Switzerland

Alan A. Chalmers
Pharma International
Allschwil, Switzerland

Switzerland has a long established regulatory system for the control of pharmaceutical products. Whereas often associated primarily with its banking and other financial institutions, its neutrality, world famous tourist attractions, exactness and fixation with timekeeping including watches, delicious chocolates and cheeses, it is also home to some of the world's major pharmaceutical companies as well as many smaller pharmaceutical manufacturers focused on international exports. In most cases exports account for over 90 percent of sales.

Switzerland is also home to many international organisations including the World Health Organisation (WHO), the International Red Cross, several United Nations' organisations, the World Trade Organisation (WTO), the International Olympic Committee (IOC), the Bank for International Settlements, and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

Switzerland, although a small country, is still a desirable market in which to register pharmaceuticals due partly to the economic attractions and considerable international influence. This chapter concentrates on the key current aspects of pharmaceutical registration in Switzerland. This chapter is also valid for the smaller adjacent country of Liechstenstein due to contractual agreements between the two countries.

Future trends discussed later in this chapter will report on major organisational changes planned for the new millennium.

COUNTRY DESCRIPTION

Switzerland lies in the centre of Europe, rather like a neutral island surrounded by the European Union (EU). To the west lies France, to the north is Germany, to the

east Liechtenstein and Austria and to the south, Italy. Both Switzerland and the principality of Liechtenstein are neutral. Switzerland is a small, fairly mountainous country; to the north is the Jura chain, then the large middle lowlands where most of the population resides (about 7 million), the massive Alpine chain of mountains and the southern extensions into the Italian plains.

Switzerland is multilingual: French, German, Italian and Raeto-romanish are the four official languages; English is the fifth "unofficial" national language and is increasingly being used. German is spoken by the majority, about 70 percent, followed by French (15 percent) and Italian (10 percent). Swiss German dialects are widely spoken although the written language is high German.

Politically neutral, Switzerland is not a member of the United Nations or the EU but it is a member of the remnants of the European Free Trade Association (EFTA) along with Norway, Iceland and Liechtenstein. Recently, trade links with Canada have been discussed.

Switzerland is actually a confederation of small national states. The official name "Confoederatio Helvetica" appears on stamps, coins and other national symbols and is also reflected in such items as the postal code CH and car registration identity plates.

Individual states, or cantons as they are called, of Switzerland are often individual republics in their own right (e.g., Geneva and Basel). In total there are 26 member cantons and half-cantons. Most have their own laws, regulations and health authorities. For practical reasons, however, there are longstanding mutual agreements particularly on such matters as health organisation and control including the regulation and control of pharmaceutical products.

OVERVIEW OF REGULATORY ENVIRONMENT

As indicated previously, Switzerland is actually a federal state so there are in fact some parallels to the United States such as the Food and Drug Administration functioning as a federal agency with national authority. There are, however, specific interstate regulations and individual state responsibilities.

In Switzerland health controls are largely a cantonal responsibility including healthcare systems, hospitals, professional education and the registration of medicines. In exceptional cases differences can exist, for instance, in the prescription status of individual pharmaceutical products from canton to canton (these are more the exception than the rule, however). To avoid duplication of effort and conflicting advice, the responsibility for pharmaceutical registration lies with the national regulatory authority, the Intercantonal Office for the Control of Medicaments (Interkantonale Kontrollstelle für Heilmittel or IKS).

Social insurance matters are a federal responsibility as are narcotics, serum, blood and blood products, vaccines, poisons and foodstuffs.

Some useful definitions include the following:

- Medicament: Substance or mixtures of substances used to diagnose, prevent or treat diseases or otherwise intended for medicinal purposes in

humans and animals (Article 1 IKS Regulations, Article 3 *Pharmacopoeia* Regulations, compliant also with EU Guideline 65/65).

- Foodstuffs: Dietary products serving to build or maintain the human body but without any claims of a medical nature (Article 3 Food Laws).
- Cosmetics: Substances or products primarily for external use or for dental use. They have protective, maintenance, cleansing purposes or function as perfumes. They are intended for use on the healthy organism and should not be used internally (IKS).

The first attempts to harmonise cantonal regulatory requirements go back to the years 1866 (Thurgau) and 1877 (Aargau) with the first intercantonal agreement signed in 1901. This founded the basis of current legislation valid to the end of the century.

The main regulative guidelines for pharmaceutical products date from 25 May 1972, updated 25 November 1999. Clinical trial regulations were introduced 18 November 1993 compliant with International Good Clinical Practice (GCP) Guidelines and came into force 1 January 1995.

REGULATORY AUTHORITIES

The national regulatory authority for Switzerland (and Liechtenstein) is the Interkantonal Kontrollstelle für Heilmittel (IKS), located in the federal capital Berne.

The IKS can be reached as follows:

Interkantonale Kontrollstelle für Heilmittel
Erlachstrasse 8.
CH 3000 Bern 9, Switzerland.
Telephone : + 41 31 322 02 11
Fax : + 41 31 322 02 12
(Manufacturing control fax: +41 31 322 04 19)

The IKS is responsible for the comprehensive assessment, evaluation and registration of pharmaceutical products as well as for manufacturing controls.

In addition, the Bundesamt für Gesundheit is involved in certain aspects of regulatory control matters and additional bodies are involved in the reimbursement process. This will be addressed in later sections.

REGULATORY REQUIREMENTS AND PROCEDURES

Regulatory Basis

The legal basis for medicament control is currently based on the Intercantonal Agreement on the Control of Medicaments from 3 June 1971 and the IKS Regulation of 25 May 1972 (updated as of 25 November 1999).

Other current basic requirements are:

- the IKS Registration Guidelines of 16 December 1977 (updated 14 May 1998)
- Advice for the Registration of New Chemical Entities (NCEs) of 14 February 1989
- Advice for the Registration of Generics in Human Medicine of 23 May 1991
- IKS Guideline on Product Information of 25 November 1988
- IKS Guideline on Advertising of 23 November 1995

Documentation

The regulatory documentation comprises the following:

- Part I General documents
- Part IA Administrative data
- Part IB Packaging texts and product information
- Part IC Expert reports
- Part II Analytical, chemical and pharmaceutical documentation
- Part III Toxicological and pharmacological documentation
- Part IV Clinical documentation

The Expert Reports in Switzerland are not quite identical to those for the EU. The differences are outlined below. Nevertheless, EU Dossiers are increasingly accepted, especially for NCEs. This has been the case since 1996.

1. Expert Reports in Switzerland ("Zusammenfassungen" or ZF equals a summary) are critically evaluating summaries. A detailed table of contents is provided prior to the summaries:

   - ZF (Part IIZ) Analytic, Technical 5 Copies
   - ZF (Part IIIZ) Toxicology, Pharmacology 15 Copies
   - ZF (Part IVZ) Clinical 15 Copies

   References are preferably to be given in the right margin indicating part, volume and page. In the EU the Expert Reports would cover:

   - Quality 10 pages
   - Safety 25 pages
   - Efficacy 25 pages

2. In each case there would also be tabular data and written summaries. Please refer to the chapter on the EU for further details.

3. Since 1996, the EU-styled Expert Reports have also been accepted by the IKS in Switzerland for the following:

   - New chemical entities (accepted since 1995)
   - New combination products
   - New dosage forms
   - New indications

   As a further compromise and demonstration of their flexibility, the IKS simultaneously agreed to accept referencing either in the text or in the margin, either directly or with one intermediate step. It also agreed that further information in an accompanying letter would be acceptable.

4. Number of copies—Regarding the number of copies required for submission, it was also agreed from 1996 onwards that these should be:

   - 2 copies of the overall scientific documentation parts II, III, IV in English, or one of the Swiss languages: German, French or Italian.
   - 15 copies of administrative data (parts IA and I B) in German, French or Italian.
   - 5 copies of part II and 15 copies of parts III and IV of Expert Reports (normally in English but the national languages are acceptable).

5. Product information—A major component of the registration documentation is also the product information. There are specific guidelines for this that cover:

   - professional information;
   - patient information;
   - phytopharmaceuticals; and
   - homeopathic and anthroposophic medicines.

   The fundamental principles of the product information are outlined in the following paragraph. It should be noted that the professional information is normally published in the annual Swiss Kompendium with regular updates (similar to the Physicians Desk Reference in the United States). It is published in standard German and French editions*.

Professional information
List A,B,C products (See number 6 below)
Obligatory
Package insert only for parenteral formulations
7 point text
Languages required: French and German

Patient information List A–D products (See number 6 below)
Obligatory
Package leaflet required (except for parenterals)
8 point text
Languages required: French, German and Italian

A comparison between the Swiss professional product information, and the Summary of Product Characteristics (SPC) is given in Appendix B.

6. Swiss legal status control system—It should be noted that there is a specific Swiss status system to indicate the level of control the approved medicaments should be subjected to as follows:

   - Professional prescription—non repeatable: A
   - Professional prescription: B
   - Pharmacy only: C
   - Drug stores only: D
   - General sales list: E

7. Packaging elements—Based on the IKS Regulations, Articles 17 and 21, and the Guidelines for Data on packaging from 16 December 1977, it is necessary to declare the composition on the outside packaging. There are additional specific guidelines and decisions concerning the declaration of excipients: (General Decision of 21 May 1990, extended 2 July 1991 for Propyleneglycol, September 1993 for Saccharin. Notes 5/90, List of Synonms in Scheiz.Apotheker Zeitschrift 127, pages 605—618, 1989, Guidelines concerning Alcohol 24 November 1989 with notes from July 1992).

   The Vignette (symbol indicating the special Swiss legal status as explained previously) is also on the outer pack as requested by IKS on 30 November 1984. A decision from October 1992 stipulates an open declaration of the expiry date (shelf life). The words "EXP" or "Verfall" (equivalent to "Expires") or "Verwendbar bis" (equivalent to "Use by") can be written on the package. In the case "EXP" is used, then in the product

*Publisher Document AG, Postfach 217, CH 4020 Basel, Switzerland; Telephone +41 61 315 11 11; Fax +41 61 315 11 15; e-mail: mail@documed.ch; Internet: http://www.documed.ch.

information a fixed text equivalent to "The medicament may only be used up until the date on the container indicated as EXP" must appear.

The storage conditions are defined by the decision of June 1991. The dosage of liquid preparation is also defined by a decision of June 1991.

Concerning supplier and manufacturer details, there are IKS decisions from June 1989 and March 1995. The supplier must be on the container and packaging, whereas the manufacturer may be given on the packaging. The distributor may be declared if permission is sought from IKS. It would be acceptable to state the main supplier if abroad plus the Swiss supplier. Logos may be from the manufacturer or main supplier but telephone numbers, general agencies or representatives may not be declared on the packaging.

8. Administrative documents—Amongst the administrative documentation to accompany a submission to IKS, the following could be envisaged as appropriate:

   - Authorisation if submission is done by a regulatory affairs agent acting on behalf of the originating company.
   - If a copy product, the agreement of the originator and the manufacturer and confirmation of identical composition, quality and manufacture.
   - Information about manufacture (specific form entitled "Herstellerangaben").
   - If manufactured outside Switzerland, a good manufacturing practice (GMP) compliance confirmation.
   - Access to a Drug Master File.
   - International registration status.
   - Tabular summary of bioequivalence if genuine generic and identification of reference product.
   - Blood products checklist.
   - Animal products checklist.
   - Various.

9. Composition—The complete qualitative and quantitative composition with active substance(s) and inactive substances separated must be submitted. The active substance must be clearly declared as such, using *pharmacopoeia* or other suitable nomenclature (INN). The excipients should be grouped together (e.g., flavours with European or Colour Index number), colours, antioxidants, preservatives etc. In the professional

and patient information for Switzerland, only obligatory declarations of excipients are required to be included, unlike the situation in the EU where the full qualitative and quantitative compositions have to be included in the equivalent documents, the Summary of Product Characteristics and Patient Information Leaflet respectively.

REGULATORY PROCEDURES

1. Legal basis—The Registration Guidelines of 16 December 1977, updated 14 May 1998, remain the basis for the registration procedures. Article 8.1 refers to NCEs, 8.2 to Generics and Article 6 to Fixed Combinations. A further guidance on NCEs was issued 14 February 1989 and for single generics on 23 May 1991. A guidance for combination products was anticipated in 1999.

2. Practical procedures—The registration dossier is submitted as outlined previously to the IKS with the stipulated number of copies. A routine control for completeness will be made and the applicant will be notified within about a month if it is satisfactory. If some additional documents are required or if it is significantly incomplete, the dossier will be returned (if it is not completed within 4 months).

   The main review procedure involves both internal IKS experts and, as appropriate, review by external experts and specialists in the field especially for the clinical documentation. After about 6 months on average, a provisional decision will be reached and in the positive case a "Voranzeige" issued to the applicant. This is equivalent to the "approvable status" in the United States and generally includes requests for additional data or amended prescribed information.

   At this stage, registration samples for analysis and samples of packaging material have to be submitted. The agreed product information also has to be finalised and package leaflets have to be printed for submission. Prices also have to be finalised once the additional data and information is approved (within 2–3 months); then the final registration will be granted and a registration certificate (Registrierungsurkunde) issued.

   The final approval for new products is normally in the form of a "monitored release" in the sense that usually the approval is conditional on additional data being provided within a specified timeframe (e.g., additional clinical data on interaction studies or specified safety data to be submitted within a year).

   Should a submission not be approved, there is a system of reassessment based on additional data submitted in response to specific questions from the IKS as to why they cannot extend approval for the product. This is known as a "Wiedererwägung" (resubmission) and can be

repeated once. Should these steps also not be successful, there remains the option of "Rekurs" or appeal. This is not resorted to very often.

3. Accelerated Approvals ("fast track")—An additional IKS notice from November 1996 introduced the concept of an accelerated registration procedure for certain categories of products including those for indications where no therapy or inadequate therapy was available and for those products with high therapeutic value. Since 1999 there has been a regular submission possibility.

   At least 6 months prior to submission of the dossier, the applicant must submit to the IKS 5 copies of a scientifically based request for an accelerated approval (Beschleunigte Registrierung Verfalven [BRV]) in about 5–15 pages. A draft product information should be supplied. The fees must also be submitted. IKS will give its response within 4 weeks.

   If positively assessed by IKS, the applicant must advise IKS at least 2 months in advance of the actual date of submission and agree to a date for a pre-submission discussion.

   At least 1 month before submission, agreement is to be reached with IKS on the detailed documentation required in the submission itself.

   After the submission is made, the formal check takes place within less than 5 days; thereafter, "the clock" runs. It stops whilst any additional questions are answered (IKS anticipates a response from the applicant within 1 to 2 weeks).

   After the approvable status is reached, the applicant is rapidly informed. Unlike the normal procedures, registration samples are not analysed prior to final approval but after marketing of the product. Overall processes of about 5 months to issue the licence are aimed for.

4. Generics—The registration guidelines of the IKS from 16 December 1977 (status 14 May 1998) including Articles 8.1 NCEs, 8.2 Known Active Substances and 6 Fixed Combinations together with the NCE advice from IKS of 14 February 1989, the Mono-Generics Advice of 23 May, 1991 and the Advice on Combination Products (Draft, final version expected 1999) form the regulatory basis.

   Generics are defined as products:

   - with the same qualitative and quantitative composition as the original product;
   - with the same dosage form and strength as the original product;
   - with proof of bioequivalence to reference (original) product; and
   - with the same indications and dosage scheme as original product.

   The reference product should preferably be a product originating in Switzerland or alternatively in the EU and ideally be a product already marketed or at least submitted for registration in Switzerland.

Concerning the product information, the claimed indications should either be the same as the original product, or less than these.

5. Combination products—A draft advice from 1994 is valid for the first registration of pharmaceutical products containing already registered active substances and are not "generics" as such. Under point 6.2 of the registration guidelines, Article 6.2 concerning clinical trials, combinations products should:

   - be sensible from a medical point of view;
   - demonstrate advantages compared to the individual components in terms of the therapeutically effective dosage; and
   - stipulate that all active substances be medically justified.

   The Registration Guidelines, Article 6 for fixed combinations stipulate that documentation about the pharmacological and toxicological profile of the combination product as well as the individual active components are to be provided.

   As far as is technically possible, details of the adsorption, distribution, metabolism and excretion (ADME) of the active substances are to be incorporated into the submission. If this is not done, reasons must be given.

   For comparison within the EU according to the guideline CPMP/EWP/240/95, combinations as submitted for registration should be justified, such as:

   - improvement of benefit/risk assessment
   - simplification of therapy
   - each substance must have a documented contribution within the combination
   - make a contribution to the claimed effectiveness—be safe and effective for the significant population, and
   - be superior to its individual substances

6. Phytopharmaca—Phytopharmaca are defined as those whose components declared as active substances are plants, of plants or plant preparations. Not included in this definition are:

   - medicinal products with active substances isolated from plants such as atropineor tubocurarine;
   - medicinal products with synthetic or semi-synthetic active substances, even if these are synthesised from plant raw materials such as Troxerutin; and

- medicinal products from other specialised therapeutic disciplines such as homeopathy or anthroposophy.

7. Patent and intellectual property aspects—Patent protection in Switzerland lasts for 20 years, with the possibility of a 5-year extension with a supplementary protection certificate (SPC). Also of interest is that the initial applicant has 10-year exclusivity protection for new active substances, new routes of administration and/or new dosage forms.

   Confidential and other company internal data submitted shall be protected against unfair commercial use and disclosure except where necessary to protect the public interest in compliance with Article 39.3 of Trade Related Intellectual Property Rights (TRIPS).

8. Pharmacovigilance—Adverse Drug Reaction (ADR) reporting is a compulsory aspect of the regulatory process and does not cease with the registration. There is an IKS database with complete data retrievable within the IKS and there are connections with international networks such as the WHO Programme for International Drug Monitoring. There is close cooperation between the IKS and other Swiss institutions including the Swiss Teratogen Information Service (STIS), The Foundation for Drug Safety, Systematic Collation of Side Effects in Medical University Clinics (SAS), the Swiss Toxicological Information Centre (STIZ) and the Swiss Medical Products Side Effects Centre (SANZ).

   To be reported are all serious ADRs from Switzerland, all new or unlabelled ADRs and increase in the frequency of ADRs.

PRACTICAL ASPECTS

As in many other countries, it is advantageous to be represented by a local company. It is actually a legal requirement that the supplier is located in Switzerland.

Whereas significant proportions of the registration dossier can be submitted in English, it should be remembered that certain essential elements must be in one of the official national languages: French, German or Italian. Once again, local representation is an advantage in this aspect as well as in the general interactions with the IKS.

Another simple but important aspect is to ensure that the correct number of copies of the various individual components of the dossier are submitted as these are very important for the general administrative process to function efficiently and effectively. Particular care should be taken with the indexing and cross-referencing.

Registration fees have to be paid irrespective of the final outcome of the application. Some examples valid in 1999 are listed here:

• medicinal products with new active substances	Swiss francs	8,000
• medicinal products with known active substances		4,000
• phytopharmaceuticals		1,800
• accelerated approval request		5,000
• conducting an accelerated approval	(BRV)	60,000

FUTURE TRENDS

A revised Swiss medical product law has been developed covering the entire country to comply as far as is possible with EU compatibility. The new law is currently being discussed in Parliament and should be in place and functioning in the year 2001.

The main changes include:

a.) a shift of responsibility from the cantons to the federal authorities;

b.) the replacement of the IKS by a national medical products institute, an independent public body;

c.) exclusivity as per TRIPS ensured;

d.) simplified procedures for various categories of medicinal products such as generics, household remedies and orphan drugs;

e.) probable acceptance of parallel imports; and

f.) prohibition of mail order supply of medicines.

Dependent partially on the overall political trends, it can be anticipated that Switzerland will increasingly adapt to EU regulatory requirements. Previous decisions have also facilitated the adoption of guidelines from the International Conference on Harmonisation (ICH); this trend is likely to be maintained.

Despite Switzerland's political neutrality and somewhat isolated position, pharmaceutical regulatory requirements are likely to be harmonised with international requirements.

APPENDICES

A Organisation chart of IKS

B Comparison Professional Product Information with EU Summary of Product Characteristics

C IKS application form for registration (German)

D IKS application form for registration (French)

REFERENCES

IKS Guidelines concerning the documentation requirements for the registration of medicinal products for human use. *Registration Guidelines.* 16 December 1977. Update 14 May 1998. *IKS.* Berne, Switzerland.

Regulations about the clinical testing of medicaments. 18 November 1993. *IKS.* Berne, Switzerland.

IKS Annual Reports to 1999.

Information leaflet on accelerated registration procedures. November 1996. IKS. Berne, Switzerland.

ACKNOWLEDGMENT

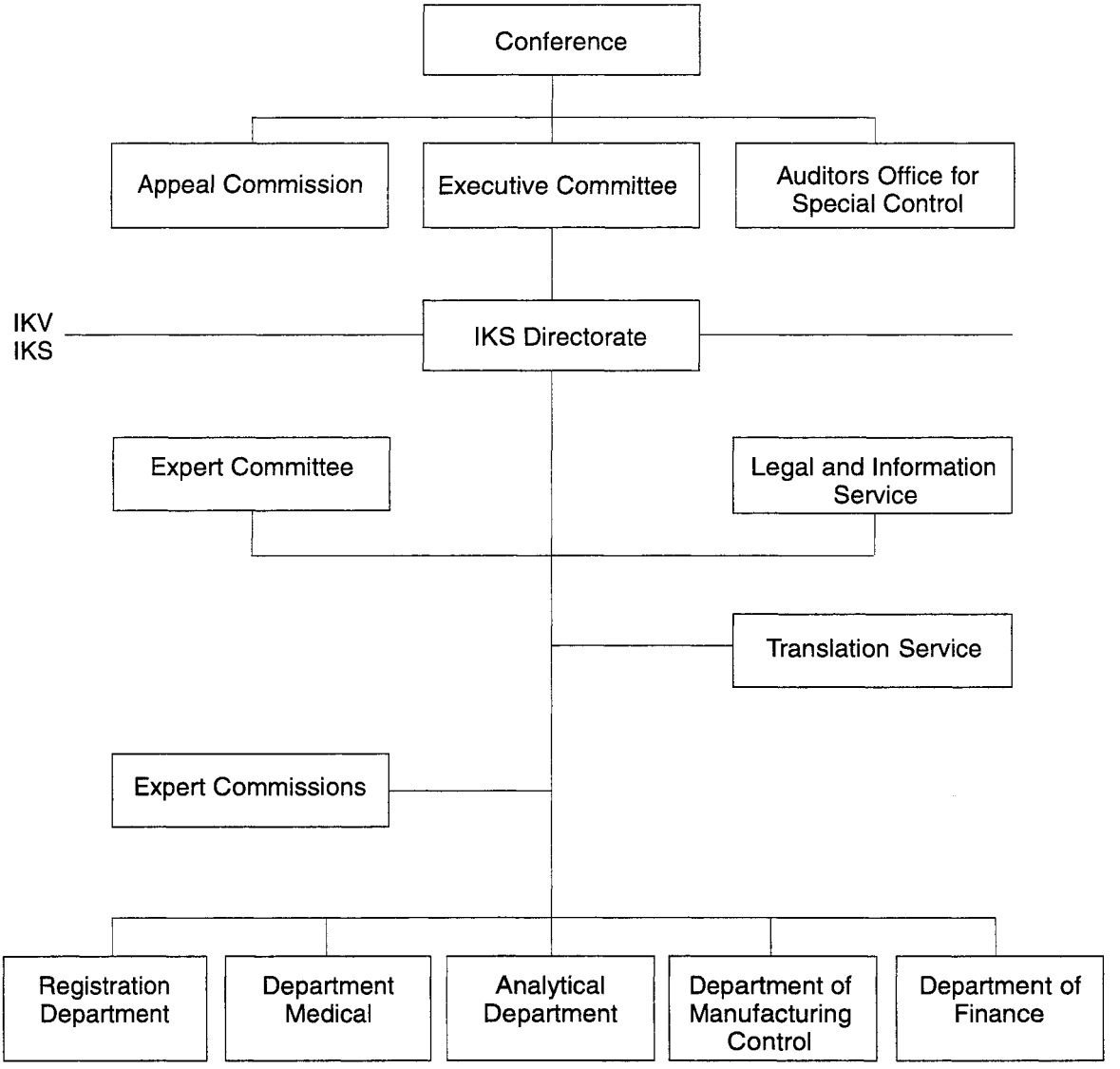
The invaluable advice given by Dr. Rolf Spang, IKS, Berne, is very much appreciated, as well as his assistance in reviewing this chapter.

ABOUT THE AUTHOR

Alan A. Chalmers has a BSc and PhD in pharmacy. He has 25 years of industrial pharmacy experience, beginning with Allen & Hanburys Research Ltd., United Kingdom (part of Glaxo). He subsequently worked for Ciba-Geigy Ltd. (latterly Novartis), mainly in Switzerland, where he gained extensive regulatory experience in all global markets. For the last 10 years Dr. Chalmers was Head of Regulatory Affairs for international markets including Central and Eastern Europe, the Middle East, Asia Pacific, Africa, and Latin America. He is currently an international pharmaceutical consultant. Dr. Chalmers is a member of the Royal Pharmaceutical Society of Great Britain, the Association of Swiss Industrial Pharmacists, the Drug Information Association and several other professional bodies. He has been a guest speaker at numerous international conferences

APPENDIX A

Organisation chart of IKS.



IKV = Interkantonale Vereinigung
(Intercantonal Conference)

IKS = Interkantonale Kontrolstelle für Heilmittel
(Intercantonal Office for the Control of Medicaments)

APPENDIX B

Comparison of Professional Product Information in Switzerland (CH) with the European Union Summary of Product Characteristics (EU).

Switzerland	European Union
1. Trade name of product	1. Trade name of product
2. Short characteristics of product	2. Qualitative and quantitative composition
3. Composition	3. Pharmaceutical form
4. Properties, therapeutic effects	4. clinical data
5. Pharmacokinetics	5. Pharmacological properties
6. Indications/usage	6. Pharmaceutical data
7. Dosage	7. Marketing authorisation holder
8. Restrictions of use	8. Marketing authorisation number
9. Unwanted effects	9. Date of first authorisation/renewal of authorisation
10. Interactions	10. Date of (partial) revision of text
11. Overdosage	11. Overdosage
12. Special remarks	12. Special remarks
13. Packages	13. Packages
14. Marketing authorisation holder	14. Marketing authorisation holder
15. Manufacturer	15. Manufacturer
16. Date of revision of text	16. Date of revision of text
	4. CLINICAL DATA
6. Indications	4.1 Therapeutic indications
7. dosage	4.2 Posology and method of administration
8a. Contraindications	4.3 Contraindications
8b. Precautions	4.4 Special warnings and precautions
10. Interactions	4.5 Interactions
8c. Pregnancy and lactation	4.6 Pregnancy and lactation
8b. Precautions	4.7 Effects on ability to drive, etc.
9. Undesirable effects	4.8 Undesirable effects
11. Overdosage	4.9 Overdosage

APPENDIX C—IKS Application Form for Registration (German)

Interkantonale Kontrollstelle
für Heilmittel (IKS)
Erlachstrasse 8
3000 Bern 9

Anmeldung zur Registrierung

(Bitte Erläuterungen beachten)

1. Bezeichnung oder Marke

Arzneiform
(Es ist für jede Arzneiform gesondert ein Formular zu verwenden)

Vertriebsfirma

Herstellerfirma

2. Zusammensetzung (inkl. Excipientien quantitativ und qualitativ

In Gewichts-bzw.biolog. Einheiten pro 1 Stück (Dragée, Tablette, Suppositorium, Ampulie usw.)
In % oder in mg pro mi (bzw.mg pro g) für Salben, Flüssigkeiten, Injektionslösungen, unabgeteilte Pulver, Teemischungen usw.

3. Anwendungsgebiet

Das Präparat soll empfohlen werden zur Behandlung oder Verhütung folgender Krankheiten, krankhaften Erscheinungen oder gesundheitlichen Störungen

Empfohlene Tagesdosis

4. Wissenschaftliche Dokumentation

Verzeichnis der **numerierten** Beilagen und Zusammenfassungen

5. Verkaufspreise (Schweiz und Ursprungsland)

sämtlicher Packungsgrössen inklusive Klinikpackungen mit Angabe der Menge ihres inhaltes

6. Beantragte Verkaufsart

☐

A. Verschärft rezeptpflichtig
B. Apotheken mit Rezept
C. Apotheken ohne Rezept
D. Apotheken und Drogerien
E. Alle Geschäfte

(Bitte entsprechenden Buchstaben ins Feld eintragen)

1st Publikumsreklame vorgesehen?*

☐

* Publikumsreklame ist nicht zulässig für Heilmittel
a) deren Verkauf auf die Apotheken beschränkt ist,
b) die lediglich provisorisch zur Registrierung angemeldet werden

(Bitte ja oder nein ins Feld eintragen)

Ort und Datum

Unterschrift des Gesuchstellers

APPENDIX D—IKS Application Form for Registration (French)

Office Intercantonal de
contrôle des médicaments (DICM)
Erlachstrasse 8
3000 Bern 9

Demande d´enregistrement

(Priére de consulter les instructions)

1. Désignation ou marque de la spécialité

Forme pharmaceutique
(Priére de remplir une formule pour chaque forme pharmaceutique))

Personne ou maison responsable de la vente

Fabricant

2. Composition qualitative et quantitative y compris les excipients

En unités de poids ou biologiques pour 1 piéce (dragée, comprimé, suppositoire, ampoule, etc.)
En % ou en mg par ml (ou en mg par g) pour les pommades, liquides, solutions injectables, poudres non divisées, tisanes, etc.

3. Champ d´application

Indication des maladies contre lesquelles la spécialité est recommandée comme préventif ou comme curatif

Dose journaliére recommandée

4. Documentation scientifique jointe a la demande

Liste des travaux **numérotés** et résumés

5. Prix de vente (en Suisse et dans le pays d´origine)

de chaque conditionnement, y compris des emballages-cliniques en en spécificant le contrenu exact

6. Mode de vente

☐

A. Sur ordonnance médicale «Ne repetatur» (NR)
B. Pharmacies sur ordonnance médicale
C. Pharmacies sans ordonnance médicale
D. Pharmacies et drogueries
E. tous les commerces

(Prière d´indiquer le mode de vente prévu par la lettre correspondante dans le rectangle ci-dessus)

La réclame publique* est-elle prévue ou non?

☐

* La réclame publique n´est pas autorisée pour les médicaments
a) dont la vente est limitée aux pharmacies
b) qui sont enregistrés provisoirement

(Prière d´indiquer oui ou non dans le rectangle ci-dessus)

Lieu et date

Signature du requérant