

SwAPP Specialty Diploma Medical Marketing

Implemented by the SwAPP Board on January 1, 2009.

Theoretical training

Subject	Hours
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
Relevant literature and publications	16
Freely chosen courses in any field of medical marketing	14
Other core fields of pharmaceutical medicine	30
Total hours	160

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

Materialiovigilance

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)

Relevant literature and publications

Read literature and relevant publications in the field

Competitive intelligence

Statistical methods & analyses

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

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.