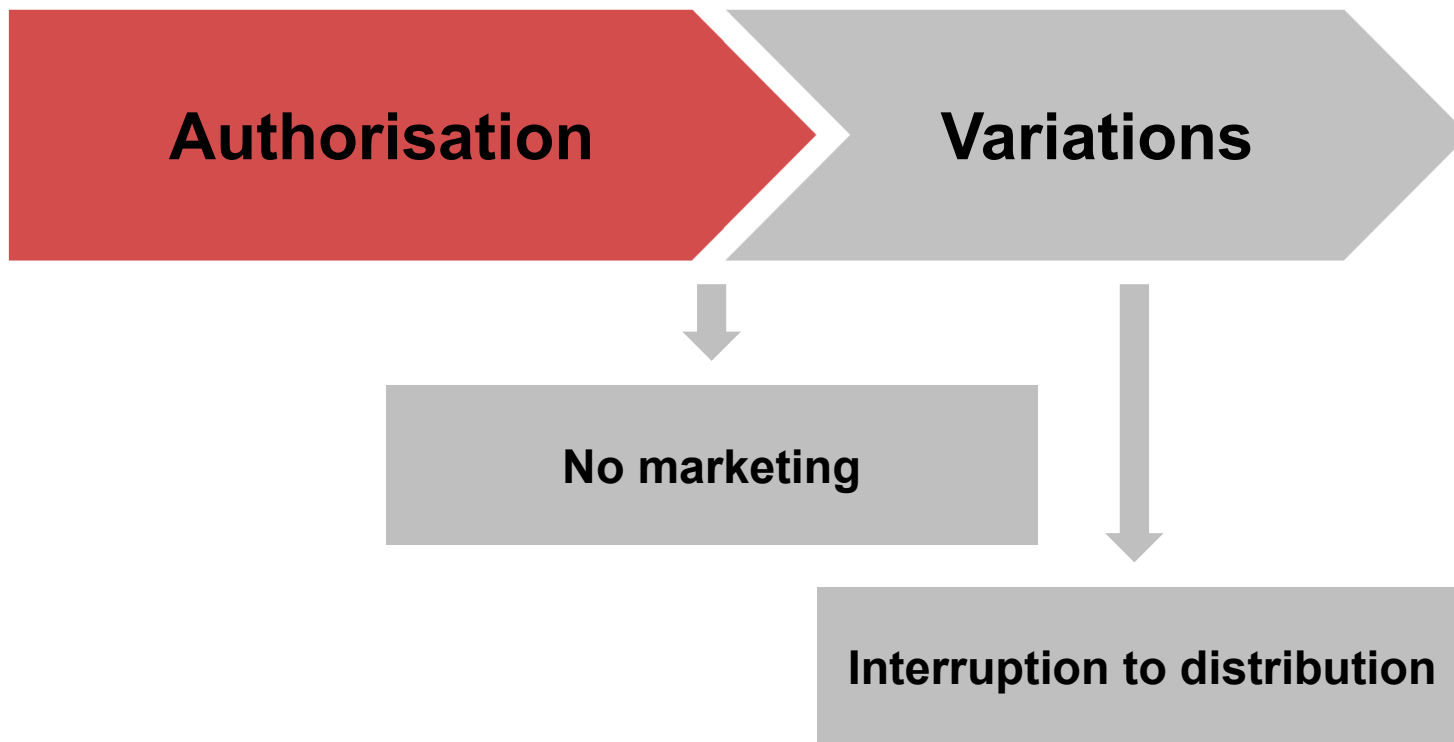




## **Best practice for the authorisation and life cycle of complementary and herbal medicines**

Julie Morciano, Regulatory Manager  
Complementary and Herbal Medicines



# Standard text concerning the indication

**According to the XY therapeutic principle...**

**Is traditionally used in ...**

- List in form *New authorisation of human medicinal products*
- Publication following formal checking

Annex 5.2 and 5.3 [TPLRO \(SR 812.212.22\)](#)

Templates for Information for patients

# Reference

- In Information for patients if no Information for healthcare professionals
- If there are several references: Reference section and page number in CTD Module 2
- Not permissible: Reference to the company's internal Core Data Sheet (CDS) or Company CDS (CCDS) or Summary of Product Characteristics (SmPC)

Requirement 2.5.3.2.4, Guidance document: Formal requirements

# Completeness of the documentation

## Examples from Annex 2 KPTPO

- Batch documentation (no. 2.2 let. g)
- Reason for choice of dilution or potency, dosage, pharmaceutical form, Administration route, etc. (no. 4.2 let. b)
- Details of age group of children and adolescents for certain indications or substances (no. 5.3 let. b)

Annexes 1–3 [KPTPO \(SR 812.212.24\)](#)

# Medicinal product name

Example: core brand

Identical **main name**

Different  
**name extensions**

Guidance document: Medicinal product name

Art. 9 para. 4 TPO

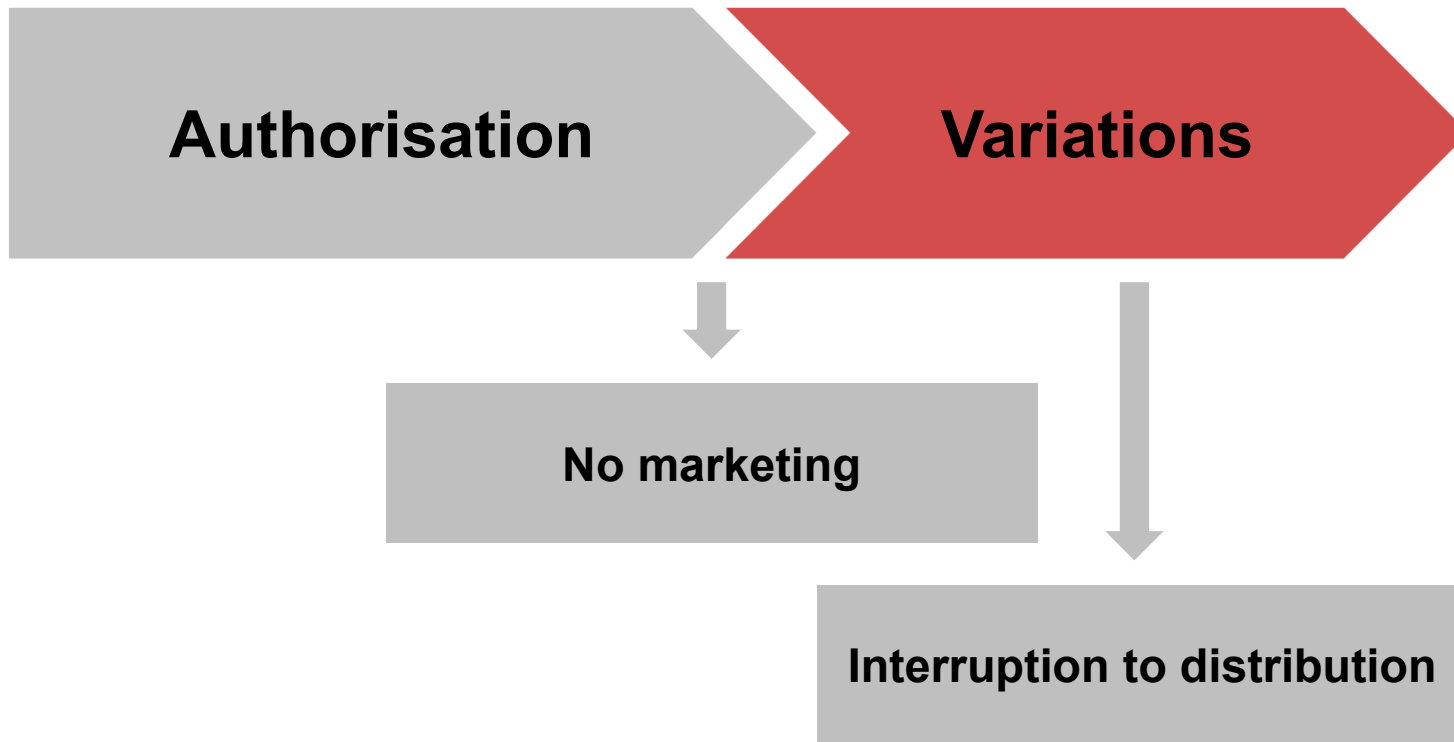
# Medicinal product name

## Possible core brand groupings

- Connected, but **non-identical indications**
- Different active substance compositions
- Prescription-only and/or non-prescription medicinal products
- Medical devices and medicinal products

Marketing authorisation holder's responsibility:

Exclude any risk of confusion **medicinal products** ↔ **medical devices, dietary supplements, etc.**





# Languages

- Medicinal product information: 3 official languages
- Packaging texts at least: 2 official languages
- Text approval: 1 official language
- Translations: Marketing authorisation holder's responsibility

Art. 26 TPO (SR 812.212.21)

Change of language of approved texts: **A.100 (type IB)**

Change of language for publication and correspondence **in justified cases:**

[adressen@swissmedic.ch](mailto:adressen@swissmedic.ch)

# Update the date of revision of the text – yes or no?

## Annex 1 – Updating the "date of revision of the text"

The "date of revision of the text" is updated when the content/scientific information is modified in the sections marked "Yes" below. This date is not updated after purely formal changes.

IHP section	PI section	Section/Title/Content	Requirement to update the "date of revision of the text"
1.	2.	Name of the medicinal product (registered trademark)	No
2./3.	11.	Composition Pharmaceutical form and active substance quantity per unit	Yes

Annex 1, Guidance document: Product information for human medicinal products

## Date of revision of the text for type IA<sub>IN</sub>/IA/IB variations

Indicate in Track Changes mode

Type IA<sub>IN</sub>/IA "MONTH YEAR" of **variation implementation date**

Type IB "MONTH YEAR" of **application submission date**

### **Exception**

Date of revision of the text: Co-marketing medicinal product = basic product

Annex 1, Guidance document: Product information for human medicinal products

## Time limits

- Type IA<sub>IN</sub>/IA: notify within **1 month** or **12 months** of implementation

Time limits exceeded? **Request as type IB variation**

### **Exception**

Type IA<sub>IN</sub>/IA variations part of a multiple application

- Type IA<sub>IN</sub>/IA/IB: time limits cannot be extended

Guidance document: Variations and extensions HAM

# Packaging

- Variations that MAHs can implement without submitting an application (section 5.7.2)
- Type IB minor variations to be notified in advance (section 5.7.3)
- Changes to packaging in connection with other applications (section 5.7.3.1)

Annex, [Guidance document: Packaging for human medicinal products](#)

# Current state of science and technology

Update medicinal product information (Art. 28 TPO)

Relevance and transferability of findings

Examples

- European Union herbal monograph and associated documents (assessment report, etc.)

**C.I.4 (type II)**

- "List of substances" (Annexes to KPTPO)

**A.100 (type IB)**

# Current state of science and technology

**Example: Homeopathically manufactured active substances**

**Variation in monograph source: B.I.b.1 i) (type IB)**

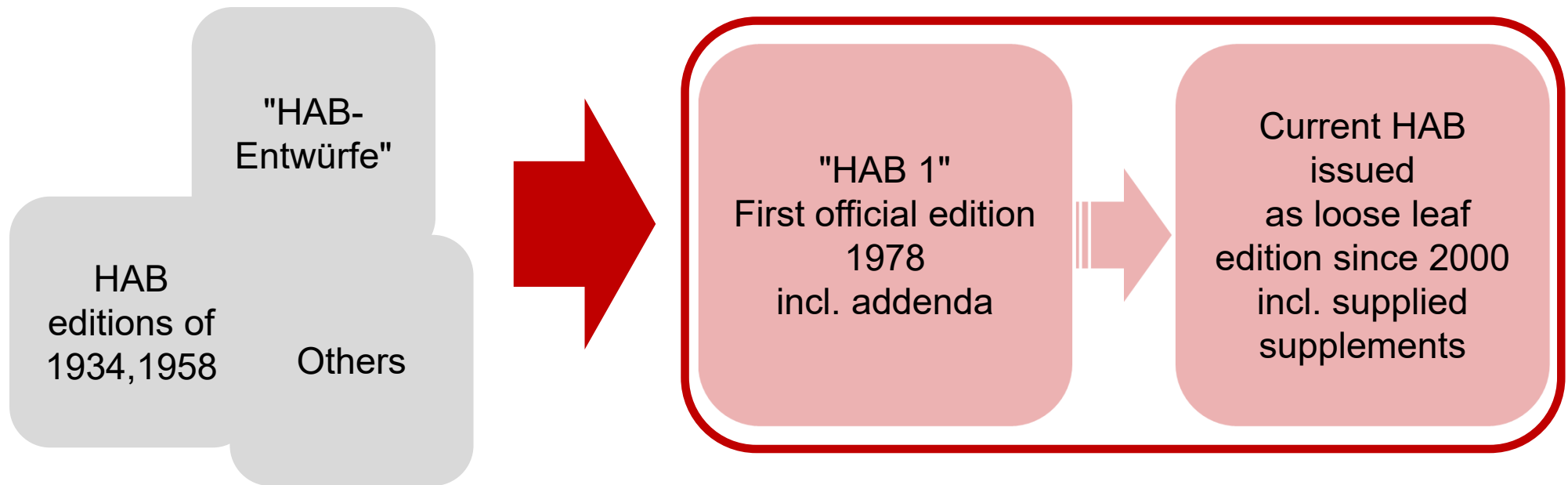
If currently:

- Company's own internal monograph
- No longer valid monograph from the HAB (homeopathic pharmacopoeia; "HAB-Entwürfe", HAB 1934, HAB 1958, etc.)

## **Mandatory**

Ph.Eur., Ph.Helv., other pharmacopoeias recognised by Swissmedic ([Art. 8 TPA](#))

## Current state of science and technology

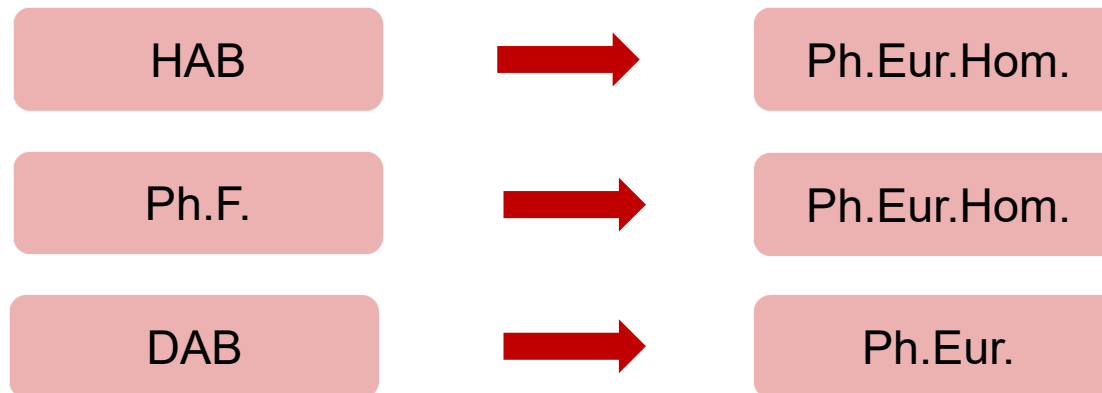




# Current state of science and technology

Example: Homeopathically manufactured active substances:

Variation in monograph source: B.I.b.1 i) (type IB)



# Current state of science and technology

**Example: Homeopathically manufactured active substances:**

## **Change in active substance: Z.4. Other authorisation extension**

- Change in starting material, production or potency
- With no fundamental change in the medicinal product (e.g. indication)
- Documentation on quality
- Proof of active substance's innocuousness and safety
- Evidence that the active substance is known and used in homeopathy

## **Change of active substance name: A.3 (type IA<sub>IN</sub> or IB)**

- Proof of change in monograph

## Current state of science and technology

### Complementary medicine (without indication)

- **With reduced dossier**

For all variations and authorisation extensions

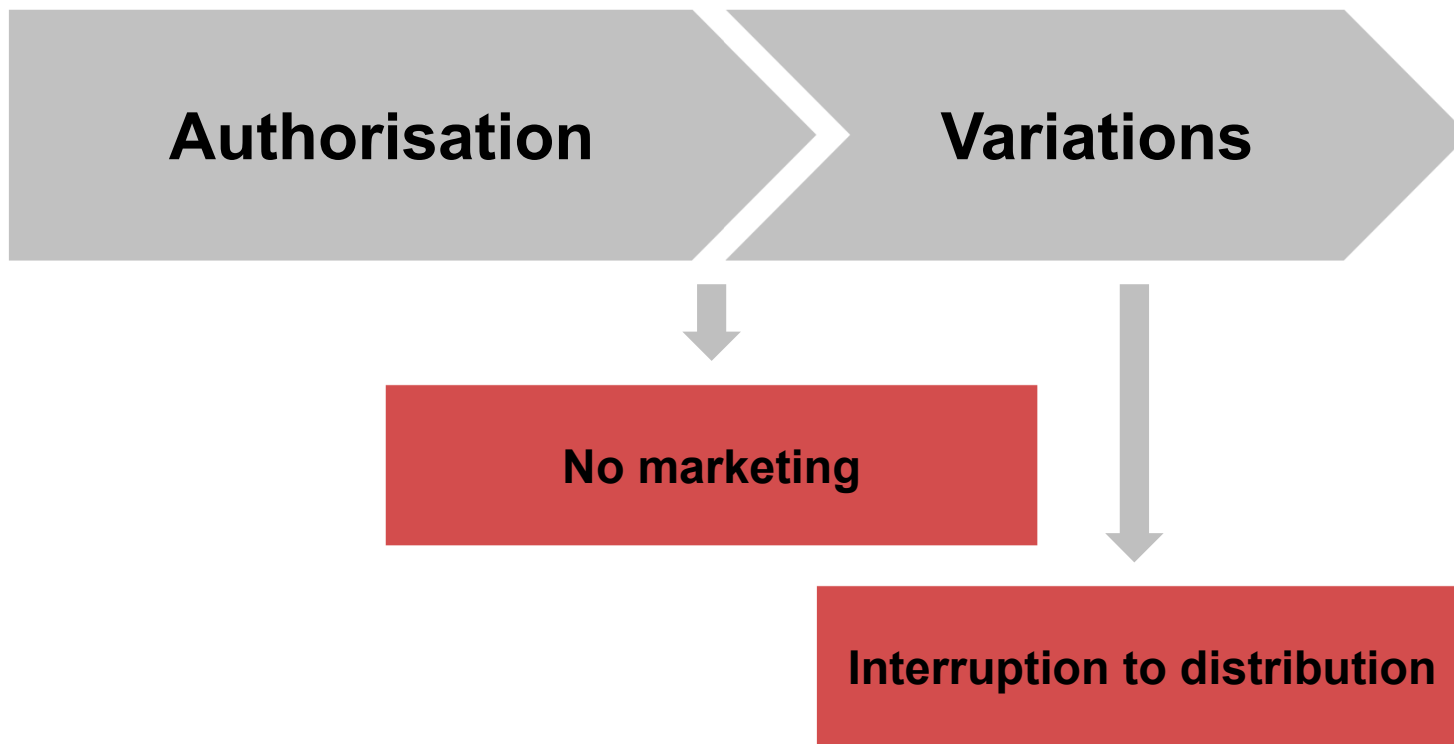
#### ***Y.1 Variation reduced dossier complementary medicinal product (type IB)***

- **Under the notification procedure (HOMANT)**

#### **Application for a variation not possible**

Application for new authorisation under the notification procedure

Discontinue current medicinal product under the notification procedure



## No marketing / interruption of distribution

- Not on the market for > 1 year      **Notify Swissmedic**
- First time or back on the market      **Notify Swissmedic**
- Not on the market for 3 years      Authorisation revoked ("sunset clause")

Form *No marketing / interruption of distribution HAM*

↳ Also applies to complementary medicinal products under the notification procedure (HOMANT)

Guidance document: No marketing / interruption of distribution

Art. 11 TPO

## Further information

- [CHM on Swissmedic website](#)
- [Frequently asked questions](#)
- From the responsible Regulatory Manager