

Quarterly bulletin



CMS Lifesciences – Russia and beyond

September 2009

Introduction

Welcome to the September edition of CMS Russia Lifesciences Quarterly Bulletin. The Bulletin will provide you with recent information on legal aspects in the sector in Russia and beyond. We assume that this information may be of importance in the course of your business activities.

Apart from Russia this issue contains contributions from China, Poland and Ukraine.

If you would like to learn more about any of the issues discussed in the Bulletin, please contact us.

Your comments and suggestions regarding the topics you would like to hear about, are also very welcome.

Best regards,
CMS Russia
T +7 495 786 40 00

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Russia



Russia: new pharmaceutical price controls

New price controls for life-saving and essential medicines have been introduced by the government.

Most of the key changes become effective from the 01 January 2010.

The key changes include:

- a significant increase in overall controls over pricing
- the introduction of new procedures and requirements
- a requirement for manufacturers to register or re-register by 1 March 2010 their maximum sale price for each of the life-saving and essential medicines on the official list under a new procedure
- a requirement for maximum retail and wholesale margins to be imposed by the Russian Regions under a new procedure
- compliance with these requirements will form part of the necessary conditions for obtaining and renewing manufacturing and pharmaceutical licences

Manufacturers' maximum prices

Manufacturers must follow a new registration process, with sanction for non-compliance or submitting false information. Prices must be registered in Russian roubles from 1 January 2011. A commission to resolve price registration disputes is being set up from 1 October 2009, with a right of appeal to the commission and/or court.

The price-setting methodology is to be developed and approved within 4 months by the Ministry for Public Health and Social Development (MoH) in cooperation with other related ministries. Further details will be released by the ministry in due course.



Wholesale and retail margins

A new procedure is being developed for adopting maximum retail and wholesale margins, which the Russian Regions must follow within 30 days of its approval. Both retail and wholesale margins must be calculated on the basis of the manufacturer's price and must take into account location, transport accessibility and other region-specific factors.

There is also a detailed procedure for wholesalers and retailers to apply the maximum margins, and a requirement for them to hold a 'price protocol' document in the prescribed form.

Controls

In two months' time, the MoH will start monitoring actual prices and volumes for all drugs on the list of life-saving and essential medicines.

Prices are subject to monthly monitoring, for Russian manufacturers by the bodies in charge of state statistics and for foreign manufacturers by the Federal Customs Service. An electronic database will also be created to facilitate monitoring by the Federal Service of Supervision in Public Health and Social Development (Roszdravnadzor).

Importers seeking import licences customs clearance for drugs on the list must also provide information on the actual foreign manufacturer's price, as well as documents confirming that it has been registered.

The MoH has also produced draft legislation (draft Law On Medicines Turnover) containing significant strengthening of pricing controls which, after any Government amendments have been made, is expected to be introduced to the State Duma in autumn 2009.

This is broadly in line with the measures introduced by the Resolution but also proposes the introduction of a complete ban on the sale of the drugs on the list whose manufacturer's prices has not been registered. It also proposes the cancellation of any manufacturer's price registrations and maximum margin approvals if they are not in line with the approved methodologies.

Law: Resolution No 654 of the RF Government dated 08 August 2009 "On development of the government control over the prices on life-saving and essential medicine"

Olessia Akimtseva, CMS Russia, olessia.akimtseva@cmslegal.ru



Inclusion of Russian branches of leading international pharmaceutical companies in the Register of Companies with a Dominant Position

The Federal Antimonopoly Service of the Russian Federation has issued order No. 193 dated 3 April 2009 on the inclusion of 10 international pharmaceutical manufacturers in the Register of economic entities that control over 35% of the relevant market or have a dominant position in the relevant market. The order refers to the Russian branches of IHCC, Johnson & Johnson, Galen Pharma, Roche-Moscow, Novartis Pharma, BIOTECH, Nycomed Distribution Center, Schering AG, Astellas Pharma and Novo Nordisk.

According to the market research agency DSM Group, the market share of Roche, Novartis, Bayer-Schering, Nycomed, Johnson & Johnson and Novo Nordisk was only 17.8% of the total monetary value of the Russian pharmaceutical market in 2008.

The Federal Antimonopoly Service (FAS) has analysed the Russian pharmaceutical market with regard to the treatment of haemophilia, cystic fibrosis, hypophysial nanism, Gaucher's disease, myeloleukemia and multiple sclerosis, as well as medicines applied after transplants of organs and (or) tissues, and has concluded that the above-mentioned companies have a leading position in the relevant market. These companies' innovative and patented pharmaceuticals do not have Russian analogues.

The following actions by companies holding a dominant position are by law to be qualified as monopoly abuse: establishing high (or low) prices for the pharmaceuticals in question; withdrawing pharmaceuticals from circulation; conducting exclusive contracts with distributors and causing disadvantages for distributors; terminating or reducing the supply of pharmaceuticals to the market; refusing to enter into contracts with certain distributors; establishing an unjustified difference in price for one same product; obstructing the entry or exit of competing products into and from the market; breaching pricing established by law, etc.

The inclusion of the companies in the register enables the Federal Antimonopoly Service to supervise their business activities, including pricing and their relations with distributors. The Federal Antimonopoly Service will evaluate high prices for pharmaceuticals that do not have Russian analogues by comparing prices on the Russian and European markets. Establishing prices exceeding European market prices, conducting exclusive contracts with distributors and imposing disadvantages on distributors will, if performed by these companies, constitute monopoly abuse.

The Federal Antimonopoly Service is entitled to impose a penalty for monopoly abuse of 0.01% to 0.15% of these companies' turnover in the relevant markets.

[Julia Fedorova, CMS Russia, julia.fedorova@cmslegal.ru](mailto:julia.fedorova@cmslegal.ru)



China



China Pharmaceutical/Cosmetic/Beverage Industries: New cap on pre-tax deductible ad fees

A new tax circular relating to the increase of the cap on deductible advertisement and promotion fees in China's pharmaceutical, cosmetic and beverage industries was introduced on 31 July 2009 ("Circular"). The Circular jointly established by the State Administration of Taxation and Ministry of Finance, is implemented as a tax transitional arrangement and aims to gradually adjust the industry structure from a tax perspective and encourages qualifying manufacturers which usually allocate a big advertising budget to consolidate and expand their market presence in China.

Expenses for advertisement and promotion can be deducted up to 30% of the turnover for the year 2008 to 2010 (compared with the current deduction rate of 15%), and the balance can be carried forward indefinitely. It is noted that trading companies which are engaged in importation or distribution of drugs, cosmetic products and beverages, are excluded from the Circular.

Further, a beverage (exclusive of alcohol) manufacturer can either deduct the expenses for advertisement and promotion itself, or alternatively have part or all of such expenses consolidated into the sales expenses incurred by its franchisor.

Last but not least, considering that the annual corporate income tax filing for the year 2008 is completed by now, we hereby kindly remind the accountants of pharmaceutical, cosmetic and beverage (exclusive of alcohol) manufacturers that any tax overpayment - deduction at a rate of 15% instead of the increased cap of 30% - can be claimed back when handling annual corporate income tax filing for the year 2009.

Jonathan Salvadoray, Shanghai, +86 21 6289 6363

Florence Xu, Shanghai, +86 21 6289 6363



Poland



Press information may be regarded as medicinal product advertising

In one of the recent rulings (C-421/07), the European Court of Justice (“ECJ”) decided that European Directive 2001/83/EC (“Directive”) is to be interpreted as meaning that dissemination by a third party of information about a medicinal product may be regarded as advertising within the meaning of the Directive, even though the third party in question is acting on his own initiative and completely independently of the manufacturer and the seller of such a medicinal product.

The case relates to the Danish proceedings, in which Mr Damgaard – a former employee of a pharmaceutical manufacturer stated on his website that a medicine of this company contained rosehip powder, which is supposed to relieve pain caused by various types of gout or arthrosis. The local agency informed Mr Damgaard that this statement constituted advertising contrary to Danish law as the product has been withheld from the market. Mr Damgaard was found guilty and sentenced to a fine. He appealed against the judgement arguing that he was not employed by the manufacturer and had no interest in that company or in sales of the product. His activities as a journalist in the health food sector were limited to communicating, to retailers and other interested parties, of information on food supplements. Mr Damgaard did not receive any remuneration for the information he disseminated concerning the medicine. In those circumstances the court of appeal decided to stay the proceedings and to refer to the ECJ for a preliminary ruling.

The ECJ referred in its ruling to the definition of advertising of medicinal products, which includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. According to the Directive, Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.

In the ECJ’s point of view, the public dissemination of information about a medicinal product which is not authorised in a particular Member State may, depending on the context in which that dissemination takes place, influence consumers’ behaviour and encourage them to purchase the medicinal product in question, which could affect public health. While that definition of advertising explicitly emphasises the purpose of the message, it does not provide any indication as to the people who disseminate that information. Thus, the wording of the Directive does not rule out the possibility that a message originating from an independent third party may constitute advertising.



Also, it does not require a message to be disseminated in the context of commercial or industrial activity in order for it to be viewed as advertising. Even if it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health, the safeguarding of which is the essential aim of the Directive.

It is crucial for the national court to determine whether a third person's actions constituted advertising – whether they are intended to promote the prescription, supply, sale or consumption of a medicinal product. The discretion enjoyed by the national authorities in determining the balance to be struck between freedom of expression and the abovementioned restrictions depends on the nature of the activities in question. If the exercise of the freedom does not contribute to a discussion of public interest and, in addition, arises in a context in which the Member States have a certain amount of discretion, the review is limited to an examination of the reasonableness and proportionality of the interference.

From the Polish legal perspective, the provisions of Pharmaceutical Law do not vary from the European legislation. Under national law, any entity providing advertising activities may be liable for those that are illegal. In practice, most of decisions are addressed to the marketing authorisation holders or their representatives in the territory of Poland. However, the General Pharmaceutical Inspector – the authority supervising pharmaceutical advertising in Poland – has recently issued a decision, in which it recognised a press article regarding negative consequences of using medicines in the course of learning by students, where some of them were poisoned. Paradoxically, in the authority's opinion the article constituted detailed instructions of using such products, therefore it encouraged their purchase. As some of the products contained narcotics, their advertising to the public was prohibited.

The aforementioned decision has been widely criticised in Poland. Most experts pointed out that according to the freedom of expression, the press should be able to publish any articles regarding important issues and inform about crucial threats. The specialists stated that the article regarded products of different manufacturers and was written without any influence of the pharmaceutical industry. Such a decision may now be discussed in the light of the recent ECJ ruling, which can change the position of some critics. Nevertheless, one should remember that the aim of purchasing a product should always be verified during an analysis of any informational material. Only one designed for the purposes of promotion should be regarded as advertising of medicinal products.

Łukasz Sławatyniec CMS Cameron McKenna, Warsaw lukasz.slawatyniec@cms-cmck.com



Ukraine



New pharmaceutical licensing regime in Ukraine

The manufacture, wholesale and retail sale of pharmaceuticals in Ukraine is subject to mandatory licensing.

Licensing framework

The general requirements of the licensing regime are set out in the Law of Ukraine No. 1775-III dated 1 June 2006 On the Licensing of Certain Types of Economic Activity.

However, more detailed licensing conditions have recently been adopted in Joint Order No. 44/27 On New Licensing Conditions for Conducting Economic Activity of Production, Wholesale and Retail Sale of Medicinal Products by the State Committee of Ukraine on Regulatory Policy and Entrepreneurship and the State Inspectorate for Control over the Quality of Medicinal Products.

Applicants for a licence must file an application with the State Inspectorate, a new government body into which the functions of various government agencies have been consolidated.

As well as having the authority to issue licences for the manufacture and sale (wholesale and retail) of pharmaceuticals, the State Inspectorate also exercises state control over the whole pharmaceutical supply chain, including imports, exports, manufacturing, distribution and quality control.

The State Inspectorate's authority derives from Resolution No. 1121 dated 20 December 2008 of the Cabinet of Ministers of Ukraine On Certain Questions of Management of Control over the Quality of Medicinal Products.

Licensing procedure

The State Inspectorate decides whether or not to issue a licence within 10 business days of receiving the application form and other required documents. Its decision is given in writing and can take a further three business days to arrive.



Applications will be refused if they contain false information or do not comply with the relevant conditions for the particular activity.

The State Inspectorate will not consider applications if they do not include all necessary documents or if they have not been submitted or signed by an authorised representative of the applicant. Instead, the applicant will be notified (within the usual timescales) that their application has not been considered, enabling them to correct the defect and apply again.

Licences are issued for a term of at least three years and are non-transferable. Licence holders cannot continue the licensed activity once their licence has expired so, as the statute does not specify any timescales, they should apply for re-registration at least 14 business days before the expiry date of their current licence.

Licence holders must apply to re-register their licence within 10 days of changing their name, residence or licensed activity.

Manufacturing

In accordance with a new licensing condition, pharmaceutical manufacturers are now required to comply with good manufacturing practice. The only exemption applies to traditional (mainly herbal) medicines, which are registered under the simplified procedure.

There is guidance on what constitutes good manufacturing practice but this has not yet been published, even though it has apparently already been adopted by the Health Ministry. Applicants to re-register a manufacturing licence should therefore pay close attention to the wording of the Joint Order, to ensure they comply with the licensing conditions.

The new rules require licence holders to ensure that their material and technical base satisfies the regulations on manufacturing and distributing pharmaceuticals and also complies with the statutory quality standards for pharmaceuticals (including those manufactured for clinical trials).

Before starting commercial production of pharmaceuticals, licence holders must ensure they satisfy the relevant technical and technological regulations and appoint authorised person to issue permits for the sale of pharmaceuticals.

There are also new requirements to keep clinical trial protocols for five years after the trial has ended and to keep protocols from each manufactured series of a pharmaceutical for at least a year after its expiry date or for five years after the relevant sales permit was issued (whichever period is longer). Examples of each ingredient and packaging material must also be kept for two years after manufacture. A further change now allows manufacturers to produce pharmaceuticals, including those not registered in Ukraine, under a commercial contract with a third party.



Distribution

It is not clear whether pharmaceutical distributors are required to follow good distribution practice and whether it is necessary for them to obtain a distribution licence. Some government officers believe that they are, although the new Joint Order does not expressly stipulate this.

There are also limits on the distribution of pharmaceuticals to destinations such as warehouses, pharmacies and their branches and pharmacy units. This means that pharmacy branches may only trade in non-prescription pharmaceuticals, and pharmacy units can only trade in ready-to-use pharmaceuticals.

Only registered pharmaceuticals may be distributed through wholesale or retail trade outlets and all pharmaceuticals sold this way must be supported by a quality certificate from their manufacturer.

Licence holders are required to keep the quality certificates (in electronic or hard copy form) for each series of pharmaceuticals for three years after sale. Distributors who keep them in electronic form can be required to provide certified copies to the State Inspectorate on request within two business days.

Wholesalers must keep a record of distribution and control quality for three years after any transactions involving pharmaceuticals. The records must indicate the date, type, series and quantity of pharmaceuticals received or supplied, as well as licensing information about the purchaser or supplier.

From 2010, each pharmacy warehouse must have an authorised person responsible for developing and maintaining a quality control system.

Qualifications

The new licensing conditions also require special qualifications for those involved in the manufacture and distribution of pharmaceuticals, with a particular emphasis on compulsory professional development and training for employees.

Compliance

Compliance with the licensing conditions is controlled by scheduled and unscheduled inspections carried out by the State Inspectorate. Scheduled inspections are carried out once each calendar year, while unscheduled inspections are only carried out when the State Inspectorate receives information that a licence holder is breaching the licensing conditions or wishes to establish whether they have eliminated the breaches detected during the last scheduled inspection.

Licence holders may have their licence revoked if they fail to eliminate breaches detected during an inspection or if they otherwise fail to meet the necessary licensing conditions or requirements, which apply to their activity. Their licence may also be revoked if they transfer their licence to a third party or fail to notify the State Inspectorate of any changes to the information contained in the documents submitted as part of their licence application.

Solomiya Lototska, CMS Cameron McKenna, Kyiv, solomiya.lototska@cms-cmck.com



The contents of this bulletin are meant to give a brief overview only and are not meant to be exhaustive or to provide specific advice. If you have a specific problem or query, it is recommended that you take specific legal advice.

Contact us

Head of CMS Russia Lifesciences

Dorin Popescou
Partner, Moscow
T +7 495 786 30 45
E dorin.popescou@cmslegal.ru

Head of CMS Lifesciences

Dr Jens Wagner
Partner, Hamburg
T +49 (0) 40 / 3 76 30 - 357
E Jens.Wagner@cms-hs.com

Head of CEE Lifesciences Group

Agnieszka Deeg
Partner, Warsaw
T +48 22 520 5698
E agnieszka.deeg@cms-cmck.com

CMS Russia
11, Gogolevsky blvd.
119019, Moscow, Russia
Tel. +7 495 786 4000
Fax +7 495 786 4001

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