



# SwAPP

Swiss Association of Pharmaceutical Professionals

CH-3000 Bern

## SwAPP Speciality Diploma Medical Marketing

Implemented by the SwAPP Board on January 1, 2009. Last revised Nov 11<sup>th</sup> 2014.

### Theoretical training

<b>Subject</b>	<b>Hours</b>
International regulations and laws	4
Swiss regulations and laws for the promotion of pharmaceutical products	16
Drug promotion surveillance by authorities, Pharmacodex group and competitors	8
Standard Operating Procedures (SOPs)	8
Promotion to the general public and to healthcare professionals	12
Medical clearing of promotion material	4
Marketing authorisations	4
Distribution and GDP	4
Sponsoring	8
Collaboration with Key Opinion Leaders, Advisory Boards	8
Rules and regulations for clinical trials, observational studies, case reports, IITs	8
Market surveillance	8
Clinical publications and ICMJE uniform requirements	8
Freely chosen courses in any field of medical marketing	14
Other core fields of pharmaceutical medicine	30
<b>Total hours</b>	<b>144</b>

#### **International regulations and laws**

Regulations and laws  
Promotion across borders

#### **Swiss regulations and laws for the promotion of pharmaceutical products**

Promotion in CH  
Pharmacodex  
Heilmittelgesetz  
Arzneimittelwerbeverordnung

## **Drug promotion surveillance by authorities, Pharmacodex group and competitors**

- Interventions by Swissmedic
- Interventions by the Pharmacodex group
- Interventions by competitors
- Complaints and criminal procedures
- Jurisdiction by the Federal Supreme Court

## **Standard operating procedures (SOPs)**

- The need for SOPs
- Creating SOPs
- Control and management of SOPs
- Necessary SOPs drug promotion, pharmacovigilance, quality control etc.

## **Promotion to the general public and to healthcare professionals**

- Legislation
- Do's and don'ts
- Misleading information
- Creating and updating promotion material for patients and healthcare professionals

## **Medical clearing of promotion material**

- Differentiating promotion from medical information
- Rules for referencing of statements
- Direct and indirect reference to medications
- Comparing medications
- Internet promotion

## **Marketing authorisations**

- Types of marketing authorisations
- Patent laws CH and EU
- Pricing and reimbursement
- Parallel imports

## **Distribution and GDP**

- Categories of products
- The responsible person
- Mail order business
- Samples: release and distribution
- Discount system and deductibles

## **Sponsoring**

- Sponsoring of events
- Collaboration and support to patient organisations
- Honoraria
- Invitations to scientific events
- Gifts and benefits

## **Collaboration with Key Opinion Leaders, Advisory Boards**

- Rules and regulations

## **Rules and regulations for clinical trials, observational studies, case reports, IITs**

- Differentiation clinical trials, observational studies, case reports
- Responsibilities of the Ethics Committee
- Responsibilities of the regulatory authorities
- Sponsoring of studies or case reports
- Legislation for notification of adverse events

**Market Surveillance**

Surveillance by the authorities  
Pharmacovigilance and obligations for notification  
Materiovigilance  
Responding to inquiries on products and adverse events

**Clinical publications and ICMJE uniform requirements**

Familiarity with the uniform requirements for manuscripts submitted to biomedical journals  
(International Committee of Medical Journal Editors)

**Freely chosen courses in any field of clinical pharmacology**

Courses in any of the above fields

**Other core fields of pharmaceutical medicine**

Courses in any topic of pharmaceutical medicine

**Practical training**

At least 3 years composed as follows: At least 2 years in the specialty area, maximally 1 year in other fields of pharmaceutical medicine.

The practical training must be in as many of the above topics as possible. Evidence must be given for: responsibility or responsible involvement in the promotion of a medication and associated training (if possible a product launch), education of sales representatives and other internal employees. Preparation and chairing of meetings, symposia and advisory boards. Handling of questions and answers from doctors, patients and from the public, and appropriate documentation and reporting procedures. Involvement in a marketing authorisation procedure, pricing and reimbursements.

For further requirements please refer to the current SwAPP Life Long Learning (LLL) Program on the SwAPP Webpage.