditional Asian Substances list)
  ⇒ the physician or therapist with TCM training is responsible for the correct choice of the product and the dosage

- Quality documentation must be available in all cases
Ordinance on complementary and herbal medicinal products (OCHM)
of 22 June 2006

- **Basic principles**
  Simplified authorization procedure for all complementary and herbal medicines
  ⇒ reference to medicines already authorized, treatment records and bibliography

- **Herbal medicines**
  ⇒ Simplified authorization procedure as previously

- **Asian/TCM medicines with/without indication**
  ⇒ Simplified authorization procedure (bibliography), justification of the composition in accordance with the criteria for Asian medicine

- **Asian/TCM medicines without indication**
  ⇒ Prescription / provision only by specialized persons having received appropriate training
  ⇒ Simplified authorization procedure for traditional medicines: proof of traditional use
  ⇒ mandatory notification for many single-substance medicines and traditional combinations (substances on TAS list)

- **Quality documentation must be available**
Safe use of complementary and herbal medicines

Safety / toxicological analysis

Quality

Efficacy / specific knowledge of the therapy

= Quality / efficacy / specific knowledge of the therapy
Additional information

Swissmedic,
Swiss Agency for Therapeutic Products
Hallerstrasse 7
CH-3000 Bern 9
Tel. +41 31 322 02 11
Fax +41 31 322 02 12
www.swissmedic.ch
www.swissmedic.ch/kpa.asp
Relevant Guidelines/Directives on Quality

- Monographs of the official Pharmacopoeiae (Swiss and European Pharmacopoeia)
- Monographs of the Pharmacopoeiae of the Peoples Republic of China (PPRC)
- Requirements on quality documentation for Asian medicinal products (www.swissmedic.ch/kpa.asp)
- Points to Consider on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (www.emea.eu.int)
- Note for Guidance on Quality of Herbal Medicinal Products (www.emea.eu.int)
- Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products (www.emea.eu.int)
- ICH Topic Q2B: Validation of Analytical Procedures: Methodology (www.ich.org)
- ICH Q7A: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (www.ich.org)
- PIC/S 009 Guide to good manufacturing practice for medicinal products
- Contaminant recommendations on heavy metals: Federal Ministry of Health: Publication of recommendations regarding maximum levels of heavy metals in medicinal products of herbal and animal origin, Draft of 17.10.1991