Good distribution practice: Regulations in major Asian economies

TITLE

Introduction

Major Asian economies, such as China, India and Japan, have a unique role in pharmaceutical supply chain. Five of the top 25 global brand manufacturers come from Japan: Takeda, Astellas, Otsuka, Daichi Sankyo, and until 2013 also Eisai. Japan is party to International Conference on Harmonization (ICH), and adopts its standards as approved by Tripartite. ICH makes recommendations towards harmonization of technical guidelines and requirements for pharmaceutical product registration. ICH brings together the drug regulatory authorities and the pharmaceutical industry of Europe, Japan and the United States.

India, as the pharmacy of the world, produces and exports enormous amount of pharmaceuticals, from generics to high-potency pharmaceutical products and biologics. India is also a major source of counterfeit pharmaceuticals, which are exported all over the world.

China is a major producer of generic drugs and major importer into the U.S. and the EU. Both India and China have hundreds of approved manufacturing facilities authorized to supply their produce to highly regulated markets. Both countries face major challenges in the area of distribution and supply chain security and integrity, and especially counterfeit pharmaceuticals. In 2013, Indian and Chinese pharmaceutical imports together accounted for 50% of U.S. drug master files. The list of Drug Master Files published by the FDA does not include manufacturing location. According to the latest Special 301 report of the Office of the U.S. Trade Representative, the business environment in China and India raises concerns over intellectual property and trade secret protection, enforcement, and market access.

There are also continuing challenges of online copyright piracy in countries such as Brazil, China, India, and Russia, and trademark counterfeiting in China and elsewhere. These continuing violations of intellectual property earned China, India and Russia their spot on the USTR Priority Watch List.

The manufacture and distribution of pharmaceutical products bearing counterfeit trademarks is a growing problem that has important consequences for consumer health and safety. Such trademark counterfeiting contributes to the proliferation of substandard, unsafe medicines. China and India are the sources of most of the counterfeit pharmaceuticals shipped to the United States. While it is impossible to determine an exact figure, studies have suggested that up to 20 percent of drugs sold in the Indian market are counterfeit.

Russia's role as a pharmaceutical manufacturer is marginal and its produce barely satisfies domestic demand. Its pharmaceutical exports are negligible. Recent military adventures of Russian leadership and consequent sanctions had profound effect on the country's economy, regulatory environment and the usual way of doing business for foreign investors. Because of economic malaise, Russia is now trying to increase its self-sufficiency in key industries and reduce its reliance on imports, including pharmaceuticals.

Japan

In 2014, four Japanese pharmaceutical manufacturers were listed among the top 25 producers by revenue. In pharmaceutical regulations, not only distribution and supply chain, Japan closely follows ICH guidelines. Japanese distribution practices are regulated by Pharmaceutical Affairs Law and ICH guideline Good Distribution Practice.

In Japan, drug lifecycle from discovery to post-market surveillance and distribution, is called “Journey of a pharmaceutical product”.

Japanese term *dō* (or *tao* in Chinese), means 'path' or 'way', including Buddhist conception of 'path'. The term refers to the idea of formulating propositions, subjecting them to philosophical critique and then following a 'path' to realize them. *Dō* signifies a "way of life", applicable to any discipline cultivated through a given art form.

Japanese market is highly regulated and controlled. In every part of the journey of pharmaceutical product, there are strict standards in place. Regulations cover everything from manufacturing to shipping and transportation after shipments.

Under the Pharmaceutical Affairs Law, compliance with the current Good Manufacturing Practice is required for a new drug to be approved. Some products, such as vaccines and blood products require each lot to be tested in order to be cleared for shipping.

In order to provide new products to hospitals and pharmacies, pharmaceutical companies develop a **supply and distribution plan** and coordinate distribution of the product with both internal and external parties. Pharmaceutical companies provide, gather and communicate information and disseminate their products in order to promote their appropriate use.

Association of Japanese Pharmaceutical Manufacturers (JPMA) published several industry guidelines relevant to distribution of pharmaceuticals and supply chain integrity and marketing of pharmaceutical products:

- JPMA Promotional Code
- JPMA Transparency Guideline
- JPMA Code of Practice
- IFPMA Code of Practice and IFPMA issue brief ensuring ethical promotion
- And Transparency Guideline for the Relation between Corporate Activities and Medical Institutions

The **Ministry of Health, Labor and Welfare** is in charge of pharmaceutical regulatory affairs in Japan for human products. Veterinary drugs are under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries.

- The **Pharmaceutical and Food Safety Bureau (PFSB)** oversees clinical studies, conducts approval reviews and implements post-marketing safety measures.

- The **Health Policy Bureau** has authority over promotion of Research & Development, production, distribution policies, and drug pricing.
- The **Pharmaceuticals and Medical Devices Evaluation Center (PMDA)** in the National Institute of Health Sciences was established to reinforce drug approval reviews.
- And the last bureau, the **Organization for Pharmaceutical Safety and Research (OPSR)** conducts compliance reviews of application data and offers consultation services on clinical trial protocols.

In Japan, Drug Retail Sellers must obtain a license from the Prefectural Governor. Pharmaceutical Affairs Law recognizes three different drug-seller license categories:

- **Store-based drug sellers (pharmacies),**
- **Household distributors authorized to sell non-prescription drugs,**
- **And wholesalers.**

Since June 2014, non-prescription drugs may be also marketed on the Internet as long as they have a marketing license and are available in traditional pharmacies. **Quality standards** can be found in the Japanese Pharmacopoeia, Japanese Pharmaceutical Codex, Japanese Pharmaceutical Excipients, and other similar standards.

Provisions on **Labeling and Package Inserts** specify required labeling of pharmaceutical products. In addition to indications, dosage, route of administration and precautions package inserts must contain also detailed instructions on how to handle the product.

- **Barcodes** are required for prescription drugs to prevent medication errors resulting from misunderstandings, to assure traceability, and to improve supply chain integrity.
- In November 2014, the revised Pharmaceutical Affairs Law introduced new **package insert notification requirement**. All package inserts must be published on the PMDA website.

The “Standards for Proper Advertisement of Drugs” provide guidance on appropriate marketing practices. In the past, there were instances of online advertising of unapproved drugs by persons acting as importers.

India

India's patent and copyright law and policies are a good example of substantial differences in understanding of the definition of counterfeit, falsified, misbranded and substandard products.

According to the **Special 301 Report**, India remains on the U.S. Trade Representative Priority Watch List in 2015. In many areas, Intellectual Property Rights protection and enforcement challenges continue, and there are serious questions regarding the future of the innovative climate in India across multiple sectors and disciplines. In December 2014, the Government of India reviewed its IPR regime and drafted a new **National Intellectual Property Rights policy**.

Predictability of **Indian patent system** is a reason for concern especially in the biopharmaceutical sector and green technology. Innovators in these sectors face serious challenges in securing and enforcing patents.

An "**invention**" under the **Indian Patents Act** is any product or process that is novel, has an inventive step, and is capable of industrial application. Section 3(d) of India's Patents Act states that *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance"* is not considered to be an *"invention"* under Indian law.

Under India's patent regime, patents can be challenged through both pre-grant and post-grant opposition proceedings at minimal cost. As a result, applications can be tied up in costly challenge proceedings for years, all the while running the potential term of the patent.

Another concern is India's **Compulsory licensing law**. India has made clear that it views compulsory licensing as an important tool of industrial policy. In the United Nations Framework Convention on Climate Change negotiations, India continues to identify patents as obstacles to the dissemination of green technologies.

Enforcement of patent rights in India is a continuing concern. Some patent holders reportedly face challenges in securing injunctions against firms that manufacture patented inventions without authorization from the patent holder.

When approving such marketing without authorization, Indian state governmental authorities reportedly do not have a mechanism to confirm whether the item to be manufactured is under patent.

Recent cases such as ***Merck v. Glenmark*** and ***Cipla v. Roche*** illustrate this problem.

India's protection against **unfair commercial use**, as well as **unauthorized disclosure**, is somewhat ineffective. This mainly affects undisclosed test or other data generated to obtain marketing approval for pharmaceutical products. Without these types of protections, companies in India reportedly are able to copy certain pharmaceutical products and seek immediate government approval for marketing based on the original developer's data.

Businesses also voiced concerns regarding **trade secret protection** in India particularly due to difficulty in obtaining remedies and damages in cases of theft by a business competitor. Risk of public disclosure of trade secrets in the course of judicial proceedings deters victims of trade secret theft from using the court system to enforce their rights.

Stakeholders also complained about significant delays at the **Trademark Registry**. Their ability to enforce their rights against potential infringement is hindered further by delays in India's judicial processes. Illicit activities such as **copyright piracy** and **trademark counterfeiting** harm consumers and legitimate producers.

In addition, the level of production, sale, distribution, importation, and exportation of **counterfeit goods** remains very troubling.

India's **actions and policies** appear to favor local manufacturing in a manner that distorts the competitive landscape.

In April 2015, the National Pharmaceutical Pricing Authority implemented pricing restrictions on more than 500 drug formulations. However, exemptions from those restrictions allow certain medicines that are manufactured in India and "developed using indigenous R&D," to be priced higher, providing an advantage to Indian companies.

In addition, a patent could be subject to **a compulsory license** if the patented product is not manufactured in India.

India is almost self-sufficient in case of formulations. Drugs are imported on quality and economic considerations and not necessarily due to non-availability from domestic sources. Imports are only restricted for some narcotics and Ozone Depleting Substances. India is a net exporter of pharmaceutical products and biologics.

An important focus area for the Indian Department of Pharmaceuticals is promotion of Indian Pharmaceutical Products in global market. The most recent regions of interest for export of Indian pharmaceuticals include Ukraine, Tunisia, European Union, and Russia.

Many Indian companies obtained **international regulatory approvals for their plants**, from agencies like the U.S. FDA, UK medicines agency MHRA, Australian regulatory authority TGA, South African MCC and the World Health Organization. India is a country with the highest number of FDA-approved plants for generic drugs' manufacture outside the U.S. Major share of Indian Pharma products is exported to highly regulated markets. Some of the leading Indian Pharma companies derive 50% of their turnover from International business.

In recent years, however, several Indian manufacturers received **FDA warning letters** for violations of current Good Manufacturing Practices. Until these issues are resolved, there is a risk that produce from the affected plants may make its way into the legitimate supply chain.

India's Guidelines on Good Distribution Practices for Pharmaceutical Products were published in January 2013.

The preamble highlights achievements of Indian pharmaceutical industry, especially access to quality medicines, adoption of global standard in manufacturing practices, and development of specialized workforce. Robust supply chain is the very foundation of quality medicines, and assurance of their safety and efficacy. Involvement of unauthorized entities in distribution and sale of pharmaceutical products is a concern because of the penetration of spurious and substandard pharmaceutical products.

The objective of the guideline is to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process from procurement and purchasing through storage, distribution, transportation, documentation and record keeping.

The guideline applies to all persons involved in any aspect of storage and distribution of pharmaceutical products, from the premises of the manufacturer to the person dispensing or administering the product to the patient.

This includes:

- Manufacturers of bulk and finished products
- Wholesalers, suppliers and distributors
- Government institutions
- International procurement organizations and donor agencies
- Certified bodies
- Logistics providers, traders, transport companies, and forwarding agents and their employees
- And Health workers.

The guideline covers pharmaceutical products and biologics. Specialized guideline Good Distribution Practices for Biological Products discuss some aspects relevant to biologics such as cold chain practices in more detail.

The overarching rules for sale, promotion and distribution of pharmaceuticals are specified in Indian Drugs & Cosmetics Act of 1940 and Drugs & Cosmetic Rules of 1945. All parties involved in the distribution of pharmaceutical products are jointly responsible for their quality and for the integrity of the supply chain. The obligation to collaborate in order to ensure quality and safety of pharmaceuticals extends to government agencies, customs, regulatory authorities and law enforcement.

Distributors shall be **authorized** to perform their functions related to the distribution of pharmaceutical products. Only **authorized** persons who hold the appropriate license can import or export pharmaceutical products to and from India. Distributors can obtain pharmaceutical products only from authorized persons and supply them to authorized persons only. Subcontractors are held to the same standard as distributors.

Organizational charts have to indicate clearly relationships and responsibilities and correspond with relevant job descriptions. A **designated person** appointed within the organization must have the authority and responsibility for the implementation and maintenance of a **quality system**. Managerial and technical personnel have to have the authority and resources to carry out their duties. Responsibilities placed on any one individual shall not to be excessive to represent a risk to product quality.

Management and personnel shall not be subject to commercial, political, financial and other pressures or **conflict of interest** that may have an adverse effect on integrity of pharmaceutical products.

Safety procedures need to be in place, including safety of personnel and property, environmental protection and product integrity.

All personnel involved in distribution activities shall receive initial and continuing **training** on Good Distribution Practices, especially product handling, safety and security, and product identification.

Personnel shall wear **garments** suitable for the activities they perform, especially workers who handle products containing materials that are highly active, toxic, infectious or sensitizing.

The management shall appoint a **responsible person** for each distribution site. This person shall have the authority and responsibility for the implementation and maintenance of the quality system.

Senior management is to ensure **adequate resourcing** with competent personnel and suitable and sufficient premises, equipment and facilities.

Deviations from established procedures shall be documented and investigated; and appropriate corrective and preventive action shall be taken to prevent reoccurrence.

Procedures for procurement and release shall be in place to ensure that pharmaceutical products are sourced only from approved suppliers and distributed by approved entities.

Pharmaceutical products have to be **traceable** throughout the supply chain.

Storage areas shall comply with **Good storage practices** (GSP). Unusable stock and hazardous materials shall be stored separately from sealable stock. Storage conditions for pharmaceutical products shall comply with the recommendations of the manufacturer. Environmental controls, namely temperature, have to be in place where necessary. Conditions as stated on the label also need to be maintained during transport.

Distributors shall **investigate** any non-compliance with storage conditions and stock discrepancies and keep documentation relating to the investigation. Adequate precautions shall be implemented against spillage, breakage, misappropriation and theft. Appropriate documentation shall accompany all products.

Narcotics and other dependence- producing substances need to be kept in safe and secure containers and vehicles.

Container labels shall include sufficient information on handling and storage requirements and precautions to ensure products are properly handled and secured at all times.

Distributors shall have written procedures for the dispatch of pharmaceutical products in order to ensure product traceability.

Provision on recordkeeping specify requirements on paper and electronic systems, including validation and backup.

Requirements for complaint handling, returned products and recalls are similar to those, which apply in Europe. If spurious pharmaceutical products are found in the distribution chain, they shall be completely segregated from other pharmaceutical products, and clearly labeled as not for sale. National regulatory authorities and manufacturer of the original product have to be informed immediately.

External **audits** are recommended to ensure compliance. **Audits and self-inspections** shall be conducted regularly to monitor implementation and compliance with the principles of Good Distribution Practice and, if necessary, to trigger corrective and preventive measures.

China

The U.S. Trade Representative Special 301 Report identified a wide range of concerns, including inadequacies in trade secret protection and "indigenous innovation" policies in China and India, and trademark counterfeiting in China and elsewhere. Proliferation of counterfeit pharmaceuticals is a particular concern in **Brazil**, **China**, **India**, **Indonesia**, **Lebanon**, **Peru**, and **Russia**.

The Office of U.S. Trade Representative has listed 37 trading partners on its **Priority Watch List**: China, India, Indonesia, and Russia among them.

The United States negotiates important intellectual property and innovation commitments with China through two very significant bilateral annual trade engagements:

- The **U.S.-China Joint Commission on Commerce and Trade (JCCT)**
- and the **U.S.-China Strategic and Economic Dialogue (S&ED)**

China is the source of counterfeit products sold illicitly in markets around the world. Counterfeit pharmaceuticals potentially threaten the health of consumers. Faulty or substandard goods that enter the supply chains of manufacturers are dangerous as well. For example, higher defect and failure rates among counterfeit semiconductors may cause malfunctions in medical devices. China and India are the sources of most of the counterfeit pharmaceuticals shipped to the United States. Large number of counterfeit goods from China also enters sub-Saharan Africa through key ports in **Kenya**, **Nigeria**, and **South Africa**.

The manufacture and distribution of pharmaceutical products bearing counterfeit trademarks is a growing problem that has important consequences for consumer health and safety. In many cases, the bulk active pharmaceutical ingredients that are used to manufacture pharmaceuticals bear counterfeit trademarks. Because such active pharmaceutical ingredients are unlawfully produced or marketed, their manufacturers are unlikely to subject themselves to regulatory oversight or comply with good manufacturing practices.

In April 2007, the United States initiated dispute settlement procedures relating to deficiencies in China's legal regime for protecting and enforcing copyrights and trademarks. Two years later, in 2009, the World Trade Organization ruled that China's denial of copyright protection to works that do not meet China's content review standards is impermissible under the TRIPS Agreement; and that China's customs rules cannot allow seized counterfeit goods to be publicly auctioned after only removing the spurious trademark.

A wide range of stakeholders in China continues to report serious obstacles to effective protection of Intellectual Property Rights in all forms, including patents, copyrights, trademarks, trade secrets, and protection of pharmaceutical test data.

For instance, in China, some domestic chemical manufacturers that produce **active pharmaceutical ingredients** have avoided regulatory oversight by failing to declare that the chemicals are intended for use in pharmaceutical products. This practice serves as a contributing factor to China's status as a major source country for harmful active pharmaceutical ingredients. In July 2014, China committed to develop

amendments, which provide enhanced regulatory control over manufacturers of bulk chemicals that can be used as active pharmaceutical ingredients.

The **theft of trade secrets** remains a particular concern. Such theft occurs inside and outside of China for the competitive advantage of Chinese state-owned and private companies. Conditions are unlikely to improve as long as those committing such theft, and those benefitting, continue to operate with relative impunity, often taking advantage of the theft in order to compete unfairly or to enter into business relationships that disadvantage their victims.

Theft may arise in a variety of circumstances, including those involving departing employees taking portable storage devices containing trade secrets, failed joint ventures, cyber intrusion and hacking, and misuse of information submitted by trade secret owners to government entities for purposes of complying with regulatory obligations.

Some central, provincial, and local government measures and actions pressure rights holders to **transfer Intellectual Property Rights from foreign to domestic entities**. The declared intentions are to promote indigenous innovation and the development of strategic industries. Government authorities may condition eligibility for subsidies and tax preferences, or deny or delay access to certain markets upon Intellectual Property Rights ownership by a Chinese entity.

In practice, **effective remedies** appear to be difficult to obtain in China. Criminal penalties for trade secret theft are not sufficient to deter such behavior. There are concerns about the extent to which China provides effective protection against unfair commercial use and unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.

In 2011, China completed its **Special Intellectual Property Rights Campaign**. The State Council established a permanent office of the National Leading Group on combating Intellectual Property Rights infringement.

A **revised Trademark Law** and implementing regulations went into effect in May 2014. Very recent draft amendments to the Patent Law may introduce new provisions of substantial additional concern. Efforts to amend the Anti-Unfair Competition Law (AUCL) of 1993 are proceeding at a slow pace.

In late 2014, China launched a pilot program of specialized intellectual property courts, currently including courts in Beijing, Shanghai, and Guangzhou. The new courts will likely provide a venue with greater Intellectual Property Expertise and experience, but the success of the courts will depend on impartial consideration of the facts and law, and their efficient operation.

In January 2013, Chinese Ministry of Health published the revised **Good Supply Practice for Pharmaceutical Products** (Revised GSP Standards). The Revised GSP Standards came into effect in June 2013 and replaced the previous version from 2000. The guidelines introduced higher requirements on quality control and inventory management, and stricter record-keeping and tracking requirements. The revised GSP comprises 187 articles in four chapters, including General Provisions, Quality Management for Wholesale of Pharmaceutical Products, and Quality Management for Retail and Supplementary Provisions. The guideline applies to distributors of pharmaceutical products.

Chapter II – Wholesale Quality Management – covers

- Quality Management System,
- Organizing Institution and Quality Management Responsibility,
- Personnel and Training,
- Quality Management System Document,
- Facilities and Equipment,
- Calibration and validation,
- Computer system,
- Procurement,
- Receiving and acceptance,
- Storage and maintenance,
- Sales,
- And Delivery from storage, Transportation and delivery, and after-sales management.

Chapter III – Retail Quality Management – covers quality management and responsibility, personnel management, documents, facilities and equipment, purchase and acceptance, display and storage, sales management, and after-sales management.

Enterprises are required to establish and describe a quality management system and determine quality policy. Any quality system needs to be audited regularly. Organization charts shall define roles and responsibilities, as well as relationships between individual functions. Most requirements are similar to those described in European guidelines on Good Distribution Practice.

Additional requirements include handling of traditional Chinese materials and medicines, ban on concurrent employment, handling of adverse reaction reports, and provisions on environmental and personal health. Education “higher than senior high school” is required for persons involved in the storage and sale of pharmaceuticals. Personnel who engage in the storage and transportation of drugs under special control, and refrigerated and frozen drugs are required to pass a specialized examination. Only Responsible Person, or legal representative of the company, has to be a licensed pharmacist.

Articles 62 and 64 specify exactly documents a distributor has to examine before engaging in business with a new partner, and what type of documents have to be requested and retained from any supplier.

Quality assurance agreement between the supplier and purchasing party needs to define clearly responsibilities of both parties and detailed specification of the materials traded, conditions of storage and transport, and responsibility for quality assurance.

The guideline contains detailed provisions on the display of drugs. For instance, prescription and non-prescription drugs shall be displayed separately, prescription drugs cannot be offered on an open-shelf for self-selection, and psychotropic drugs and toxic Chinese medicines shall not be displayed at all.

Supplementary provisions add sanctions for distributors who fail to comply with this guideline according to Article 79 of the Pharmaceutical Administration Law.

Russia

In 2013, Russia was still one of the emerging markets where pharmaceutical companies were lining up with investments. Russian pharmaceutical sector was, and still is, highly dependent on medicine imports. Almost 80% of drugs sold in Russian pharmacies are imported as medicinal products; the remaining 20% are manufactured from imported active pharmaceutical ingredients. Additionally, Russian government regulates the prices for essential 608 drugs. The lists differ from one region to another.

After the annexation of Crimea, undeclared invasion of Ukraine, and imposition of Western sanctions, Russian economy contracted substantially. Ruble devaluated steeply, and growing inflation undercut the purchasing power of Russians. Contrary to general perception, study conducted by Ernst &Young in late 2014 revealed that pharma executives do not see serious threats to their operations and investment plans in Russia and most of them have not been affected by the situation.

Russia, at that time a fast growing, emerging market with strong demand for investment, had its own rules for entry. The global pharmaceutical industry approached Russia with two distinct market strategies: they opted either for building local manufacturing capabilities or for partnership with domestic companies.

Apparent imbalance of regulatory requirements for foreign producers as opposed to domestic, restrictions on interaction between healthcare workers and pharma representatives, and lack of clear understanding of current legislation makes operations in the region difficult. According to the EY report, 77% of pharmaceutical companies in Russia struggle with excessive bureaucracy and corruption.

Russia is also a major market for **counterfeit pharmaceuticals**. Russia remains on the **Priority Watch List** in 2015 as a result of continued copyright infringement and trademark counterfeiting. The lack of enforcement of trademarks has resulted in the continued problem of counterfeit goods in Russia.

Russia made commitments in the World Trade Organization Working Party Report to implement protections against “unauthorized disclosure of, or reliance on, undisclosed test or other data generated to obtain marketing approval for pharmaceutical products”.

Counterfeit pharmaceuticals manufactured in Russia are available through online pharmacies. In 2014 Russia’s State Duma adopted new legislation aimed at criminalizing pharmaceutical counterfeiting as well as the distribution of fake and adulterated medicines.

The new Federal Law “**On amendment of the Federal Law On circulation of pharmaceuticals**” No. 429-FZ was signed into law on 22 December 2014. This act introduced significant amendments into the existing law No. 61-FZ of 2010.

The amendment introduced new definitions, separated clinical trials from registrations; established new grounds for cancellation of registration; enacted good practices rules;

established procedure for interchangeability of pharmaceuticals; imposed registration obligation an Marketing Authorization Holder; amended rules on pricing and reimbursement for essential and vitally important medicines; and established cease and desist order for illegal pharmacies.

New terms and definitions include biological medicinal products, immune-biological medicinal products, biotech medicinal products, gene-therapy medicinal products, orphan drugs, and homeopathic products.

The term “original medicine” was replaced with “reference medicinal product”. This definition stands for a product, which has been registered in Russia for the first time, including generics. “Generic medicinal product” then refers to a drug that is biologically equivalent to “reference medicinal product”.

The new law somewhat clarified powers of federal executive authorities and procedure for fast track procedure for “first three” medicines registered in Russia and for pediatric medicines.

The new act introduced procedure for determining interchangeability of medicinal products and, in particular, parameters for comparison. The requirement to demonstrate bioequivalence does not apply to reference medicinal products, herbal medicines, homoeopathic products and medicinal products, which have been approved in Russia for over 20 years.

State-authorized and financed Expert committee shall determine interchangeability of products registered before 1 July 2015. Applications for determining interchangeability shall be submitted by end of 2016. From January 2018 this information shall be included in Russian national Register of medicinal products.

Manufacturers and wholesalers shall comply with Good distribution practice and Good practices of storage and transportation as approved by authorized bodies.

The need to conform the manufacturing of medicines to the GMP (Good Manufacturing Practices) standards has been a mandatory licensing requirement in Russia since January 2014. In reality, however, this requirement has not worked properly. Russia does not yet have a formal procedure to confirm GMP compliance, and in the difference from other countries, it does not issue GMP certificates to compliant manufacturers. This made definition and detection of counterfeit and adulterated pharmaceuticals effectively impossible.

This has changed with the new law. After 1 July 2015, Russian Ministry of Public Health will be authorized to issue a GMP certificate based on the results of a manufacturing inspection

by authorized experts.

Many of the new amendments must be specified by government decrees or orders of the Ministry of Healthcare and other authorities. The rules on Good manufacturing practice, Good distribution practices, and Good practices of storage and transportation of medicinal products, as well as good pharmacy practice are yet to be approved.

http://www.lexology.com/library/detail.aspx?g=710ebbe9-cca5-40eb-ba8b-e429d53b6c8f