

## NEW PRESIDENT STEPS IN WITH A NEW DECREE

On the day of his inauguration, newly re-elected President Putin had issued 11 new Decrees. The one that we share with you is the Decree "On Improvement of Public Health Policy". While some parts of it are nonessential, the document is quite entertaining and thus we present it to you in its entirety. Please see our analysis below.

### From the Desk of the President of the Russian Federation:

In order to further improve public health policies aimed at preserving and promoting the health of Russian citizens, increase their life expectancy, I resolve:

#### 1. To the Government of the Russian Federation:

##### a) To ensure by 2018:

reduction in mortality from diseases of the circulatory system down to 649.4 cases per 100 thousand population;

reduction in mortality from neoplasms (including malignant) down to 192.8 cases per 100 thousand population;

reduction in TB mortality down to 11.8 cases per 100 thousand population;

reduction in deaths from road accidents down to 10.6 cases per 100 thousand population;

reduction in infant mortality, primarily by reducing it in the regions with high levels of this indicator, down to 7.5 per 1 thousand live births;

**bring the share volume of domestic production of medicines according to the nomenclature of the list of strategically important medicines and the list of vital and essential drugs up to 90 percent;**

b) by March 1, 2013 develop and approve a package of measures aimed at improving the provision of medical care on the basis of the state program of the Russian Federation "Promotion of public health";

c) by January 1, 2013 develop and approve a strategy for the development of medical science in the Russian Federation until 2025;

d) by November 1, 2012 provide the development and submission to the State Duma of Federal Assembly of Russian Federation the draft federal law on the protection of public health from the effects of tobacco consumption.

2. To the Government of the Russian Federation jointly with the executive bodies of subjects of the Russian Federation:

a) to further work towards the implementation of measures to promote healthy lifestyle of citizens of the Russian Federation, including the promotion of culture of healthy nutrition, fitness and wellness programs, alcohol and drug abuse prevention, combating tobacco consumption;

**b) by January 1, 2013, together with noncommercial organizations, to develop Strategy of drug supply and its implementation plan in the Russian Federation until 2025;**

c) by July 1, 2012 to approve an action plan to implement the Principles of State Policy of the Russian Federation in the field of nutrition until 2020;

d) by May 1, 2013 develop a package of measures to ensure staffing of the health care system of the Russian Federation with medical personnel, providing for the adoption by the subjects of the Russian Federation of programs aimed at improvement of the training of medical personnel, to assess their level of qualification, to phase out the scarcity of health personnel, as well as to implement differentiated measures of social support for health care workers, especially in the most underserved jobs;

e) by January 1, 2016 to complete the modernization of the controlled substance service of the Russian Federation.

3. In the 1st quarter of each year Executive bodies of subjects of the Russian Federation must submit to the Government their reports on the state of public health and health care organizations from previous fiscal year.

4. This Decree shall enter into force upon its official publication.

May 7, 2012, 15:50

## OUR ANALYSIS

We have highlighted the paragraphs that in our assessment will affect pharmaceutical and clinical trial industries in Russia. Mr. Putin's call for increase of domestic production of medicines is not new. There is, however, a question of how this Decree can be implemented. As we have mentioned in our previous communications, Russia's pharmaceutical industry is still in the state of disarray. Some steps are taking place to revitalize it through direct and indirect investments into joint ventures and acquisitions of early stage European and US pharmaceutical companies. There has also been a call from the Government to transition to GMP standards by 2013. To date it remains unclear as to how these plans can become reality. With almost 90% of the pharmaceutical market of so-called strategically important medicines represented by foreign products, increasing a domestic share to 90% in such a short period of time seems unattainable. Creation of domestic pharmaceutical companies that could compete even on the local market will take much more than 6 years. We all know that on average a drug development cycle takes 15 years.

Based on our discussions with some of the insiders, the most tangible solution would be to mandate foreign Pharma to move its production facilities to Russia. It will probably start with requiring small investments, such as blister packaging plants and will subsequently move towards true CMC production. Furthermore, for optics purposes, foreign Pharma is likely to be asked to form Russian subsidiaries – this way the “production of medicines” will look truly domestic.

When it comes to registering new medicinal products in Russia, with or without future plans of producing them locally, legislative changes have already been implemented. Since 2010 the Russian government requires of all new drug entities seeking approval in Russia to have at least part of phase II-III multicenter clinical trials to be conducted locally. If the manufacturer does not fulfill this requirement, a registration trial needs to be repeated in Russia.

Mr. Putin's new decree solidified the prognoses of many – there will continue to be a push towards domestic R&D and production. How will foreign Pharma respond to this challenge remains to be seen. In our view, bypassing the country that is thriving on oil and gas and that has recently shown impressive and steady growth in its pharmaceutical sales will be difficult.