

Israel

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Philippines

Legislator wants health warnings and labels to be available in local languages

Patient Safety

Philippine drugs agency urged to act on foreign product labels

A member of the Philippines House of Representatives has demanded that the country's Bureau of Food and Drugs (BFAD) ensure that pharmaceutical-related health warnings and advisories and product labels are available in languages that the public can understand¹.

Many health products, for example, are sold with labels printed in English and, while English is one of the official languages of the Philippines, many people do not understand it, according to Aurelio Gonzales Jr, the representative who filed the resolution. The term "No Approved Therapeutic Claim" was particularly difficult to understand, Mr Gonzales said. Resolution 169 urges the BFAD to ensure that guidelines, advisories, health warnings and labels are translated into Filipino, the other official language in the Philippines², or the regional languages of the country.

References

1. Philippines House of Representatives press release, 19 September 2007, www.congress.gov.ph/press/index.php?pg=details&pressid=1872
2. Republic of the Philippines website, accessed 4 October 2007, www.gov.ph/

Russia

Russia wants to complete GMP certification of all registered drug manufacturers by the end of 2009

Agency Activity

Russian regulator seeks to certify all manufacturers for GMP by 2010

Russia's service for the supervision of healthcare and social development (Roszdravnadzor) has prepared a plan that aims to complete good manufacturing practice (GMP) certification of all drug manufacturers registered in the country – whether foreign or domestic – by 1 January 2010. The agency's deputy director, Andrei Mladentsev, presented the draft GMP implementation plan at a 19 September meeting with the Ministry of Healthcare and Social Development (MoH), the pharmaceutical industry and healthcare experts^{1,2}.

According to Roszdravnadzor, the majority of domestic pharmaceutical companies in Russia founded during the Soviet era or in the early 1990s have not yet started modernisation procedures that would make their drug manufacturing processes GMP compliant. Standardising the regulatory requirements for domestic and foreign drug producers is an essential part of the GMP certification process, since drugs registered in the country come from 1,264 factories located outside the Russian Federation. Thus, as well as inspecting domestic manufacturers, Roszdravnadzor said that it plans to inspect all foreign drug manufacturing sites. This would require 407 additional inspectors and cost an estimated \$1.5-2 billion for staff training and implementation of new manufacturing procedures, among other things.

Licence revocations

Roszdravnadzor said that it was also seeking to simplify the procedure for revoking the manufacturing licences of companies that fail to meet GMP requirements by 1 January 2010. Under current legislation, a manufacturer's licence can only be revoked if the agency initiates court proceedings. Therefore, it is seldom implemented in practice.

Participants at the meeting discussed the social consequences of revoking manufacturers' licences and possible lay-offs that would result in Russian factories after 1 January 2010. The acting minister of healthcare and social development, Mikhail Zurabov, noted that the proposed timeline was too tight for companies to meet GMP requirements and requested an additional feasibility assessment². Participants were generally positive about the process of transition to total GMP compliance in the Russian pharmaceutical industry, but no definitive deadline was set.

Industry views

Industry representatives welcomed the idea of obligatory GMP certification, as the absence of such requirements is currently believed to slow down pharmaceutical development in Russia. They also believe that the lack of GMP certification is an obstacle to the exportation of Russian-made drugs. In 2006, domestically-produced pharmaceuticals accounted for 68% of the Russian market, or 35% of its estimated annual medicines expenditure, according to Roszdravnadzor. However, the majority of the 1,925 domestic pharmaceuticals registered in the country are generics, with only 65 being original substances that were developed in Russia or the Soviet Union.

Any significant shortage of drug supplies after the closing of noncompliant sites as a result of GMP

Certification should encourage the exportation of Russian-made drugs

inspections is not expected, since the top 25 pharmaceutical companies registered in Russia (out of 640) account for 80% of total drug production. Ten of these manufacturers have already been inspected for GMP by the World Health Organization (WHO), while others have implemented GMP standards as part of their internal manufacturing processes.

Next steps

After further consultation with stakeholders, Roszdravnadzor is expected to present a detailed GMP implementation plan to the MoH, which will then be reviewed by the Russian Security Council. Considerable legislative work – including amendments to the Russian Drug Law – is necessary before the GMP plan can be implemented.

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References

1. Information statement for Roszdravnadzor open hearings “On the Roszdravnadzor action plan concerning implementation of GMP standards in the pharmaceutical industry”, 19 September 2007, www.roszdravnadzor.ru/i/upload/files/1190620000.16677-23246.doc
2. Roszdravnadzor press release, 24 September 2007, www.roszdravnadzor.ru/about/news/11684

Classification and Switching

South Korea undecided on classification of plant-origin anti-inflammatory drug

The Korea Food and Drug Administration (KFDA) has been unable to make a decision on whether a plant-based anti-inflammatory drug should be classified as a prescription-only medicine rather than an over-the-counter (OTC) drug. At an advisory meeting of the subcommittee for drug reclassification of the agency’s Central Pharmaceutical Affairs Council on 5 October, consumers and professional groups such as the Korean Pharmacists Association and the Korean Medical Association discussed a request by SK Chemicals to switch its product, called Joins (Clematis mandshurica, Trichosanthes kirilowii and Prunella vulgaris), from OTC to prescription-only status.

The product, which was launched in March 2002, is indicated for symptoms associated with osteoarthritis, and more recently, rheumatoid arthritis. It had sales of about €9.3 million last year. At the time of approval, Joins was categorised as an OTC drug on the basis that it was a traditional Chinese medicine with only plant-based active ingredients, and therefore it had low toxicity. However, SK targeted mainly physicians when promoting the drug; consequently more than 90% of its sales have been from prescriptions, which is one of SK’s arguments for switching. In addition, SK has claimed that drugs indicated for rheumatoid arthritis are not suitable for OTC status. This is supported by the Korean Orthopaedic Association, according to the company. Another reason for the company’s request to switch is to survive the government’s pricing policy, which does not reimburse for OTCs.

The subcommittee will revisit the issue at its next meeting, which is expected to take place at the end of October or early in November. The Korean Pharmacists Association is reportedly against the switch. On the other hand, the Korean Medical Association and consumer groups support the switch.

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Reimbursement

New Spanish procedure for declaring medicines as innovative products

Pharmaceutical manufacturers in Spain must provide demonstrative scientific evidence to support applications to have their products deemed innovative for reimbursement purposes¹.

In new guidelines that set out the application procedures, the Spanish Agency for Medicines and Healthcare Products (AEMPS) emphasises that the evaluation of the therapeutic contribution of a medicinal product is the determining factor for declaring a new pharmaceutical form as a “pharmaceutical innovation of therapeutic interest”, and this contribution must be based on a product’s efficiency, safety or usefulness in special populations.

The agency published the guideline procedure on 25 September, at the request of the pharmaceutical industry, within the framework of the 2006 Law on Guarantees and Rational Use of Medicines and Healthcare Products². Among other things, the law introduced measures to promote research and development, making the degree of innovation of a medicinal product one of the criteria used to determine its funding by the country’s national health system. It also set up a new reference pricing system, which was implemented on 1 March and affects all medicines on

Russia

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South Korea

The debate over whether a plant-based drug for rheumatoid arthritis should be OTC or prescription-only is continuing

Spain

Manufacturers must provide scientific evidence to support innovativeness claims