

February 18th, 2013 | Press Release

For Immediate Dissemination

To: All Partners of the Russian Pharmalicensing Group PLC (RPG) Company.

Receipts for medicines will be written out as per INN.

In the end of 2012, the Russian Ministry of Health published the Order of December 20, 2012, on its website, please see below:

«Pursuant to the Order of the Russian Ministry of the Health of December 20, 2012, #1175H «On Establishing a Procedure for Prescribing and Writing out Medicines, Receipt Forms for Medicines, and a Procedure for Filling out These Forms, Keeping Them on File and Storage», medicines should be prescribed and written out as per the international non-patented name (INN) or a grouping name if INN is not available, and if both are missing – as per a trade name.

This regulation is enacted in order to preclude an opportunity of prescribing certain medicines to patients merely on the basis of an arrangement between a physician and a pharmaceutical company that is directly forbidden by i.2 p.1 art. 74 of the Federal Law «On Foundations of Citizens' Health Care in the Russian Federation», thus eliminating a factor of corruption.

At the same time, this document does not deprive a physician from the right to select a customized therapy for a patient, including that in cases of intolerance to the medicine.

As far as differences in the efficacy and safety of medicines with the same INN are concerned, the Ministry pursues a consistent policy to solve this problem. At present, the Russian Government has approved the Strategy of Medicine Supply to General Public in the Russian Federation Through 2025. One of its crucial components is revision of the pharmaceutical market. Issues on the agenda include revising all the assortment of medicines, original pharmaceuticals and their analogues, consistently removing from the



market those of them which were registered on a basis of limited clinical studies without substantial efficacy evidence. Each non-patented pharmaceutical item should be coincided with a line of marketed medicines (trade names) with identical properties. This is the only way to ensure that a patient shall be provided with necessary efficient quality and safe medicines.

At present, the order is in the course of state registration with the Russian Ministry of Justice. The document is coming into effect on July 1, 2013.

The Ministry justifies such a decision as the making of a legal environment which shall excluded the possibility of forfeit and falsified produce entering the pharmaceutical market»

Source: Website of the Russian Ministry of Health: <http://www.rosminzdrav.ru/health/remedy/154>

Opinion of Russian Pharmalicensing Group on this Order is as follows:

1. In Russia, there is low acceptance and ambiguous, and, at times, even negative public opinion on generics which is mainly attributed to a high level of distrust regarding the efficacy and safety of generics and a high level of comfort with the brand. However, Russian physicians seem to be more reluctant to accept writing out as per INN than pharmacists, who deal with INN on a regular basis by the virtue of their profession, or that of the general public, which was never investigated nor taken into consideration by the Ministry of Health. Pharmaceutical companies should take this fact into consideration when targeting the physicians and pharmacists and in the allocation of resources for promotion.
2. The MoH's intention to implement new pro-generic policies has a potential to reverse the trend. By mandating physicians prescribing by INN, it is expected to save millions of public funding.
3. The given order of the MoH aimed to encouraging or mandating a physician to prescribe by INN in Russia may receive a pushback from physicians and patients, and it will take time to have it fully or



partially implemented. The Law is coming into effect as of July 1, 2013, in a “traditional” vacation period for major market subjects: physicians, pharmacists, sales force of pharmaceutical companies. Therefore, one should not expect an orchestrated action in the implementation of this order all over the Russian territory.

4. Physicians’ concerns over losing prescribing freedom and a lack of punitive provisions may lead them to continue prescribing brands in a short and midterm.
5. On the one hand, it is yet unclear how a physician shall proceed if a patient demands that a certain brand be prescribed. On the other hand, pharmaceutical companies are in a position to promote a product brand and the company on a patient level. Apparently, pharmaceutical companies shall have to adjust their marketing strategies with a change in the rearrangement of communication in a physician-pharmacist-patient pattern.

A future market outlook, in RPG's view, shows that unless the right incentives for key stakeholders are set, it is unlikely that there will be a dramatic increase in prescription by INN, what the Russian Ministry of Health is counting on. For branded manufacturers as well as for non-branded ones (these are mainly Indian and Russian manufacturers), it will be important to monitor changes in markets with historically strong contribution/attention to branding to determine whether Russian physicians will continue to remain loyal to brands.

About Russian Pharmalicensing Group PLC.

Russian Pharmalicensing Group (RPG) specializes in licensing, business development and the registration of pharmaceutical and VMPs including pharmacovigilance, biotech, APIs, medical devices, food supplements and life science with high regional prevalence in Russia, Ukraine and ex-USSR countries. RPG is headquartered in Moscow, Russia. Registered in Russia No: 5117746056194.

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