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W P F O C U S

A T T O R N E Y S A T L A W

**THE LICENSING OF THERAPEUTIC PRODUCTS IN SWITZERLAND
under the new Federal Medicinal Products and Medical Devices Act**



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THE LICENSING OF THERAPEUTIC PRODUCTS IN SWITZERLAND

*under the new Federal Medicinal Products and
Medical Devices Act*

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1. INTRODUCTION

On January 1, 2002 the Swiss Federal Act concerning Medicinal Products and Medical devices (the Therapeutic Products Act) entered into force after being passed unanimously by the Swiss Federal Council and Council of States on December 15, 2000. The entry into force of the Therapeutic Products Act marked a total reform of the handling of therapeutic products in Switzerland. Therapeutic products are now among the few goods to have a federal act dedicated especially to them.

The Act uses the term 'therapeutic product' as a generic term for medicinal products (meaning drugs including vaccines and blood products) and medical devices (meaning products for medical application whose main effect is not achieved by a medicine). In Switzerland there are around 8000 registered therapeutic products, 90% of them in the field of human medicine and 10% in the veterinary field. Turnover in medicinal products for human use amounts to around CHF 6 billion per year, accounting for around one-eighth of total health costs.

Pharmaceuticals are a major industry in Switzerland. They generate a bigger export surplus than any other sector. Just 10% of Switzerland's medicinal products are sold at home: 90% are exported.

The new Therapeutic Products Act makes the control of therapeutic products a federal responsibility. The Act merges the previous cantonal, intercantonal and federal legal provisions and modernises and updates them where necessary.

The purpose of the new Therapeutic Products Act is to guarantee that the population is supplied with top-quality, safe and effective therapeutic products. The Swiss Agency for Therapeutic Products

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(Swissmedic) is responsible for licensing and testing of these products. Swissmedic incorporates the previous Intercantonal Office for the Control of Medicines (IOCM) and the specialist Therapeutic Products Unit of the Swiss Federal Office for Public Health (SFOPH), which used to include the Pharmacy and Biological Departments.

2. RETROSPECTIVE: THE MEDICAMENTS SYSTEM BEFORE ENTRY INTO FORCE OF THE THERAPEUTIC PRODUCTS ACT
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2.1 THE INTERCANTONAL OFFICE FOR THE CONTROL OF MEDICINES (IOCM)

Before the entry into force of the Federal Medicinal Products and Medical devices Act, the cantons were almost exclusively responsible in the medicaments field. The Confederation was only responsible for licensing vaccines and immunobiological medicaments. To guarantee uniform control of medicaments, the cantons concluded the first concordat on medicaments as long ago as 1900. This agreement was totally revised four times, most recently in 1971. All the Swiss cantons, plus the Principality of Liechtenstein, were signatories of the Concordat. The control of medicaments was handled by the Intercantonal Office for the Control of Medicines.

The concordat settlement proved its worth over many years. The IOCM's findings were acknowledged to be of high quality, and it processed registration applications quickly by international standards. But the concordat had two weaknesses. One was that the IOCM's registration orders only had advisory status. Enforcement was left to the cantons. The other weakness was that the IOCM's rulings could only be referred to its Appeals Commission. Because the rulings were non-binding, the

Federal Supreme Court was powerless to subject them to substantive review.

A new medicaments concordat in 1988 would have rectified these weaknesses, but it failed to be ratified due to the withdrawal of two cantons.

2.2 MISCELLANEOUS PROVISIONS AT FEDERAL LEVEL

In addition to the medicaments concordat and the implementing regulations issued under it, there were already various regulations at federal level concerning the therapeutic products sector, before the Therapeutic Products Act came into force.

Most had come about piecemeal as the lawgiver's reactions to newly emergent risks to public health. Such provisions included the Epidemics Act, the Narcotics Act, the Pharmacopoeia Act, the Animal Diseases Act, the Medical devices Order, the Order concerning In Vitro Diagnostic Medical devices and the Federal Decree on the Control of Blood, Blood Products and Transplants. The SFOPH was competent for the control of immunobiological and blood products and the narcotics, and for issue of the Pharmacopoeia.

2.3 ISSUES OF OVERLAP AND GAPS IN THE LAW

The varied regulation of therapeutic products led to problems of overlap and gaps in the regulations. Thus, before entry into force of the Therapeutic Products Act, there was no definitive regulation of the import and export of therapeutic products. There was no statutory regulation of certain areas of in vitro diagnostic medical devices and problem substances such as silicon or amalgam, either.

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3. PRINCIPLES OF THE NEW THERAPEUTIC PRODUCTS ACT

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3.1 REGULATORY STRUCTURE

The new Therapeutic Products Act comprehensively regulates the handling of therapeutic products in Switzerland. The previous federal and intercantonal law on medicaments have now been brought together and enacted in a single Act. Unclear competences and legal loopholes have been resolved. The Act concentrates on basic provisions. It contains many provisions for delegation of the enactment of orders representing the law, and implementing orders, to the Federal Council and Swissmedic. This saves the Act going into detail and ensures a certain consistency. Special attention has been paid to a configuration compatible with European provisions.

The Act comprises 96 articles grouped into nine chapters. Chapter One contains the general provisions. Chapter Two, the real core of the Act, governs the handling of pharmaceuticals. Chapter Three governs the handling of medical devices. Chapter Four contains provisions about the Pharmacopoeia, clinical trials, and other matters. Chapter Five governs the legal form, organisation and tasks of Swissmedic. The other chapters contain enforcing rules, conditions of administrative procedure and legal protection, the legal elements of offences and the final provisions.

3.2 PURPOSE

The purpose of the Therapeutic Products Act, as of its predecessors, is to ensure that only high-quality, safe and effective therapeutic products are placed on the market (Therapeutic Products Act Article 1).

The aim of the law is also to protect consumers of therapeutic products from deception, to ensure moderate and appropriate use of therapeutic products and safe, orderly supply nationwide, including the necessary advice for this.

The Act applies to all therapeutic products handling (medicinal products and medical devices). It covers all processes, from the start of development of a therapeutic product up to its use in humans and animals. The Act also applies to narcotics used as medicinal products for medical purposes and to therapeutic processes directly associated with therapeutic products (e.g. somatic gene therapy).

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PRINCIPAL POINTS AT A GLANCE:

- Obligation to obtain approval for the manufacture, trading, import and export of medicinal products.
- Licensing obligation for all medicinal products placed on the market in Switzerland (except formulae magistralis and officinalis, individual preparations of house specialities for an establishment's own customers, and preparations for clinical trials).
- The approving and licensing authority is the Swiss Agency for Therapeutic Products (Swissmedic).
- The task of Swissmedic is no different from that of its predecessors: to guarantee quality, safety and effectiveness.
- Reporting obligation for undesirable effects of therapeutic products.
- Simplified licensing procedure for therapeutic products with known active agents, alternative medicine, house specialities and hospital pharmacies.
- Simplified second registration after expiry of the term of protection for the original preparation.
- Possibility of parallel imports of therapeutic products without patent protection.
- Regulation of import and export of therapeutic products.
- Ban on mail-order trading for therapeutic products not prescribed by a doctor.
- Public advertising allowed for therapeutic products not requiring a prescription.
- Ban on pecuniary incentives for the dispensing of therapeutic products.
- Regulation of clinical trials on humans.
- Own responsibility of manufacturers and sellers in the field of medical devices.
- Application of provisions for medical devices to all in vitro diagnostic medical devices.

In addition to their desired effects, therapeutic products often have undesired side-effects. These are consciously accepted when assessing the ratio of benefits to risk. Those best able to minimise risk are people who have a particular specialist knowledge. The Therapeutic Products Act therefore makes own responsibility the central principle of the whole therapeutic products system. Anyone handling therapeutic products, in other words manufacturing, distributing or dispensing them, must take all measures to ensure that the health of humans and animals is not endangered. He is responsible for this himself. To guarantee safety, the principle of approval applies to the field of therapeutic products. Thera-

peutic products require approval in the form of a licence. For medical devices, on the other hand, the principle of supervision applies. The distributor is required to ensure that the design of a medical device complies with the statutory requirements. There is no need for approval. The content of the Therapeutic Products Act is limited to protecting public health. The prices of medicinal products fall outside its scope. When paid by the social welfare insurance funds, the prices are governed by the Health Insurance Act, which prescribes the criterion of cost-effectiveness for the inclusion of therapeutic products on the 'Specialities List' (SL) of the Federal Social Insurance Office (FSIO).

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3.3 ENFORCEMENT

Although legislation in the field of therapeutic products is now a federal matter, the cantons continue to play an important role in enforcement. Thus the Therapeutic Products Act prescribes that the Confederation shall operate the Swiss Agency for Therapeutic Products (Swissmedic) with the cooperation of the cantons (Therapeutic Products Act Article 68), and that the cantons shall handle all enforcement functions not specifically assigned to the Confederation (Therapeutic Products Act Article 83).

The Confederation is responsible, in particular, for enacting regulations concerning specifications for therapeutic products, licensing therapeutic products, manufacturing and wholesaling approvals and import and export approvals. The cantons remain competent for monitoring the market. Theirs is the task of monitoring the dispensing of therapeutic products by pharmacies, drugstores, doctors' practices and hospitals. Inspections of business also fall partly within their competence. They are also responsible for appointing and supervising the ethical committees for clinical trials.

4. MEDICINAL PRODUCTS

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Medicines are products of chemical or biological origin which are intended for medicinal application to a human or animal organism, especially for the recognition, prevention or treatment of illnesses, injuries or disabilities (Therapeutic Products Act Article 4 paragraph 1a).

The control of therapeutic products is achieved through a system of manufacturing, licensing and trading approvals. The condition for the granting of an approval is always the applicant's warranty of safety and quality of activity. The Therapeutic

Products Act sets forth the principles for granting licences and approvals. Detailed provisions are enacted in the form of orders (the Order concerning Approvals in the Pharmaceuticals Field, the Order concerning Therapeutic products, the Order concerning the Advertising of Therapeutic products, the Order concerning Medical devices, the Order concerning Clinical Trials of Therapeutic products and the Order concerning the Pharmacopoeia).

4.1 MANUFACTURE

Approval is required to manufacture therapeutic products and mix them with feeds (Therapeutic Products Act Article 5). Exceptions are governed at the level of orders, whereby the manufacture of therapeutic products on a formula magistralis or formula officinalis, on the manufacturer's own formula, according to the Pharmacopoeia or other formulary recognised by Swissmedic may be subjected to a cantonal approval or registration obligation. A manufacturing approval is granted when the necessary technical and operating conditions are met and a suitable quality assurance system is in place. The competent cantonal authority inspects compliance with these conditions.

Medicinal products must be manufactured according to the rules of Good Manufacturing Practice (GMP). The existing international standards of GMP include those of the Pharmaceutical Inspection Convention (PIC), the World Health Organization (WHO), the EU and USA, and these must be respected. Quality assurance is required. Staff must be qualified for their tasks, and the premises and equipment must be appropriate. Hygiene must be guaranteed. Documentation of production processes must be produced, and the production stages recorded.

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There is an obligation on manufacturers and distributors of therapeutic products to register undesired effects and incidents with Swissmedic.

4.2 LICENSING OBLIGATIONS

Medicinal products ready for use, which are placed on the Swiss market, require a licence from Swissmedic (Therapeutic Products Act Article 9). They must meet the specifications of the Pharmacopoeia. The applicant must hold a manufacturing, import or wholesaling approval. A product is ready for use when it is in the final form dispensable to consumers. Medicinal products which are not ready for use may be traded unlicensed, but cannot be dispensed in that form. Cantonal licensing is no longer possible.

The following do not require a licence:

- Medicinal products on a formula magistralis. These include medicinal products made up in a pharmacy against a medical prescription for a designated person (or a group of people) or a designated animal (or stock of animals).
- Medicinal products on a formula officinalis. These are medicinal products made up in small quantities at a pharmacy or drugstore according to a special preparations monograph of the Pharmacopoeia or other such formulary recognised by Swissmedic, and which are intended for dispensing to the business's own customers.
- Medicinal products made up by a dispensing centre under the dispensing competence of the person responsible for making them, on that person's own formula, in small quantities intended for the centre's own customers.

Exceptionally, Swissmedic may approve dispensing of an unlicensed therapeutic product for use against life-threatening illnesses under specified

conditions, if a major therapeutic benefit can be expected from this and no similar medicinal product is available.

The condition for licensing a medicinal product is proof that the medicament or process is of high quality, safe and effective. In this regard, effectiveness must be weighed against risk. The benefit of a preparation must outweigh its potential risk. When the licence is granted, the applicant company becomes the licensee. As such it is responsible for the distribution of the medicinal product concerned and bears responsibility for medical supervision of the product. To ensure the exchange of information and access to the responsible persons, a domicile in Switzerland (residence, registered office or branch) is a condition of licensing.

4.3 LICENSING PROCEDURE

The Therapeutic Products Act identifies three different licensing procedures:

4.3.1 THE ORDINARY PROCEDURE

The ordinary licensing procedure (Therapeutic Products Act Article 11) requires submission of a full licensing file. The procedure comprises a thorough examination of the method of manufacture, composition, quality and shelf life of the medicinal product, its therapeutic effects and side effects. The results of the physical, chemical, galenic and biological and/or microbiological, pharmacological, toxicological and clinical tests must be submitted. The licensing procedure may also comprise an inspection of the manufacturing company. The licensing documents include information about the medicinal product. A distinction must be made here between the product technical information intended for persons authorised to prescribe,

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dispense or apply the product and the product information for the patient, addressed to consumers in the form of a package insert. The Annexe to the Therapeutic Products Licensing Order governs the required content of the information text in detail. The text must, in particular, include data on the composition of the product, the active agents, indications and contra-indications, dosage, side effects and warning notes.

If Swissmedic does decide to grant a licence, the licensee is entitled to place the medicament on the market, i.e. to distribute and dispense it.

The IOCM has, for some years, provided a *fast-track procedure*. The federal legislation preserves this option. It is used to handle licensing applications for important new therapeutic products especially quickly, under certain conditions and for correspondingly higher fees.

A concession is allowed for *second applications*. If a licence application is made for a medicinal product which is essentially the same, and intended for the same application, as an original preparation already licensed, the application may rely on the pharmacological, toxicological and clinical tests of the original preparation, provided the owner of the original agrees or the term of protection of the original has expired. The period of protection is 10 years. This ensures the protection of the first applicant required by Article 39 of the TRIPS (Trade-Related Intellectual Property Rights) Agreement, Annexe 1.6 to the GATT/WTO Agreement.

A LICENSING APPLICATION MUST CONTAIN THE FOLLOWING (THERAPEUTIC PRODUCTS ACT ARTICLE 11):

- The designation of the medicinal product and the names of the manufacturer and distributor;
Method of manufacture, composition,
- quality and shelf-life;
Proof of residue and withdrawal periods of
- therapeutic products for animals raised for food production;
Therapeutic and undesired effects;
- Marking, medicinal product information,
- type of dispensing and application;
Results of the physical, chemical, galenical,
- biological or microbiological, pharmacological and toxicological tests;
Results of clinical trials.
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A concession is also available for medicinal products already licensed in another country with similar control of medicinal products. In this case account is taken of the results of the tests carried out there. This does not, however, mean that licensing decisions of other countries are recognised in advance, as happens in the EU for medicinal products with known active agents (in the EU, registrations with new active agents are handled centrally by the European Medicines Evaluation Agency, EMEA, in London).

4.3.2 THE SIMPLIFIED PROCEDURE

The simplified licensing procedure (Therapeutic Products Act Article 14) can be used for certain categories of medicinal product, designated by Swissmedic, which guarantee the requirements of quality, safety and effectiveness. The following, in

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particular, are eligible: medicinal products with known active agents; preparations of alternative medicine; house specialities (these are medicinal products manufactured for stock by a pharmacy or drugstore according to the Pharmacopoeia or other recognised formulary, but which are only dispensed to their own customers); medicinal products made in hospital pharmacies for hospital use; and orphan drugs (important medicinal products for rare diseases).

The simplified procedure sets less strict requirements for the licensing file to be submitted.

Depending on category, certain documents do not have to be submitted, or a simplified proof of effectiveness is sufficient. This may, for example, apply to medicinal products with known active agents.

Parallel imports represent a special category within the simplified licensing procedure. The Act does not use the term 'parallel imports', which means that another marketer from a country with an equivalent licensing system makes a licensing application for a therapeutic product already licensed in Switzerland. A simplified procedure is provided for this. Nevertheless, a second licence cannot be given while the original preparation, licensed to the first applicant, is protected by patent. Swissmedic gives the owner of the original preparation the opportunity to furnish prima facie evidence of any patent protection (Therapeutic products Order, Article 18).

In practice there is wide scope for licensing parallel imports, which are possible for around 40% of the medicinal products available in Switzerland.

4.3.3 THE REGISTRATION PROCEDURE

If the conditions of the simplified procedure are met, but it is inappropriate to follow such a procedure, Swissmedic may prescribe a simple registration obligation, instead of a licensing procedure, for certain medicinal products or categories (Therapeutic Products Act Article 15). Preparations with a low hazard potential, such as herbal teas, cough sweets or individual homeopathic remedies without indication, will be eligible for this procedure.

4.4 VALIDITY OF THE LICENSING DECISION

A licence for a medicinal product is valid for a period of five years (Therapeutic Products Act Article 16). Nevertheless, Swissmedic may also adapt the licensing decision to changed circumstances during this period, or revoke it. Swissmedic may review groups of medicinal products, regardless of the period of the licence, and adapt or revoke the licensing decision according to the results of such collective review.

The licence is renewable on application before expiry of the licence period, provided the conditions continue to be met. A licence may be renewed more than once. Some medicaments have been registered for decades.

As an interim provision, registrations of medicinal products of the IOCM, the SFOPH and the Federal Veterinary Office (FVO), which were already effective on entry into force of the Therapeutic Products Act on January 1, 2002, remain valid for five years. Applications for licensing of medicinal products which have not hitherto required licensing but which do now require a licence must be submitted within one year of entry into force of the Therapeutic Products Act. In vitro diagnostic medical devices may continue to be circulated in accordance with the previous law until December 7, 2003.

4.5 IMPORT AND EXPORT

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The Therapeutic Products Act regulates the import and export of therapeutic products for the first time. The approval of Swissmedic is required for commercial import and export of therapeutic products ready for use and commercial trading in them abroad, when conducted from Switzerland (Therapeutic Products Act Article 18). Exceptions are allowed for medical personnel engaged in crossborder work, international organisations and import of small quantities for personal use. Approval is granted if the necessary technical and operating conditions are met and a suitable quality assurance system is in place. Those who already hold a manufacturing licence also receive such approval.

Medicinal products exported from Switzerland must be of equally high standard to those cleared for distribution in Switzerland. A double standard for export to developing countries is no longer lawful. The export of medicinal products which are banned in the country of destination, and trading in such products abroad, are prohibited.

4.6 DISTRIBUTION, PRESCRIPTION AND DISPENSING

Medicinal products are categorised as prescription and non-prescription on licensing (Therapeutic Products Act Article 23). Cantonal approval is required for retailing of both categories. A further category exists of freely saleable therapeutic products. These do not require retailing approval. Prescription medicinal products may only be dispensed by pharmacists on medical prescription (or without prescription in justified exceptional cases), and by other medical personnel in accordance with the provisions governing self-dispensing. Non-prescription medicinal products may also be dispensed at drugstores or by other persons with appropriate training.

The IOCM used to divide its registered medica-

ments into two dispensing categories requiring prescription and three dispensing categories not requiring prescription. Category A comprises medicaments with a stricter prescription obligation. One such prescription is only valid for dispensing of the medicament once at a pharmacy. A prescription for category B medicaments allows repeated dispensing at a pharmacy. Medicaments in dispensing Category C can be sold without prescription, but only at pharmacies. On the other hand, medicaments in Category D can also be sold in drugstores, and Category E products in all shops. The new Act allows this categorisation to be continued, though authorisation to dispense is more dependent on the training of the persons dispensing.

4.7 WHOLESALE, RETAIL AND MAIL-ORDER TRADING

Approval is required both for wholesaling and retailing of medicinal products except those freely saleable (Therapeutic Products Act Articles 28 and 30).

Swissmedic issues wholesale approvals if the necessary technical and operating conditions are met and a suitable quality assurance system is in place. The recognised rules of Good Distribution Practice (GDP) must be complied with. These include not only compliance with the conditions of distribution and storage, but a system of traceability and recall of defective products. In the EU, there are corresponding European Commission Guidelines (94/C 63/03).

The cantons grant approval for dispensing medicinal products in pharmacies, drugstores and other retail businesses.

Mail-order trading in medicinal products is in principle prohibited (Therapeutic Products Act Article 27). Mail-order trading means trading in goods offered in catalogues, brochures or adver-

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tisements which are dispatched to customers. The term also includes direct mail such as is offered by a health insurer. The cantons may grant approval for mail-order trading in medicinal products if a medical prescription has been obtained for the product concerned. This applies both to prescription and non-prescription medicinal products. In addition, appropriate advice and sufficient medical monitoring must be assured. The practice known as 'sending on' is not covered by the prohibition of mail-order trading, and is allowed in an individual case after initial contact in person with an expert adviser.

4.8 ADVERTISING

Advertising of medicinal products is in principle allowed (Therapeutic Products Act Article 31). However, public advertising, i.e. advertising aimed at the general public, is only allowed for medicinal products obtainable without prescription. Public advertising of medicinal products requiring a prescription is prohibited. Such advertising is also not allowed for medicinal products which contain narcotics or psychotropic substances, or which are commonly abused or may lead to habituation and dependency. Advertising for specialists is permitted for all medicinal products, provided it is directed exclusively at people who prescribe or dispense them.

The advertising of medicinal products must not be misleading or contrary to public order or good morals. It must not lead to excessive, abusive or wrong use of such products. Moreover, advertising of medicinal products which cannot be placed on the Swiss market is not allowed. How this provision can be enforced on crossborder media, however, is an open question.

In relation to advertising, it must be pointed out

that the Order concerning Health Insurance, Article 65, paragraph 6, precludes advertising of medicinal products paid for by the health insurance funds. Whoever places a non-prescription medicinal product on the market must therefore choose between advertising and acceptance by the health insurance funds.

It should also be noted that it is prohibited to promise pecuniary incentives to all persons who prescribe or dispense medicinal products, and that such persons are prohibited from accepting such incentives. Customary commercial rebates, and rebates justified on economic grounds, which impinge directly on price, are exempted.

4.9 BLOOD AND BLOOD PRODUCTS

The general provisions for medicinal products apply to blood and blood products. Additional provisions had already been provided, before entry into force of the Therapeutic Products Act, in a federal decree (the Federal Decree on the Control of Blood, Blood Products and Transplants). Apart from the provisions concerning transplants, these provisions are now incorporated in the Therapeutic Products Act.

Approval is required to take blood for transfusions and for the manufacture of medicinal products (Therapeutic Products Act Article 34). Swissmedic's approval is also required for each individual import of blood or blood products.

Where donors give blood, the party taking the blood is subject to special obligations to check the fitness of the donor. The donated blood must be tested for pathogens. Finally, there is an obligation to record all relevant data in detail. Such records must be kept for 20 years.

5. MEDICAL DEVICES

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5.1 NO OFFICIAL LICENSING

Medical devices are products, instruments, apparatus, in vitro diagnostic devices, software and other items intended for medical use but whose main effect is not achieved by a therapeutic product (Therapeutic Products Act Article 4 paragraph 1b). They include a very wide range of products such as implants, prostheses, infusion pumps, heart pacemakers, hearing aids, computer tomographs, dialysis appliances, ultrasound equipment, catheters, surgical stitching equipment and dressing material. The problem of the side-effects of such products differ from those of medicinal products.

The monitoring of medical devices is fundamentally different from the control of medicinal products. Such a device may be placed on the market without prior official approval. Instead, the person or company placing the device on the market is bound to monitor and maintain it systematically. In this respect, the Therapeutic Products Act follows the Europe-wide provision, whereby no official licence is required to place medical devices on the market. Nevertheless, unlike EU law, the Swiss Federal Therapeutic Products Act provides for the possibility of the Federal Council imposing an approval obligation to place certain medical devices on the market. A medical prescription obligation or registration obligation may also be introduced for medical devices which pose particular health risks.

In principle, medical devices may be imported and exported freely. The same applies to advertising. In both cases, orders may impose exceptions, where necessary for the protection of health.

A medical device, when used for its intended purpose, must not endanger the health of any person coming into contact with it. The claimed performance or effectiveness must be demonstrable (Therapeutic Products Act Article 45).

Those placing a medical device on the market must be able to prove that it meets the basic requirements. This will be the case when the manufacture, production and testing of the product are in accordance with internationally harmonised and officially recognised standards. The specific requirements for medical devices are contained in the Medical devices Order. This Order already applied before entry into force of the Therapeutic Products Act. It refers to the EU directives in the field of medical devices (90/385/EEC, 93/42/EEC and 98/79/EC). Specification of the basic requirements is left to international standards such as those issued by order of the European Commission or the European Free Trade Association (EFTA) by the European standards committees. As a member of EFTA, Switzerland participates in standardisation by CEN (the European Committee for Standardisation) and CENELEC (the European Committee for Electrotechnical Standardisation).

Those who place a medical device on the market must have followed a conformity assessment procedure. The conformity declaration (self-assessment) or conformity certificate (third-party assessment) documents that the medical device conforms to the basic requirements. Whether to involve an external assessment body depends principally on the hazard potential of the device to be checked.

5.2 CONFORMITY ASSESSMENT PROCEDURE

5.3 PRODUCT MONITORING AND MAINTENANCE

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In the absence of a licensing obligation, market supervision becomes very important. Whoever places medical devices on the market is bound to maintain a product monitoring system which allows the gathering and evaluation of experience with these devices, and to ensure that the knowledge thus gained is used in manufacture or further development (Therapeutic Products Act Article 47). There is an obligation to report undesired effects and incidents to Swissmedic.

Persons who use a medical device commercially or on third parties are subject to a maintenance obligation. They are bound to take all measures necessary to preserve the performance and safety of the medical device. Implementation of such maintenance must be demonstrable. For certain medical devices, e.g. technically complex products such as computer tomographs or breathalysers/narcosis equipment, the maintenance obligations may be governed by Order.

6. CLINICAL TRIALS

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6.1 PRINCIPLE

The licensing of a new therapeutic product requires clinical trials, which are a means of research. Freedom of research is guaranteed by the constitution (Article 20). Human experiments are restricted by the inalienable dignity of the human being.

The Therapeutic Products Act provides that clinical trials of therapeutic products on humans must be conducted in accordance with the recognised rules of Good Clinical Practice (GCP) (Therapeutic Products Act Article 53). At international levels, the Guidelines for Good Clinical Practice, devised by the International Conference of Har-

monisation (ICH), are authoritative. The new statutory provisions also rely on the former IOCM rules on clinical trials of therapeutic products, which were applicable from November 18, 1993. The participants in a clinical trial are the sponsor, the monitor and the tester. The sponsor is whoever arranges or funds a clinical trial. The sponsor bears the main responsibility for the trial, and must take out insurance. The monitor is a person designated by the sponsor and who monitors the course of the trial and ensures that the statutory provisions and the rules of GCP are complied with. The monitor compiles a report about the trial. The tester bears practical responsibility for carrying out a clinical trial and, in trials of therapeutic products, must be a doctor.

6.2 CONDITIONS AND REPORTING OBLIGATION

The following conditions must be met in order to conduct a clinical trial:

- The persons undergoing the trial must have expressly agreed to the trial of their own free will, in writing or by written certificate, after being thoroughly briefed on the nature of the trial and the risks and inconveniences associated with it (informed consent). Such briefing also covers claims for compensation and the right to revoke the consent at any time.
- Full compensation for any harm must be guaranteed.
- The competent ethical committee must be in favour of the trial.

The provisions are especially restrictive for trials on persons who are under age or lack understanding, and for trials in medical emergencies. Clinical trials must be reported to Swissmedic before execution. If Swissmedic makes no objection within a given period (30 days for therapeutic

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products and 60 days for medical devices), the trial can be started. Swissmedic may prohibit a trial or tie its implementation to conditions if the requirements are not met. It may also control the conduct of a clinical trial, but is not bound to do so.

6.3 ETHICAL COMMITTEES

The cantons appoint ethical committees which have to guarantee the protection of persons undergoing clinical trials. They assess the clinical trials especially from an ethical point of view, but also with regard to scientific quality. The ethical committees also check whether the expected benefit outweighs the foreseeable risks, whether legally acceptable consents have been obtained from the subjects of the trial, whether they are fairly compensated and whether sufficient insurance cover exists. The ethical committees include both doctors and people with wide experience in ethical, social and legal matters. The supervision of the committees is a matter for the cantons.

7. THE SWISS AGENCY FOR THERAPEUTIC PRODUCTS

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7.1 LEGAL FORM AND STATUS

The licensing authority for therapeutic products is the Swiss Agency for Therapeutic Products (Swissmedic), which has come about through the merger of the former IOCM and the Therapeutic Products Unit of SFOPH. Swissmedic is operated by the Swiss Confederation with the assistance of the cantons. It has the legal form of an institution in public law with its own legal personality. The Agency is independent in its organisation and management (Therapeutic Products Act Article 68). Swissmedic has its headquarters at the premises of former head office of the IOCM (Erlachstrasse 8, Bern). Important information can be obtained from its website (www.swissmedic.ch).

7.2 ORGANISATION

The organs of Swissmedic are:

- The Agency Council;
- The Director; and
- The Auditing Body.

The Agency Council consists of a maximum of seven members. These are appointed by the Swiss Federal Council, and the cantons have the right to apply to nominate three members. The Council's tasks are based on those of the Board of Directors of a limited company. It has to approve the Agency's strategy and organisation, its business planning and budget. The Council also monitors fulfilment of the service mandate and service agreement. It is also competent to approve the Agency's organisational regulations and scale of fees. It also approves the annual report and accounts. It has no right of technical instruction in the handling of individual expert questions.

The Director of the Agency is elected by the Federal Council, while the Agency Council itself

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appoints the other members of the directorate. The Director is responsible for the operational management of the Agency, on the principles of delegation and agreed objectives.

The auditing body audits the accounts, compliance with the service mandate and agreement and the proper functioning of the Agency's planning, control and reporting systems.

The Agency's staff are employees in public law. In exceptional cases, their appointments may be governed by the Swiss Federal Code of Obligations. As is known, Switzerland no longer has civil servants at federal level.

Swissmedic is self-funding and keeps its own accounts. The Confederation and cantons have given Swissmedic an endowment capital of CHF 14.5 million, of which the Confederation pays CHF 9.5 million and the cantons CHF 5 million. The cantonal share represents part of the compensation which the Confederation had to pay to take over the assets and liabilities of the IOCM.

The Agency funds itself from the Confederation's payments for the tasks allocated under its mandate and for its services as a public institution, from fee income and income from services. According to the service mandate, annual expenditure of CHF 49 million is expected, with a federal contribution of CHF 21 million.

throughout the therapeutic products sector. In particular, it grants manufacturing approvals and licences for therapeutic products, and import, export and wholesaling approvals (the cantons remain competent for retail approvals). Swissmedic is competent for market supervision, together with the cantons. It also issues the Pharmacopoeia. The Agency is also responsible for informing the public about special events concerning therapeutic products, which endanger health, and for issuing behaviour recommendations. Swissmedic also handles the international relations necessary to its tasks. The Federal Council grants Swissmedic a service mandate under which it can assign not only the statutory functions, but other tasks to the Agency. The Federal Department of the Interior concludes an annual service agreement with the Agency in the context of the mandate (Therapeutic Products Act Article 69).

To handle its tasks, including around 500 licensing applications per year, the Agency has 240 full-time positions at its disposal (by way of comparison, the American FDA employs 9000 people).

**8. ADMINISTRATIVE PROCEDURES AND
LEGAL PROTECTION**

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7.3 TASKS

Swissmedic is the authority which grants approvals

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The administrative procedures and legal protection are governed by the Administrative Procedures Act (SR 172.021) and the Federal Legal Protection Act (SR 173.110). Swissmedic is entitled to appeal against orders of the cantonal authorities within the scope of the Therapeutic Products Act. This is intended to ensure fair application and uniform enforcement of the Act.

There is a possibility of appealing to the Therapeutic Products Appeals Commission against the rulings of Swissmedic and other federal authorities under the Therapeutic Products Act. This is a new federal appeal body. In the election of its members, care must be taken to ensure that its membership includes reasonable legal and specialist expertise.

Administrative court appeals can be lodged against rulings of the Appeals Commission at the Federal Supreme Court. This marks a significant improvement in the legal protection, since hitherto the decisions of the Appeals Commission of the Intercantonal Association for the Control of Medicines have been final.

Born in 1946, he is a qualified attorney-at-law. After studying at Bern University and further studies at Lausanne and Paris, from 1971 to 1977 he worked for an international Swiss bank in Zurich, London and the USA. Since 1978 he has practised as a legal counsel and trial lawyer. His main fields of activity are civil, contractual and company law, competition law, financial law and medical law.

Dr. Rieben was the Secretary to the Board of the Intercantonal Association for the Control of Medicines.

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