Life Sciences

Contributing editor
Alexander Ehlers

2018

GETTING THE DEAL THROUGH

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Law Business Research

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 3708 4199
Fax: +44 20 7229 6910

First published 2010
Ninth edition
ISSN 2042-4329

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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Preface

Life Sciences 2018

Ninth edition

Getting the Deal Through is delighted to publish the ninth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Brazil and the Netherlands.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgelleschaft mbB, for his continued assistance with this volume.

GETTING THE DEAL THROUGH

London
November 2017

Slovenia

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Kirm Perpar Law Firm, Ltd

Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

Healthcare in Slovenia is organised as a public service, provided through the public health-service network and by physicians and private legal entities providing services on the basis of concessions from the Ministry of Health. Healthcare services provided by private physicians are paid directly and in full by the patient.

The public health-service network is organised on three levels (primary, secondary and tertiary), which differ in many aspects, including, but not limited to, differences in organisation, allocation of providers in the territory and also from the perspective of specialisation and complexity of services provided.

Primary level care is organised through a widespread network of providers established by local authorities and private providers with concessions granted from municipalities. The primary level health-service network, which should provide equal accessibility to all people without discrimination, provides initial contact with doctors for diagnostics and treatment of acute and chronic diseases, promotion of health and healthy lifestyles, disease prevention, counselling and patient education. On the primary level, provision of urgent and emergency medical services and the ambulance service is also organised. The majority of all health services are provided by general practitioners, paediatricians, gynaecologists and dentists, and their scope is limited to outpatient services.

Secondary level care is organised by the state and consists of public hospitals and different private entities that have obtained concession from the Ministry of Health. Compared with the primary level, the network of providers is less widespread, although designed in a manner that should provide easy accessibility to health services for all patients. At the secondary level outpatient and inpatient health services are provided by specialised physicians. The scope of services provided differs slightly from one hospital to another, principally because of the differences in hospital size and the territories they cover. Private legal entities with concession predominantly provide outpatient services, although the number of private hospitals with concession also providing inpatient services has risen in recent years and the same trend is expected to continue in the future.

Tertiary level care currently consists of two university medical centres located in Ljubljana and Maribor, which work very closely with medical faculties in Ljubljana and Maribor. In both institutions, the most complex operations and treatments, research and educational activities are conducted simultaneously with healthcare services that are usually provided within the secondary level.

An integral part of the Slovenian healthcare system is the Health Insurance Institute of Slovenia (ZZZS), which provides compulsory health insurance while also being actively involved in all activities that determine the scope of health service programmes.

2 How is the healthcare system financed in the outpatient and inpatient sectors?

The Slovenian healthcare system is based on solidarity with a relatively high level of spending on health and social security alongside participation in a compulsory health insurance system. This is financed through three sources of funding: public funds and revenue; private funds collected through voluntary health insurance; and private funds for self-paying services. Both inpatient and outpatient sectors are financed in the same manner.

The majority of public funds are collected from healthcare insurance, which is compulsory for all citizens with permanent residence in Slovenia. Therefore, everyone pays contributions to the ZZZS, which afterwards distributes the collected funds to the healthcare providers as well as to other beneficiaries. The amount of contributions is determined proportionally under the solidarity principle, taking into account a person's income or other circumstances. Compulsory insurance healthcare services are either covered as a whole or as a proportion. Complete coverage of costs is provided mostly only for children, students and for certain illnesses and conditions. As for situations where the compulsory insurance does not cover the whole service, the difference in costs can be covered either by direct payment by the patient, payment by the insurance company, where the patient has concluded their voluntary health insurance, or, in some cases, from the government budget (prisoners, war veterans, etc).

In 2014, the healthcare expenditure in Slovenia amounted to €3.188 million. The structure of financing consisted of 71 per cent of public funds and 29 per cent of private funds. In 2014, the costs for inpatient services represented 47.3 per cent of total current expenditure for care; costs for outpatient services represented 22.3 per cent; and costs for medicines and other medicinal products represented 22.2 per cent.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

Advertising of medicinal products to the general public and healthcare professionals is governed by the Medicinal Products Act (ZZdr-2) and the Rules on advertising of medicines are adopted on its basis. In connection with advertising homeopathic and traditional medicines, rules on homeopathic medicines for human use and Rules on the traditional medicinal products of plant origin are also relevant. The abovementioned legislation implements Rules on advertising contained in EU Directive 2001/83/EC and other relevant EU legislation adopted within the Slovenian legal system.

4 What are the main rules and principles applying to advertising aimed at healthcare professionals?

The definition of advertising of medicinal products is very broad and includes all marketing activities designed to promote the prescription, supply, sale or consumption of medicinal products and is allowed only in connection with medicines that marketing authorisations have been obtained for. The advertising of advanced therapy medicinal products prepared on a non-routine basis is expressly prohibited under the relevant Slovenian legislation.

Advertising activities aimed at healthcare professionals can be conducted through publications in professional and scientific literature and directly through visits of adequately trained medical sales representatives. All advertising activities must be conducted in the Slovene language and in line with the information contained in the summary of product characteristics (SmPC) that was approved by the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (JAZMP).

The properties of medicinal products must be described objectively and without exaggeration and all information provided must be accurate, unambiguous, up to date and verifiable, and must promote efficient and safe use of the medicinal product. All quotations, tables and any other illustrative means originating from professional and scientific literature must be reproduced correctly and in a manner that objectively presents essential content and precisely indicates the cited sources. Information on new medicinal products could be also provided within sales promotion events, primarily for professional and scientific purposes, during which any accompanying hospitality must be limited.

Advertising activities conducted through personal visits of medical sales representatives, aimed at healthcare professionals employed by public institutions, are allowed only during the period dedicated to professional preparation. Furthermore, it is expressly forbidden to provide, supply, promise or offer healthcare professionals any gifts, pecuniary advantages or benefits of any kind, unless they are inexpensive and relevant to the practice of medicine or for pharmacy practice. Specimens of medicinal products may be provided only in cases when provision of special instructions on the application of medicinal products from the healthcare professional is necessary to the patient.

It should be also noted that the Forum of International Research and Development Pharmaceutical Companies, EIG (FIRDPC) adopted a Code on the informing and communication of prescription-only medicines to, and cooperation with, healthcare professionals, which is merely a recommendation and is not legally binding. Nevertheless, the Code is widely accepted and applied throughout the respective medicinal fields, and it is advisable to follow its rules and recommendations.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertising activities aimed at the general public are only allowed in connection with non-prescription medicinal products. All advertising activities and publications of any information intended for the general public is prohibited in relation to medicinal products containing psychotropic drugs or narcotics. Medicines used in vaccination programmes may only be advertised to the general public under special conditions and under exceptional circumstances.

All advertising activities must be conducted in a manner that makes clear that it is an advertisement and must clearly identify that the product advertised is a medicinal product. Every part of the advertisement, and all its constituent elements, must adhere to the information contained in the SmPC. The description of the medicinal product advertised must be balanced, objective and without any exaggeration regarding its characteristics. Safe and efficient use of medicinal products must be promoted.

All communications of an advertising nature must contain the name of the medicinal product, the international non-proprietary name of the active ingredient, even if only one is contained in the medicinal product, all information necessary for reasonable, correct and rational use of the medicine and an express legible warning on the importance of the usage instructions, emphasising that the instructions must be read carefully prior to use. It should also contain instructions advising on the potential risks and adverse side effects of the medicinal products, which should be obtained from a doctor or pharmacist. In the case of audiovisual media, this information must be provided both audibly and visually.

Advertising aimed at the general public must also refrain from all communications that could mislead the consumer on the importance of having consultations with healthcare professionals, the possibility of side effects associated with use of the medicinal product, the safety and efficacy of the medicinal product, the fact that the product advertised is a medicinal product and the positive effects the medicinal product could have.

The advertising of traditional medicinal products of plant origin and homeopathic medicinal products is also subjected to strict regulation.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

Based on our experience, the most common infringements have been committed in relation to rules governing advertising to healthcare professionals. In recent years, relevant rules have been changed in a manner that should decrease the possibilities of undue influence on prescription medicinal products. This is especially evident from the limitations on the visit times of healthcare professionals, the creation of a sales representative's register and the obligation to keep records of all conducted visits. Implementation of the above changes has, in practice, not been easy, which has led to some infringements still occurring.

7 Under what circumstances is the provision of information regarding off-label use to healthcare professionals allowed?

Slovenian law prohibits the conduct of any activities of an advertising nature that includes any information, including therapeutic indications, not contained in the marketing authorisation obtained or content of the approved SmPC. Provision of information on off-label use is therefore not allowed. Although it should be noted that in line with the common practice of pharmaceutical companies to seek different and innovative ways in which as much beneficial information as possible is provided, the provision of information regarding off-label use should not be exempt from such endeavours.

8 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sector?

ZZdr-2 governs the collaboration with healthcare professionals for the purpose of conducting non-interventional clinical tests of medicinal products and also from the perspective of donations, gifts and other transfers of value. The same rules apply for the collaboration with physicians in the outpatient and inpatient sector.

Guidance on how the collaboration should be conducted has been further elaborated in several other legal documents (which do not have a basis in legislation), so qualify as soft law. Regardless of their nature, those documents are very important and widely accepted. Such guidelines were, for example, issued by FIRDPC and by the Slovenian Commission for the Prevention of Corruption.

As of 2017 new Pharmacy Practice Act (ZLD-1) is in force and collaboration of the pharmaceutical industry with pharmacists and pharmacies is subjected to strict limitations that should prevent undue influence possibly effecting professional independence and guarantee that pharmacists and pharmacies will focus on goals providers of public service should focus on.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

Rules on collaboration with healthcare professionals are strict and extensive, and apply to, among other things, promotional activities, donations and conduct of clinical trials. The main principles common to the aforementioned are prohibition of undue influence, provision of transparency and protection of public funds.

In respect of promotional activities one of the most important rules is the rule prohibiting supply, offers or promises of gifts, pecuniary advantages or benefits in kind, to persons qualified to prescribe or supply medicinal products, unless they are of small value and relevant to the practice of a healthcare professional. Special limitations also exist in connection with promotional events, which must be predominantly intended for the provision of new knowledge to healthcare professionals and their agenda must be accordingly limited to professional and scientific objectives. Hospitality in the form of accommodation, registration fees and travel expenses is allowed, but must be strictly limited to healthcare professionals (not spouses and family) and be of a reasonable extent and of secondary importance.

Furthermore, it should be also noted that all donations from the pharmaceutical industry should be provided to healthcare institutions and not directly to individual healthcare professionals. As described in question 14, manufacturers are subject to an obligation to disclose transfers of value.

Collaboration with healthcare professionals employed by public institutions, for the purpose of conducting of non-interventional clinical tests, is possible only if consent has been obtained by the employer. All payments made directly to healthcare professionals are allowed only in connection with services provided outside their employment within their spare time.

Provisions of ZLD-1 also adhere to the spirit and ideas embodied in other relevant legislation and should therefore enable achievement of same goals also in respect of collaboration with pharmacists and pharmacies.

10 What are the most common infringements committed by manufacturers with regard to collaboration with healthcare professionals?

Based on past experience, the infringements commonly occurred in connection with donations, which were often in the form of covering costs for scientific events provided directly to individual healthcare professionals instead of healthcare organisations. There were also numerous cases where excessive hospitality was provided, such as paying for trips and luxury accommodation.

Furthermore, engaging healthcare professionals to provide their services to manufacturers (eg, lecturing, advisory services) has, in certain cases, been abused in order to influence the healthcare professional and gain undue advantage for the manufacturer. Such attempts were observed primarily in relation to healthcare professionals who were members of expert groups with the potential to influence the prescription of medicinal products on a larger scale.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The law does not govern the collaboration of the pharmaceutical industry with patient organisations. The FIRDPC adopted the Code of practice on relationships between the pharmaceutical industry and patient associations, which corresponds with the rules adopted by the EFPIA. Regardless of their nature, those rules are very important and widely accepted in practice.

In line with the main principles of the Code adopted by the FIRDPC, collaboration must be carried out in a manner that independence of patient organisations is guaranteed and all partnerships between patient organisations and the pharmaceutical industry must be based on mutual respect and its objectives and scope shall be transparent. Provision of any support must be based upon written agreement and must be clearly acknowledged and publicly disclosed. Patient organisations must not promote particular prescription-only medicine, nor should such action be requested from them. Pharmaceutical companies may not request from a patient organisation that it becomes its sole funder or sole sponsor, or to be granted such status in relation to any of the activities conducted. Rules very similar to those applying to healthcare professionals, apply with respect to the organising of events held by pharmaceutical companies intended for patient organisations.

12 Are manufacturers' infringements of competition law pursued by national authorities?

There is no record of manufacturers' infringements of solely national competition law. In recent years, one of the larger Slovenian manufacturers has been involved in a European Commission procedure against pharmaceutical companies concluding 'pay-for-delay agreements' and was in the end found guilty of the infringement and ordered to pay a fine. Based on publicly available information, the fine has been paid, but legal redress has been sought.

In recent years, there was also a procedure by the Slovenian Agency for Protection of Competition (AVK) against several Slovenian wholesale distributors of pharmaceutical products, which were found guilty of violations of competition law, specifically of illicit concerted practice. The decision delivered by the AVK has been confirmed by the Slovenian Administrative Court and also by the Slovenian Supreme Court. The decision on fines has not yet been issued.

13 Is follow-on private antitrust litigation against manufacturers possible?

Such follow-on private antitrust litigation is possible, but there is no available record of case law in which a claimant succeeded with his or her claim.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

Most of the relevant rules have already been described in question 9. As most funds are public, pharmaceutical manufacturers must also adhere to provisions of the Integrity and Prevention of Corruption Act. Therefore, all transfers of value, including, but not limited to, gifts, must be accordingly reported unless they are of insignificant value. Pharmaceutical companies must also refrain from all actions that could result in undue influence on healthcare professionals or other decision makers in the healthcare sector. All contracts concluded with a public entity with a value in excess of €10,000 must contain an anti-corruption clause, which stipulates that the agreement is null in case of undue influence in the form of the provision of gifts, pecuniary and non-pecuniary advantages, etc.

In line with ZZdr-2, pharmaceutical manufacturers are obliged to establish a register of sales representatives and have a duty to register all contact between medical sales representatives and healthcare professionals. Information from both registers must be submitted to the JAZMP.

From the perspective of the EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations adopted by the FIRDPC, under which all transfers of value to healthcare professionals and healthcare organisations from 2015 onwards must be disclosed publicly, is the most important document.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

The provisions of the Act on medical devices on advertising are similar to the provisions in ZZdr-2, but are less detailed and less restrictive from the perspective of advertising to healthcare professionals and the general public. Regulations regarding collaboration with healthcare professionals are also far less detailed. The main reason for less detailed regulation is the absence of as strict EU legislation within the field of medicinal products.

Pharmaceuticals regulation

16 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

ZZdr-2 governs the granting of marketing authorisations and the placing of medicinal products on the market. Additional rules are contained in the Rules on the marketing authorisation for medicinal products for human use. Slovenian legislation closely follows EU Directive 2001/83/EC on the Community code relating to medicinal products for human use.

17 Which authorities may grant marketing authorisation in your jurisdiction?

The JAZMP is authorised to conduct a national procedure for the marketing authorisation of medicinal products and it also acts as a representative of Slovenia and delivers decisions in respect of Slovenia in the mutual recognition procedure and decentralised procedure governed by EU law. Both procedures laid down by EU legislation were accordingly implemented in the Slovenian legal system.

The marketing authorisation for medicinal products could be also obtained within the centralised procedure conducted in accordance with Regulation (EC) No. 726/2004, which must be read in conjunction with Regulation (EC) No. 1901/2006 of the European Parliament and the Council on medicinal products for paediatric use and Regulation (EC) No. 1394/2007 on advanced therapy medicinal products.

18 What are the relevant procedures?

Marketing authorisation may only be granted to an applicant established within EU territory. As stated in question 17, marketing authorisation could be obtained within the national procedure run by the JAZMP, or within the mutual recognition or decentralised procedure in which the JAZMP acts as Slovenia's representative and delivers decisions for Slovenia at the end of the procedure. Irrespective of the procedure chosen, an application must be accompanied by particulars listed in article 8, paragraph 3 of Directive 2001/83/EC. Easements regarding documentation are applied to the marketing authorisation of generic medicinal products.

If marketing authorisation for the medicine has already been obtained in the centralised procedure, prior to the marketing of the medicinal product, a national identification must be obtained from the JAZMP.

19 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

The JAZMP has the authority to withdraw the marketing authorisation it has granted if the medicinal product under the same proprietary name has not been marketed for three consecutive years from the time that the marketing authorisation became effective.

In particularly substantiated cases, the JAZMP may decide that marketing authorisation for the medicinal product will not be withdrawn if it is necessary for the provision of an uninterrupted supply of medicinal products or for the protection of public health.

20 Which medicines may be marketed without authorisation?

Marketing without marketing authorisation is possible for galenical preparations prepared in pharmacies for direct distribution that are described in the *European Pharmacopeia* and its Slovenian appendices are in line with formulations described therein and extemporaneous preparations prepared in line with prescriptions issued by a doctor, dentist or veterinarian. Marketing without authorisation is also possible for certain veterinary medicinal products intended solely for use with certain animal species.

In respect of advanced therapy medicinal products prepared on non-routine basis, a special permit for preparation is required in place of a marketing authorisation.

Also, a marketing authorisation is not required for conducting clinical trials. Under extraordinary circumstances (eg, infections, threat of epidemic and pandemic outbreak, intoxication or radiation), the marketing of certain medicinal products without marketing authorisation could be allowed. Physicians responsible for a patient's treatment can also demand medicine that has not been granted a marketing authorisation (see question 21). On the grounds of prior permission from the JAZMP, distribution of medicinal products under the compassionate-use programme could be allowed in accordance with article 83 of Regulation (EC) No. 726/2004.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Article 5(1) of EU Directive 2001/83/EC has been implemented within the Slovenian legal system, which provides physicians providing a patient's treatment with an option to, under his or her full personal responsibility, demand medicinal products without a marketing authorisation for Slovenia, if he or she finds it necessary. A concluding opinion to such a demand must be obtained by the head of the Slovenian clinic that specialises in the treatment of the relevant diseases. On these grounds, the application for a temporary marketing authorisation could be filed with the JAZMP by wholesale distributors of pharmaceutical products.

Manufacturers of medicinal products that sponsor ongoing clinical trials that are approved by the JAZMP, or an applicant for a marketing authorisation in a centralised procedure according to article 6 of Regulation (EC) No. 726/2004, may file an application for a permit for distribution of medicinal products under the compassionate use programme, under which it is allowed to distribute to groups of patients with chronic or severe diseases who cannot be sufficiently cured with medicines that have marketing authorisations.

Rules for both of the above-mentioned exceptions are further elaborated by Regulations on the conditions and procedures for granting import permits for medicinal products for human use.

Pricing and reimbursement of medicinal products

22 To what extent is the market price of a medicinal product governed by law or regulation?

Rules on price regulation do not differ between the outpatient and inpatient sectors. Prices of medicinal products not financed from public funds are not regulated and are freely determined by the manufacturer or distributor.

In respect of medicinal products financed from public funds, the maximum allowed price (MAP) is determined in the mandatory procedure run by the JAZMP, which must be initiated by an authorisation holder prior to launching the medicinal product on the market for the first time (question 25).

Owing to ongoing efforts to reduce healthcare expenses, the JAZMP's competence to declare mutual interchangeability of medicinal products on the grounds of the application filed by the holder of a marketing authorisation, or on the grounds of the initiative of an expert institution, is also relevant as compulsory health insurance run by the ZZZS, in respect of medicinal products from certain therapeutic groups, only covers the costs of medicinal products with the most effective balance between costs and the product's therapeutic effectiveness. Irrespective of the limitation described, costs of medicinal products listed on the positive or intermediary list are covered if it is required for treatment due to health reasons.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

Slovenian legislation does not govern any mandatory negotiations, as the majority of decisions are delivered within the administrative procedure.

The decisive factor for the coverage of costs of medicinal products is inclusion of the product on the positive or intermediary list, as proportions of coverage differ. A decision on inclusion on the positive or intermediary list is delivered by the ZZZS in the administrative procedure. As indicated in question 22, decisions delivered by the JAZMP on the MAP and mutual interchangeability of medicinal products are also very important in respect of the coverage of costs.

Irrespective of the MAP decided upon, holders of marketing authorisations and wholesalers of medicinal products might, on a voluntary basis, enter into negotiations and conclude separate agreements for lower prices of medicinal products with the ZZZS, providers of health services funded from public revenue and several other subjects.

24 In which circumstances will the national health insurance system reimburse the cost of medicines?

Rules on the coverage of costs do not differ between the outpatient and inpatient sectors. As indicate in question 23, the ZZZS, as provider of compulsory health insurance, covers the costs for the most effective medicinal products from certain therapeutic groups, unless, due to health reasons, treatment with other medicinal products from a positive or intermediary list is required. Coverage of costs does differ from one list to another (see question 2).

The value of costs covered (not the percentage of coverage), is determined by the ZZZS for medicinal products from each therapeutic group, taking into account the JAZMP's decision on the MAP and interchangeability of medicinal products. The value must not be lower than the price of the cheapest medicinal product from certain therapeutic groups. Costs of medicinal products prescribed under the compassionate use programme are covered by the manufacturer.

As sole responsibility for the prescription of medicinal products lies with physicians, a patient cannot be sanctioned for a prescription for off-label purposes. Therefore, medicinal products are issued to the patient under the standard terms and conditions of health insurance described above. Although the ZZZS is competent for ex-post prescriptions' supervisions, if irregularities are discovered, contractual penalties could be imposed on providers of health services.

Update and trends

Based on developments in previous years, significant changes in the relevant legislation are not expected at this point. However, it should be noted that several new implementing regulations are expected to be passed on the basis of legislation currently in force.

25 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The decision regarding the pricing of medicinal products that are financed from the public revenue is delivered by the JAZMP in a procedure stipulated by ZZdr-2 and by the Rules on the Pricing of Medicinal Products for Human Use. The same rules also stipulate the criteria and procedures for determination, amendments and publications of regulated prices of medicinal products.

MAPs are determined on the principle of external price referencing, taking into account prices of medicinal products in Austria and France and Germany. If the medicinal product is not marketed in any of the reference countries, MAPs are formulated that take into account the value of the manufacturer's element of price and the profit margin pharmaceutical wholesale distributors are entitled to. MAPs are determined twice a year and a decision is usually delivered within 90 days.

In cases when, due to the size and other characteristics of the Slovenian market, the MAP does not enable authorisation holders to supply the market, under article 159 of ZZdr-2, an extraordinary higher allowed price (EHAP) may be determined for medicinal products for human use. Such a procedure falls within the JAZMP's competence and is further defined by the Rules on the Pricing of Medicinal Products for Human Use.

Under the Healthcare and Health Insurance Act ZZZS is the competent authority for the delivery of decision regarding financing from public revenue finance within the administrative procedure. As indicated in question 23, the percentage of purchase cost coverage differs between different lists of medicinal products, varying from zero per cent for unlisted medicinal products up to 100 per cent for medicinal products listed on positive lists. The ZZZS's decision regarding listing on one of the lists is based upon several different factors including, but not limited to, the importance of the medicine for public health, priority tasks of the healthcare programme, therapeutic importance of the medicine and the assessment of the medicine's pharmaceutical economic data. Another medicinal product from a therapeutic group can be added to any of the lists only if it can be demonstrated that it has equal or greater therapeutic and economic value compared to an existing medicinal product.

The percentage of purchase costs of the medicinal products not covered by the ZZZS is usually covered by the voluntary health insurance. (For additional information, see question 2.)

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

Under ZZdr-2, mandatory discounts for medicinal products can be determined where it can be established that such a discount is in the public interest for the purpose of securing financial sustainability for the financing of medicinal products from the public revenue, or in cases where competition does not exist or is not sufficient. Discounts are prescribed by a decree issued by the Minister for Health for a 12-month period.

Discounts do not apply to medicinal products, distribution of which is permitted under the compassionate use programme and for medicinal products included on the list of essential or necessary medicinal products. It does not apply to medicinal products included on the list of interchangeable medicinal products that an MAP has been determined for and to medicinal products that an EMAP has been determined for. A marketing authorisation holder can also avoid such discounts if a special discount is proposed for certain subjects.

Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Under article 23 of ZZdr-2, all subjects included in the marketing of medicinal products are obliged to immediately notify the JAZMP of any suspicion that medicinal products have been falsified or are of inadequate quality. In order to aid detection of falsified medicinal products, packaging of certain groups of medicinal products must contain protective element. The JAZMP has the authority to deliver its decision on whether a medicinal product should be recalled and decide whether the public should be notified. Pharmaceutical inspectors organised within the JAZMP are authorised to search premises, prohibit the marketing of medicinal products and to order the destruction of medicinal products.

The above-mentioned provision of ZZdr-2 implements the provisions of Directive 2011/62/EC, amending EU Directive 2001/83/EC in the Slovenian legal system. One of the main reasons for adopting ZZdr-2, which was enforced in 2014, was the implementation of EU legislation within the Slovenian legal system.

As counterfeiting and illegal distribution of medicinal products may also infringe trademarks or patent rights or both, a holder also has an option to file an application for customs action governed by EU Regulation 608/2013.

28 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

As described in question 5, advertising of prescription-only medicinal products to the general public is not allowed. However, in recent years, the central database of medicinal products, which also includes an approved summary of product characteristics and instructions for use, has been made publicly available. As of 2017, Rules on the central database of medicinal products for human use, adopted on the ground of ZZdr-2, govern its content and functioning.

29 Outline major developments to the regime relating to safety monitoring of medicines.

In order to implement the provisions of Directive 2010/84/EU and EU Directive 2012/26/EU on pharmacovigilance in the Slovenian legal system, the ZZdr-2 was adopted in 2014. The rules and guidelines are further stipulated by the Rules on pharmacovigilance of medicinal products for human use. Healthcare professionals are obliged to report any suspicions of adverse reactions to medicinal products to the national pharmacovigilance centre (as of 1 July 2017 this is JAZMP) no later than within 15 days of its identification. Such a report could be also submitted by patients or their relatives. The obligation to establish a sufficient pharmacovigilance system is also imposed on holders of marketing authorisations. Therefore, authorisation holders are obliged to appoint sufficiently qualified responsible persons who must ensure that the pharmacovigilance system is established and maintained and that all relevant information is sent to the JAZMP, the European Medicines Agency, European Commission and the EudraVigilance database.

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

The vaccination regime in Slovenia is regulated with the Contagious Diseases Act (ZNB) and Rules on vaccination, immunisation and protection against the spread of infectious diseases. Under article 22 of the ZNB, vaccination is mandatory for haemophilus influenzae type B, diphtheria, tetanus, whooping cough, infantile paralysis, measles, mumps, rubella and hepatitis B. In certain situations, obligatory vaccination can be also instructed for rabies, yellow fever, typhus, tick-borne encephalitis, influenza, tuberculosis and, for specific epidemiologic reasons, for other contagious diseases. Mandatory vaccination may be omitted only in exceptional cases (eg, when vaccination is not possible due to health reasons).

A vaccination record must be kept in the patient's medical record and in the patient's vaccination booklet. Upon vaccination, the National Institute for Public Health must be also notified. During several different stages in life (eg, before children enter nursery, before students start with their higher educational level in their school programme, at first employment), when an individual is examined by a physician, the physician must verify whether or not all mandatory vaccinations have been performed. The physician is obliged to carry out any missing vaccinations.

Obligatory vaccinations are financed through compulsory health-care insurance, while voluntary vaccinations are financed through direct payment by the patient, or in some cases, the patient's employer. Costs for voluntary vaccination are not recoverable.

In Slovenia, the vaccination rate for mandatory vaccinations in 2014 (the last available data) was fairly high, reaching the 94.9 per cent rate for vaccinations against haemophilus influenzae type B, diphtheria, tetanus, whooping cough and infantile paralysis, and the 93.7 per cent rate for vaccinations against measles, mumps and rubella. It has, however, still not reached the World Health Organization (WHO) target rate of 95 per cent. On the other hand, the rates for voluntary vaccination are still very low. The vaccination rate for tick-borne encephalitis is estimated at 7 per cent and for influenza, only 3.3 per cent. A particular problem concerns the level of vaccination against influenza in the 65 and above age group, which stands at only 10.9 per cent. Slovenia therefore falls within the group of European countries with the lowest rate of vaccinated people for influenza aged 65 and above, missing the WHO target rate of 75 per cent.

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ISSN 2042-4329

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

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