Poland

Domański Zakrzewski Palinka Sp. k.
Marcin Matczak, Tomasz Kaczyński & Piotr Najbuk

1. OVERVIEW OF THE MEDICAL PRODUCT REGULATORY SYSTEM IN POLAND

1.1. Medical product regulators, such as government agencies

The key institutions regulating the medicinal product market include:

- the Ministry of Health, which issues decisions on reimbursement of medicinal products;
- the Office for the Registration of Medicinal Products, Medical Devices and Biocides (Registration Office), which issues decisions on marketing authorisations (see sections 2.1 and 2.4);
- the National Health Fund, which funds the national healthcare system; and
- the Main Pharmaceutical Inspector (MPI), which, for example, supervises medicinal product manufacturing and marketing requirements (see section 2.1).

1.2. Role of private parties

The role of private parties in medical product regulatory system in Poland is limited. Pharmaceutical sector representatives may participate in the process of applying the law under public consultation. They can submit informal applications, arguments and opinions.

Pharmaceutical companies are also taking steps aimed at self-regulation within the sector, eg by adopting a *'Code of good marketing practice in the pharmaceutical sector, cooperation with heath service representatives and patient organisations'*.

1.3. Types of health care products that are regulated in the jurisdiction (eg drugs, biologics, natural health products, traditional medicines, homeopathic medicines, medical devices)

The Pharmaceutical Law of 6 September 2001 is the main law regulating the medicinal products' market. It is largely based on EU law. The Pharmaceutical Law contains legal provisions concerning medicinal products, homeopathic medicines and traditional herbal products.

Medical devices are mainly regulated in the Medical Devices Law of 20 May 2010.

Dietary supplements and foodstuffs for special dietary purposes are regulated by the Act on Food Safety and Nutrition and secondary legislation adopted on the basis of that Act.

2. DRUGS

2.1. In general, what are the requirements for a drug to be manufactured, advertised and/or sold within the jurisdiction? (Do drugs need to be approved or licensed?)

According to Polish law, separate permits must be obtained for the production/import and marketing of a drug. The requirements regarding these permits vary and hence different entities issue such permits.

In the cases of a manufacturing permit and a permit for the import of a medicinal product from outside the EU/European Free-Trade Agreement (EFTA), the entity applying for a permit must:

- file a licence application;
- supply details of quality assurance, including fulfilment of Good Pharmaceutical Practice requirements;
- have the appropriate premises and technical and control equipment to manufacture, control and store the medicinal products listed in the application; and
- hire a qualified person.

Consent to manufacture/import a medicinal product is issued by the Main Pharmaceutical Inspector (Główny Inspektor Farmaceutyczny). Fees are charged for granting manufacturing permits, import permits, amendments to manufacturing permits and amendments to import permits.

To market a medicinal product, the marketing authorisation holder (MAH) must apply for authorisation from the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (an application for authorisation is subject to a fee).

To obtain authorisation, the MAH must file the appropriate application, containing all the required elements. The application must also include all the documents required under the Pharmaceutical Law, including details of the packaging, accompanying leaflet and the results of adequate clinical and non-clinical trials.

Medical products may also be introduced into trade under a central procedure in accordance with European Parliament and Council Regulation 726/2004.

2.2. Are there exceptions to the requirements (for clinical trials and compassionate use)?

Certain medicinal products do not require marketing authorisation. These include:

- medicinal products used exclusively for scientific research;
- medicinal products used by manufacturers;
- tested medical products used exclusively for clinical trials; and
- semi-finished products manufactured for use in the latter part of the manufacturing process implemented by the manufacturer.

Imported medicinal products may also be marketed without the need for authorisation if their use is necessary to save the life or health of a patient, provided that the given medicinal product holds marketing authorisation in

the country from which it is imported and holds a valid permit on admission into trade (a so-called special-purpose import).

Some medicinal products can benefit from the abridged procedure for marketing authorisation – the MAH does not have to provide the results of non-clinical or clinical trials in certain circumstances (see below). The MAH can show that:

- its medicinal product is the equivalent of a reference medicinal product already marketed in Poland or in another EU or EFTA member state (except Switzerland), and obtain consent from the MAH of the reference medicinal product to the results of clinical and non-clinical trials being used in the application;
- its medicinal product for humans is the equivalent of a reference medicinal product (generic product) already marketed in Poland or another EU or EFTA member state (except Switzerland); and
- at least eight years have passed from the day the first authorisation to market the reference medicinal product was issued in an EU or EFTA member state (except Switzerland) to the day the marketing application for the generic of a reference medicinal product is filed in Poland (data exclusivity).

Regardless of marketing authorisation, the generic of a reference medicinal product cannot be placed on the market until 10 years have elapsed from the day that the initial authorisation for the reference product was issued in an EU or EFTA member state, except Switzerland (marketing exclusivity). This 10-year period can be extended by 12 months if authorisation is obtained for a new indication or indications by the reference medicinal product which, in the Registration Office's opinion, are significant clinical benefits.

The MAH can also show that:

- the active substance or substances in the medicinal product have been both:
    - widely used for medical purposes in an EU or EFTA member state (except Switzerland) for at least 10 years from the first systematic and documented use of the substance in a medicinal product; and
    - deemed effective and of an acceptable safety level. In this case, the results of non-clinical or clinical trials are replaced or supplemented by scientific publications.

In the case of an application containing new therapeutic indications based on relevant non-clinical or clinical trials of substances widely used for medical purposes, one year's data exclusivity is granted from the day of the decision.

In addition, the MAH does not have to provide detailed documentation (for example, a description of the product manufacturing process and control methods) if it obtains the consent of another MAH to use the documentation of a medicinal product already marketed in Poland, of the same quality and quantity concerning active substances, and of the same pharmaceutical form.

2.3. Are there different rules for patented and generic drugs?

Despite the fact that Poland has no separate legislation concerning generic drugs, there are certain separate rules for this category of drugs.

The Pharmaceutical Law provides a streamlined process for generic drugs (reference equivalents of medicinal products) as concerns marketing (see section 2.2). In their case, there is no need to provide reports on mandatory trials when applying for marketing authorisation, provided that the reference medicinal product (of which the given generic drug is the equivalent) has already received such authorisation.

2.4. Who regulates the manufacture, advertising and sale of drugs?

As mentioned above, in Poland there are various procedures for issuing marketing authorisation for drugs and different procedures for issuing permits for their manufacture. Therefore, a number of institutions monitor a medicinal product at each stage of its existence, from the production line to the time at which it is transferred to the final user.

As regards marketing authorisation for drugs, the decision body is the Chairman of the Office for Registration of Medicinal Products (URPL) (see section 2.1). Prior to issuing or refusing to issue authorisation, he may order a medicinal product to be tested and may obtain an opinion of the Commission for Medicinal Products. Authorisation is issued for a period of five years.

The trade and advertising of medicinal products with marketing authorisation are supervised by bodies operating under the State Pharmaceutical Inspectorate, including the Main Pharmaceutical Inspector and Regional Pharmaceutical Inspectors. The duties of the State Pharmaceutical Inspectorate include:

- inspecting the conditions in which drugs are manufactured and imported in accordance with the requirements of Good Manufacturing Practice and checking the conditions of transport, reloading and storage of medicinal products and medical products;
- inspecting the quality of medicinal products in trade;
- inspecting pharmacies and other entities conducting retail and wholesale trade in medicinal products and medical products
- inspecting the quality of prescription and over-the-counter drugs prepared in pharmacies;
- inspecting the proper labelling and advertising of medicinal products and proper labelling of medical products;
- inspecting trade in intoxicating and psychotropic substances;
- opining on the fitness of premises designated as a pharmacy, warehouse or non-pharmacy trade outlet;
- keeping a register of generally accessible and hospital pharmacies and pharmacy outlets; and
- keeping a register of pharmaceutical warehouses and pharmaceutical manufacturing plants.

2.5 Are there fewer requirements for drugs that have been licensed/ approved in other jurisdictions?

Foreign marketing authorisations can be recognised in Poland under the following procedures:

2.5.1. Centralised procedure

The European Medicines Agency (EMA) in London can carry out this procedure. It enables a product to be marketed in all EU member states at once.

2.5.2. Decentralised procedure

Under this procedure, the product is registered in a member state which is specified as the reference state and then registered in secondary member states where the applicant would like the product to be marketed. This procedure is used as an alternative to the centralised procedure (see above), and enables a product to be registered in selected member states at the same time. The Chairman of the URPL is required to issue marketing authorisation within 30 days after acknowledging an assessment report prepared by the relevant body of the reference country.

2.5.3. Mutual recognition procedure

This applies where a medicinal product is marketed in the EU and the applicant applies for it to be registered in another member state. The Chairman of the URPL is required to issue marketing authorisation within 30 days after acknowledging an assessment report prepared by the relevant body of the reference country.

2.6. Is it possible to sell/buy drugs to/from other jurisdictions?

The sale and purchase of medicinal products from abroad is permitted once the conditions laid down primarily in the Pharmaceutical Law are met.

The Pharmaceutical Law permits the import of medicinal products, which it defines as any step taken to import a prepared medicinal product from beyond EU member states and EFTA countries. A permit from the Chairman of the UPRL is required to commence the business of importing (see section 2.1).

The purchase of medicinal products from the EU and EFTA countries is possible once a warehouse permit has been obtained from the Main Pharmaceutical Inspector. An undertaking wishing to operate a warehouse should submit a relevant application for a permit. A fee is charged for issuing a permit.

An undertaking conducting the business of operating a pharmaceutical warehouse is required:

- to be in possession of buildings enabling the proper conduct of wholesale trade;
- to employ a qualified person – a warehouse manager; and
- to meet the other requirements laid down in Article 78 of the Pharmaceutical Law.

National pharmacies may obtain supplies of medicinal products in warehouses within the EU and EFTA countries. A generally accessible pharmacy may only be run once a permit is obtained to run a pharmacy. The award, refusal to award, amendment, withdrawal or confirmation of

expiry of a permit to run a pharmacy all fall within the remit of the Regional Pharmaceutical Inspector.

Undertakings operating warehouses within the EU and EFTA countries may also import medicinal products by means of parallel import. Parallel import requires a permit of the Chairman of the URPL. The permit is issued for a period of five years and attracts a fee. Once a parallel import permit is obtained, the entity authorised to perform parallel imports is required to inform the following bodies of the anticipated date of marketing a medicinal product within the Republic of Poland at least 30 days prior to the planned date of marketing:

- the Main Pharmaceutical Inspector;
- the Chairman of the URPL; and
- the marketing authorisation holder within the Republic of Poland.

Not all medicinal products may be imported by means of parallel import. A product imported under this procedure must fulfil all the following conditions:

- the imported medicinal product has the same active substance – at the very least: the same medical indications, the same strength, the same means of administering the drug and the same form as a medicinal product with marketing authorisation within the Republic of Poland or a similar form which does not cause any therapeutic differences in relation to a medicinal product with marketing authorisation within the Republic of Poland; and
- the imported medicinal product and medicinal product with marketing authorisation within the Republic of Poland are, in the country from which the product is imported and within the Republic of Poland, simultaneously reference medicinal products or simultaneously equivalents of reference medicinal products.

Due to the nature of the parallel import procedure, marketing authorisation does not have to be obtained from the Chairman of the URPL, as referred to in section 2.1, for medicinal products that have obtained a parallel import permit.

2.7. Is it permitted to advertise drugs to consumers and, if so, are there restrictions on advertising?

2.7.1. Legislation and regulatory authority

Chapter 4 of the Pharmaceutical Law is the main legislation regulating the advertising of medicinal products.

The Ministry of Health Regulation of 21 November 2008 on the advertising of medicinal products (Advertising Regulation) governs, among other things:

- the terms and conditions for medicinal product advertising;
- the form of the advertisement and the data that it must contain; and
- how the advertisement will be circulated.

These provisions implement Directive 2004/27/EC on the Community code relating to medical products for human use (Code for Human Medicines Second Amendment Directive).

The general rules concerning advertising under the Act on Combating Unfair Competition 1993 also apply.

The Main Pharmaceutical Inspector (MPI) monitors compliance with the regulations on medicinal product advertising. Where the law is breached, the MPI can order that the recipient of its decision to:

- cease the medicinal product advertising;
- display the decision on the breach in the places where the advertisement was shown and publish a retraction; and
- rectify the breach.

2.7.2. Restrictions

It is forbidden to advertise medicinal products that:

- are not authorised for marketing;
- are marketed without obligatory marketing authorisation, on the basis of specific regulations; or
- contain information which is inconsistent with the Summary of Product Characteristics.

If an advert is to be aimed at the public generally, it cannot concern medicinal products that:

- are available only on prescription;
- contain psychotropic and intoxicating substances; or
- are on the list of reimbursable medicines.

There are several categories of conditions that must be met for the advertising of a medicinal product to be admissible, including requirements:

- that the advertising cannot:
  - be misleading;
  - involve benefits being offered or promised in exchange for purchasing a medicinal product;
  - be aimed at children, or contain any element aimed at children;
- that the medicinal product must be presented objectively with reliable information about its application.
- that the advertising must contain certain data set out in the Advertising Regulation (this data must be given in wording that complies with the Summary of Product Characteristics); content requirements are regulated separately for the advertising of medicinal products aimed at persons authorised to write prescriptions and advertising aimed at the general public; or
- that regulate the forms of advertising that are admissible and the content of mandatory warnings accompanying an advertisement.

3. MEDICAL/ASSISTED DEVICES (TOGETHER 'MEDICAL DEVICES')

3.1. In general, what are the requirements for a medical device to be manufactured, advertised and/or sold within the jurisdiction? (Do medical devices need to be approved or licensed?)

In order to market medical products, the manufacturer or authorised representative is required to provide notification to the Chairman of the

URPL 14 days prior to the planned date of marketing. Introduction into use also requires notification (see section 3.3 below).

Medical products must satisfy many of the requirements laid down in the Act on Medical Products, including basic requirements regarding design, manufacturing, packaging and labelling of a medical product. A medical product must be marked appropriately with the EC mark.

3.2. Are there exceptions to the requirements (for clinical trials and compassionate use)?

By way of exception, under the Act on Medical Products, the Chairman of the URPL may apply an administrative procedure allowing the marketing or introduction into use of a medical product within the Republic of Poland for which compliance assessment procedures have not been performed to confirm that the relevant requirements have been met. This procedure can be applied by the Chairman of the URPL where a product is necessary for specified preventative, diagnostic or therapeutic purposes.

A medical product that fails to meet the requirements laid down in the Act on Medical Products may be presented at fairs, exhibitions, demonstrations, presentations and scientific or technical symposia, provided that it is not used to collect or to test samples collected from participants of such events and that it contains information stating that it cannot be marketed or used until such time as the requirements laid down in the Act on Medical Products are met.

3.3. Who regulates the manufacture, advertising and sale of medical devices?

The producer or authorised representative is required to notify the Chairman of the URPL when a medical product is marketed for the first time. In certain cases, a notified body authorised by the Minister of Heath decides whether a medical product is compliant with the requirements for marketing and use.

A distributor and importer which has their place of residence or registered office within the Republic of Poland and which has marketed a product intended for use in this territory is required to notify the Chairman of the URPL of this fact immediately, at the latest within 7 days from the date the first product is marketed in the Republic of Poland.

The Chairman of the URPL conducts supervision in a 'negative' manner, meaning he may issue a decision prohibiting trade or use of a given medical product or summons the manufacturer or authorised representative to remedy any breaches of the Act. The Chairman of the URPL conducts supervision in cooperation with other public authorities, eg the Main Pharmaceutical Inspector and the State Sanitary Inspector. These authorities are required to inform the Chairman of the URPL of any improprieties ascertained concerning medical products.

3.4. Are there fewer requirements for medical devices that have been licensed/approved in other jurisdictions?

There are somewhat fewer requirements concerning the notification obligation. In the event of introduction of a medical product into use, the importer or distributor must notify the Chairman of the URPL of this fact within 7 days of the date of introduction into use. However, the first introduction into use requires notification to the Chairman 14 days prior to this fact.

3.5. Is it permitted to advertise medical devices to consumers and if so, are there restrictions on advertising?

The advertising of medical products to the public is permitted. The Act on Medical Products states that the advertising of medical products may not mislead recipients by:

- ascribing properties, functions and actions which it does not possess;
- creating the false impression that therapy or diagnosis using the product will definitely be successful or failing to provide information about the expected risk associated with use of the product in accordance with its anticipated application or a period longer than expected; or
- suggesting administration or properties of a product other than declared when performing the compliance assessment.

The general rules concerning advertising under the Act on Combating Unfair Competition 1993 also apply (see section 2.7).

3.6. Is it possible to sell/buy devices to/from other jurisdictions?

Such conduct is permitted in principle. Imported medical products must satisfy the same requirements as medical products manufactured within the Republic of Poland. A manufacturer that does not have its place of residence or registered office in a member state and which markets a product under a trade name is required to appoint an authorised representative for this product, ie an entity with its registered office in a member state, with which member state authorities and institutions can correspond concerning the manufacturer's duties laid down in the Act on Medical Products instead of with the manufacturer.

An entity that supplies or makes a product available following its marketing within the EU is a distributor.

An importer, on the other hand, markets a product originating from outside the territory of the member states.

Importers and distributors are required to act with due care in order to ensure the safety of products, in particular not to supply products or make products available that they know or should know, based on the information and professional experience they hold, do not meet the requirements laid down in the Act on Medical Products. Such entities should check whether the products they market, introduce into use, supply or make available are properly labelled and have appropriate instructions for use. Furthermore, they must cooperate with the Chairman of the URPL, for example, as regards monitoring the safety of medical products.

Prior to marketing a product, an importer is required to check whether:

- the manufacturer or authorised representative has conducted the proper procedure to assess the product's compliance;
- the manufacturer has appointed an authorised representative for the product;
- the product is labelled with the EC mark and the identification number of the notified entity that participated in the compliance assessment (if relevant); and
- the information provided by the manufacturer satisfies the basic requirements.

An importer with its place of residence or registered office within the Republic of Poland is required to hold and keep, among others, a copy of the compliance declaration and copies of compliance certificates, and to make them available on demand to the Chairman of the URPL for a period of five years from the date the product is marketed. During customs clearance of a product, the importer is required to submit copies of the necessary documents, such as compliance declarations and compliance certificates.

4. BIOLOGICAL PRODUCTS

4.1. In general, what are the requirements for a biologic to be manufactured, advertised and/or sold within the jurisdiction? (Do biologics need to be approved or licensed?)

In principle, biological medicinal products are allowed to be marketed once they have been approved under the central procedure (decision to award marketing authorisation) by the European Commission via EMA in accordance with Regulation 726/2004. Biological medicines subject to the obligatory central procedure are set out in Annex No 1 to the Regulation. If a given biological drug is not required to be registered centrally, it can receive marketing authorisation from the competent national authority, ie the Chairman of the URPL

The issues of manufacturing, distribution and advertising are subject to the exclusive jurisdiction of the national authority. The Main Pharmaceutical Inspector is responsible for supervision over these areas.

The requirements concerning the registration in the central procedure are laid down in detail in the guidelines issued by the EMA.

4.2. Are there exceptions to the requirements (for clinical trials and compassionate use)?

The requirements concerning clinical trials are laid down in the Pharmaceutical Law, which implements European legislation. In principle, the requirements are uniform for all medicinal products (see section 2.2).

4.3. Are there different rules for patented and generic biologics?

Yes. A full dossier is required for a patented (reference) drug, ie presentation of a full set of trials, whereas for a generic drug biocomparative tests are required to be submitted in the place of clinical trials.

However, if a biological medicinal product that is similar to a reference medicinal product does not meet the requirements as an equivalent of a reference medicinal product, in particular due to differences in the basic materials or processes for manufacturing such products, the authorised entity is required to present the results of clinical or non-clinical trials as regards the requirements that have not been met in accordance with schedule 1 to Directive 2001/83/EC as amended by Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products ([2009] OJ L242, 3).

4.4. Who regulates the manufacture, advertising and sale of biologics?

The bodies of the State Pharmaceutical Inspectorate.

4.5. Are there fewer requirements for biologics that have been licensed/approved in other jurisdictions?

No, the legislation has been fully harmonised with EU legislation.

4.6. Is it possible to sell/buy biologics to/from other jurisdictions?

Yes, on the same basis as other drugs (see section 2.6).

4.7. Is it permitted to advertise biologics to consumers and, if so, are there restrictions on advertising?

Yes, on the same basis as other drugs (see section 2.7).

5. NATURAL HEALTH PRODUCTS

5.1. Is there a category of products that includes traditional medicines, homeopathic medicines, dietary supplements, vitamins, minerals, or similar products ('Natural Health Products')?

The concept of 'Natural Health Products' containing all of the above-mentioned categories of products does not exist in Polish law. Traditional herbal medicinal products are distinguished in the Pharmaceutical Law as a particular type of medicinal product, which is subject to separate regulation, particularly as regards obtaining marketing authorisation.

A similar situation arises regarding homeopathic medicinal products, which have also been distinguished mainly due to the different rules for marketing (simplified procedure).

Polish law ascribes the other products mentioned, ie vitamins and minerals, to the category of dietary supplements. They are subject to numerous rules distributed among various items of national and directly applicable EC legislation.

5.2. If so, what are the requirements for Natural Health Products to be manufactured, advertised and/or sold within the jurisdiction? (Do Natural Health Products need to be approved or licensed?)

5.2.1. Traditional herbal medicinal products

The permits necessary to commence manufacturing traditional herbal medicinal products are issued in the manner described in section 2.1.

The sale and advertising of traditional herbal medicinal products requires marketing authorisation, as in the case of other medicinal products. However, in their case, the procedure for obtaining authorisation is significantly streamlined. The applicant is not required to submit safety tests and clinical trials, as in the procedures concerning other medicinal products. Instead, an application wishing to register a traditional herbal medicinal product is required to submit documentation indicating that the given product is not harmful in specified conditions of application. A necessary condition to receive such authorisation is the submission of documentation confirming the history of application, ie indicating that the product has been safely applied for at least 30 years, of which a minimum of 15 years is in an EU member state or an EFTA country. These requirements concerning the duration of application of products were laid down in order to confirm the traditional operation of such products.

5.2.2. Homeopathic medicinal products

Like any medicinal product, homeopathic products must obtain marketing authorisation in order to be legally sold and advertised. This authorisation can be obtained following submission of an application together with the documentation required by the Pharmaceutical Law in Article 10, with results, summaries and reports on the following tests*:*

- pharmaceutical: physico-chemical, biological or microbiological tests;
- non-clinical: pharmaceutical and toxicological tests; and
- clinical tests.

However, it should be borne in mind that the full procedure only applies to homeopathic medicinal products that have specified medicinal indications, ie contain information about the medical designation of the drug and which have not yet been applied in therapy or have not been described in medical literature.

If the *'active substance or active substances of a medicinal product have established medical application within the territory of a European Union member state, member state of the European Free Trade Agreement (EFTA) or party to the Agreement on the European Economic Area, for a period of at least 10 years, counting from the first systematic and documented application of this substance in a medicinal product and recognised effectiveness and an acceptable level of safety, the results of non-clinical or clinical trials are replaced or supplemented by publications from scientific literature'*, the applicant is not required to present trial results.

In addition, if an entity has obtained the consent of another marketing authorisation holder for *'use of documentation regarding a medicinal product with the same composition in terms of quality and quantity in relation to active substances and the same pharmaceutical form, earlier admitted to trade within the*

Republic of Poland, for the purposes of assessing an application', it is not required to present full documentation, as it is exempt from the need to submit the above-mentioned trial results.

Furthermore, for homeopathic medicinal products meeting certain conditions, there is a specific, streamlined registration procedure laid down in Article 21 of the Pharmaceutical Law. This can be applied to homeopathic products that:

- are administered orally or externally;
- do not contain indications regarding application on the label or leaflet; and
- are characterised by the appropriate level of dilution guaranteeing safety of use, ie they contain no more than 1/10,000 parts of the parent solution or no more than 1/100 of the smallest dose of active substance contained in a medicinal product issued on a Polish prescription.

Applications for marketing authorisation for such products require a small number of documents to be submitted and do not require evidence of therapeutic effectiveness.

The same procedures apply to obtaining permits to manufacture homeopathic medicinal products as in the case of other medicinal products (see section 2.5).

5.2.3. Dietary supplements

In order to produce dietary supplements, production plants have to apply for approval to the State County Sanitary Inspector or the State Border Sanitary Inspector. It is much easier and shorter to obtain such approval than to obtain a permit to manufacture medicinal products. In addition, a large number of undertakings conducting the business referred to in Article 63 of the Act on Food Safety and Nutrition are not required to hold a certificate. Such entities are only required to apply for entry into the register of production plants.

As opposed to medicinal products, the marketing of dietary supplements is regulated by the Act on Food Safety and Nutrition. An entity marketing a dietary supplement for the first time is required to notify the Main Sanitary Inspector of this fact by completing an electronic form available on its website. After receiving notification, the Main Sanitary Inspector may conduct proceedings to clarify whether the given product is compliant with the declared classification and whether it satisfies the requirements for a given foodstuff (including a dietary supplement). If such proceedings are conducted, the Main Inspector may obtain the opinion of the Dietary Supplements Unit operating under the Sanitary and Epidemiology Committee or require the entity being inspected to submit an opinion from a scientific entity or an opinion of the Office for the Registration of Medicinal Products, Medical Products and Biocidal Products.

5.3. Who regulates the manufacture, advertising and sale of Natural Health Products?

In respect of traditional herbal medicinal products and homeopathic medicinal products, marketing authorisation is issued by the body referred to in section 2.4, ie the Chairman of the Office for the Registration of Medicinal Products, Medical Products and Biocidal Products. He is also responsible for conducting inspections and the possible withdrawal of authorisation.

Matters associated with granting a licence to manufacture such products, on the other hand, fall within the remit of the Main Pharmaceutical Inspector (see section 2.4).

The bodies responsible for inspecting permits to manufacture dietary supplements are, as mentioned, State County Sanitary Inspectors and State Border Sanitary Inspectors.

The trade and advertising of dietary supplements are supervised by the Main Sanitary Inspector. It can also obtain the opinions of other bodies or order a manufacturer to obtain and submit an opinion (see section 5.2).

5.4. Are there fewer requirements for Natural Health Products that have been licensed/approved in other jurisdictions?

5.4.1. Traditional medicinal products

In the case of traditional medicinal products, the fact that the product is applied in another country facilitates obtaining the marketing authorisation necessary to market it in Poland as a traditional herbal medicinal product used as a medicine for medicinal purposes for a period of at least 30 years before the date of the application, including at least 15 years in an EU member state, a member state of the EFTA or a party to the agreement on the European Economic Area.

Whilst there is also a procedure enabling a product used in EU or EFTA member states for less than 15 years to be granted marketing authorisation, it is longer and less convenient for the producer.

5.4.2. Homeopathic medicinal products

The procedure for registering homeopathic medicinal products is streamlined for a large number of them that satisfy certain requirements (see section 5.1). However, there are no additional benefits arising from the fact that a product has received marketing authorisation in another country. In such a case, the procedures mentioned in section 2.5 can be applied.

5.4.3. Dietary supplements

Under Article 6(3) of the Act on Food Safety and Nutrition, dietary supplements that do not meet the requirements for marketing authorisation may still be authorised if they were:

'1) manufactured or marketed in another European Union member state in accordance with the law of that country, or

2) manufactured in a member state of the European Free-Trade Agreement or European Economic Area or were manufactured or marketed in the Republic of Turkey in accordance with the law of such countries to the extent that they benefit

from the free flow of foods under agreements entered into with the European Community
— provided that they do not constitute a risk to human health or life.'

5.5. Is it permitted to advertise Natural Health Products to consumers and, if so, are there restrictions on advertising?

In relation to homeopathic medicinal products, the same restrictions apply as in the case of other medicinal products (see section 2.7). The rules also apply to traditional herbal medicinal products, whereas in such a case, under the Ordinance of the Minister of Heath regarding the advertising of medicinal products, every advertisement must be accompanied by a notice with the wording: 'A traditional herbal medicinal product with certain indications arising exclusively from long-term use'.

The requirements concerning the advertising of dietary supplements are different. Above all, the Act on Food Safety and Food Products provides that the labelling of dietary supplements may not:

'1) mislead the consumer, in particular:
a) as regards the characteristics of a foodstuff, including its name, type, properties, composition, amount, longevity, source or place of origin, methods of manufacture or production,
b) by ascribing the foodstuff action or properties that it does not possess,
c) by suggesting that the foodstuff has particular properties, if all similar foodstuffs have such properties;
2) ascribe the foodstuff properties preventing or curing diseases or refer to such properties or contain nutritional or health statements inconsistent with Regulation 1924/2006.'

Furthermore, the Act provides that *'The labelling, presentation and advertising of dietary supplements may not contain information asserting or suggesting that a balanced and varied diet may not provide sufficient amounts of nutritional components for the organism'*. Preventing producers from including such messages is part of the policy intended to popularise healthy eating habits among citizens and to reduce the irrational consumption of dietary supplements.

The legislature also requires manufacturers of dietary supplements to market, present and advertise their products under the name 'dietary supplement'. This name may not be replaced with an (invented) trade name. This provision allows the simultaneous use of a trade name and the name 'dietary supplement' immediately next to it. This restriction is meant to prevent consumers from confusing a dietary supplement with a medicinal product.

5.6. Is it possible to sell/buy Natural Health Products to/from other jurisdictions?

5.6.1. Traditional medicinal products and homeopathic medicinal products

The rules for selling and buying such products are the same as in the case of other medicinal products (see section 2.6).

5.6.2. Dietary supplements

Dietary supplements imported from EU countries can be marketed in the Republic of Poland once the same conditions are met as for dietary supplements produced in Poland (eg they are subject to a notification obligation – see section 5.2) under the free flow of goods within the EC.

The import of dietary supplements from third countries is also permitted, although they also must satisfy the requirements mentioned in section 5.2. In addition, dietary supplements imported from third countries are subject to sanitary border controls. Sanitary border controls may also be applied to dietary supplements imported from the EU. Such controls are undertaken on the basis of an application to perform a sanitary border control of an entity operating on the food market responsible for the goods being imported or on the basis of a notice by a customs authority.

6. FUTURE DIRECTIONS

This year, EU legislation on pharmacovigilance is planned to be implemented into Polish law. The implementation is primarily to apply to provisions of Directive 2010/84/EC and Regulation 726/2004/EC and to implement Regulations 520/2012 and 198/2013. The draft amendments impinge upon the duties of marketing authorisation holders both at pre-registration stage (eg description of the system for supervising pharmacotherapy safety, risk management plan) and post-registration stage (eg processing notices regarding undesired action, additional monitoring of the safety of application of medicines).

In the short term, it is also planned to implement the amendments made by Directive 2011/62/EU amending Directive 2001/83/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. The amendments will impose new duties in this area upon manufacturers, importers and wholesalers.

Further planned amendments that could potentially affect the demand for and price of medicinal products concern the rules for the operation of the health service financed from public funds.

First, public authorities are taking steps to reduce the number of refundable items, eg by reducing the price of refunded drugs.

Secondly, there is a plan to decentralise the health service by creating regional National Health Funds instead of a single monopolistic payment body operating at nationwide level.

Thirdly, there is a plan to create legal frameworks for the effective functioning of additional heath insurance.