Clinical Trials in Russia
Orange Paper
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Contents

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Executive Summary

The Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (alias RosZdravNadzor, RZN) approved 178 new clinical trials of all types including local and bioequivalence studies during the second quarter of 2010 demonstrating a 38% increase over the corresponding period of last year.

The main contribution into the total number of studies is made by multinational multi-center clinical trials, although the number of them decreased by 7% over Q2 2009 and stood at 77 new studies in Q2 2010.

The number of the local clinical trials conducted in Russia by domestic and foreign sponsors increased from 27 to 68 clinical trials demonstrating a notable 152% increase over the same point in 2009.

The proportions between local and foreign companies significantly changed over the corresponding period of last year. The share of local sponsors increased by 16% and accounted up to the half of the total number of studies in Q2 2010.

Clinical trials in Russia in Q2 2010 were sponsored by companies from 23 countries. Russian sponsors are still on the top with the maximum number of initiated trials (87). American sponsors with 20 studies took the runner-up place, they are followed by German (16), Swiss (10) and the UK (7) sponsors. Top 6 is concluded by the Danish manufacturers with six new studies in Q2 2010.

The number of patients which are planned to be enrolled in the Phase I-IV trials launched in the second quarter of 2010 stood at 15,287 patients, demonstrating a 24% increase over the last year number.

The Swiss *Novartis* sponsoring eleven new studies is on the top of the heap in the second quarter of 2010. *GlaxoSmithKline* with six new trials in Q2 2010 took the runner-up place. It is followed by *Johnson & Johnson* sponsoring five new studies and *Teva* with four new studies but with the bigger number of patients and sites. The top five is concluded by *Novo Nordisk* also having four new studies in Q2 2010.

The Russian pharmaceutical company ZAO *Rafarma* sponsoring four new clinical trials ranked number one among domestic pharmaceutical manufacturers by the number of new studies in the second quarter 2010. OOO *Materia Medica* with three new trials took the runner-up place. It is followed by ZAO *Biocad,* OAO *Nizhpharm* with the same number of studies (three), but different number of patients and sites. ZAO *Firn M* takes the 5th place with two studies.

Sixty four per cent of the new studies in Q2 2010 were conducted in the six leading therapeutic areas. The maximum number of trials (24) were initiated in Oncology; 20 clinical trials in Endocrine diseases; 13 new studies in Respiratory diseases; 11 new studies in Cardiovascular, 10 in Genitourinary diseases and 9 in Psychiatry were initiated in Q2 2010.

The Center for Drug Evaluation and Research (CDER) of the FDA approved 26 new drugs during Q2 2010; four of them are new molecular entities (NME); others are the new dosages, manufacturers or indications of the already marketed drugs. Three of the approved drugs were tested in clinical trials in Russia.

During the period from January 1 to March 31 2010 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMEA) reviewed 14 applications to market drugs in the EU. Eight of the drugs which received positive opinions were (or are being) tested in clinical trials in Russia.

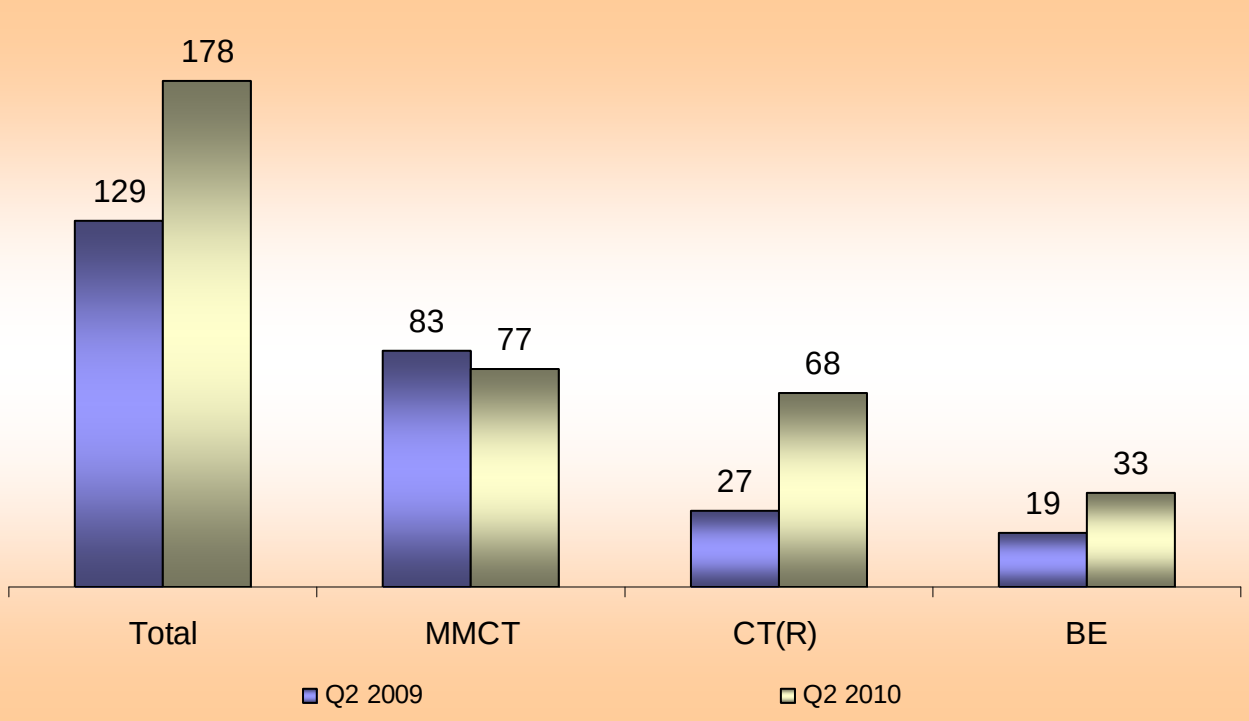
Clinical Trials by Type and Manufacturing Country

The RZN approved 178 new clinical trials of all types including local and bioequivalence studies during the second quarter of 2010; demonstrating a 38% increase comparing to the corresponding period of last year. As shown in the Figure 1, the main contribution into the total number of studies is made by multinational multi-center clinical trials conducted in Russia by domestic and foreign sponsors (the MMCT bar in the Figure 1) although their number decreased by 7% over the same point in 2009 and stood at 77 studies.

Number of clinical trials conducted in Russia by domestic and foreign sponsors notably increased from 27 to 68 studies, which is 152% more over Q2 2009 (presented as CT(R) in Figure 1).

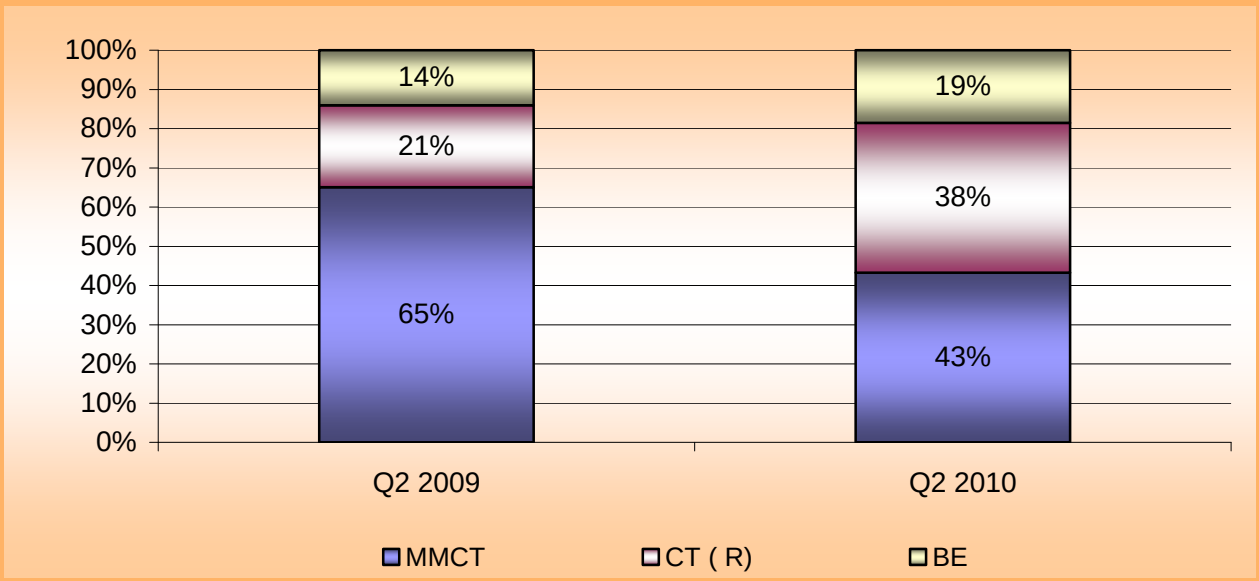
The number of bioequivalence studies (BE in Figure 1) in the second quarter of 2010 increased by 14 new trials and stood at 33.

Figure 1. Clinical trials approved by RZN in Q2 2010



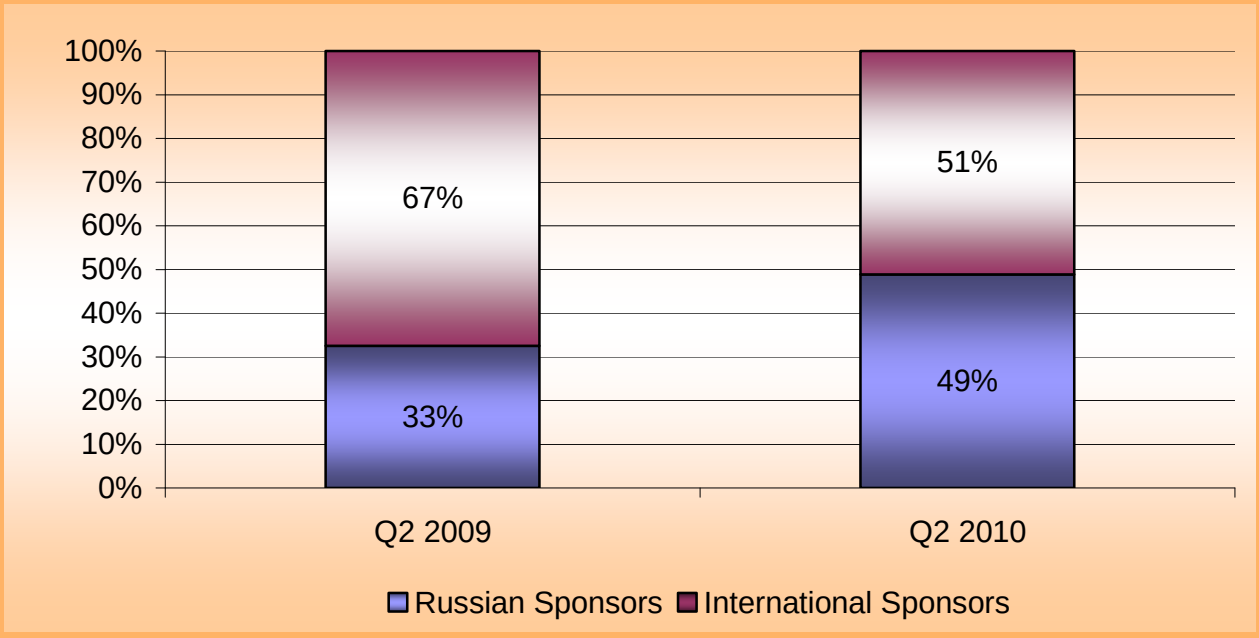
The proportions between different study types (multinational multi-center clinical trials, local studies and bioequivalence trials) changed significantly over the same point in 2009. The share of multinational multi-center clinical trials decreased from last year's figure and stood at 43% of the total number of clinical trials approved by RZN in the second quarter of 2010. The shares of the local trials and bioequivalence studies in Q2 2010 stood at 38% and 19% of the total number of studies, respectively, while they accounted to 21% and 14% in Q2 2009.

Figure 2. Clinical trials by type in Q2 2010



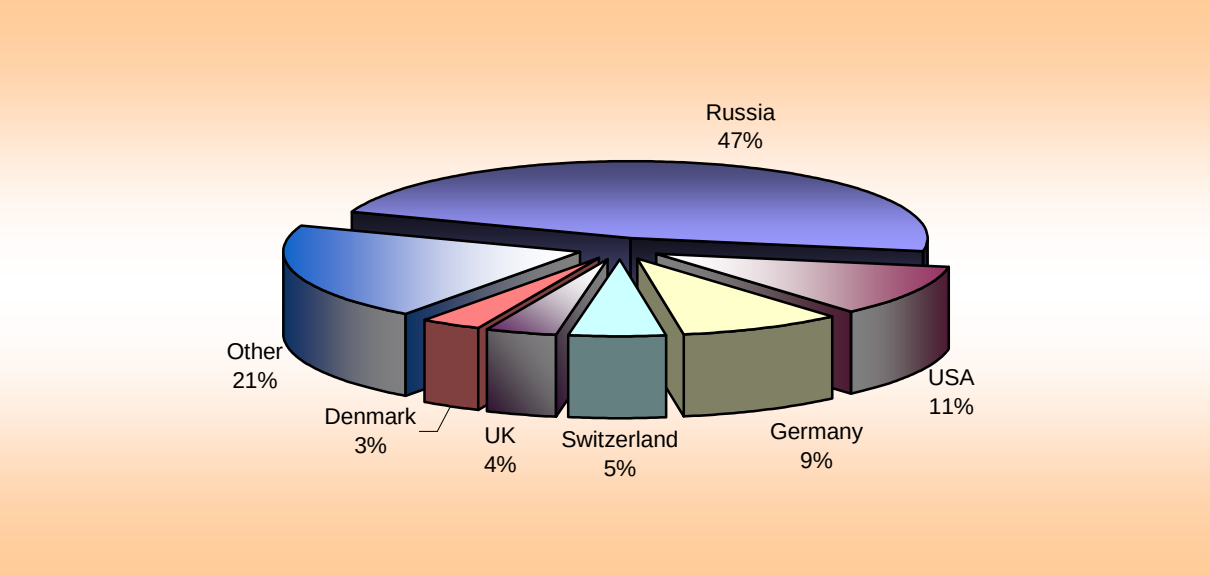
The proportions between local and foreign companies significantly changed over the corresponding period of last year. The share of foreign sponsors decreased from 67% to 51%, while the share of local sponsors increased by 16% and accounted up to the half of the total number of studies.

Figure 3. Russian and International sponsors in Q2 2010



Clinical trials in Russia in Q2 2010 were sponsored by companies from 23 countries. Figure 4 demonstrates the input of the leading countries of sponsor's origin into the total number of clinical trials. Russian sponsors are still on the first place with the maximum number of initiated trials (87). American sponsors with 20 studies took the runner-up place, they are followed by German (16), Switzerland (10) and the UK (7) sponsors. Top 6 is concluded by the Danish manufacturers with six new studies in Q2 2010.

Figure 4. Countries presented on the Russian clinical trials market in Q2 2010

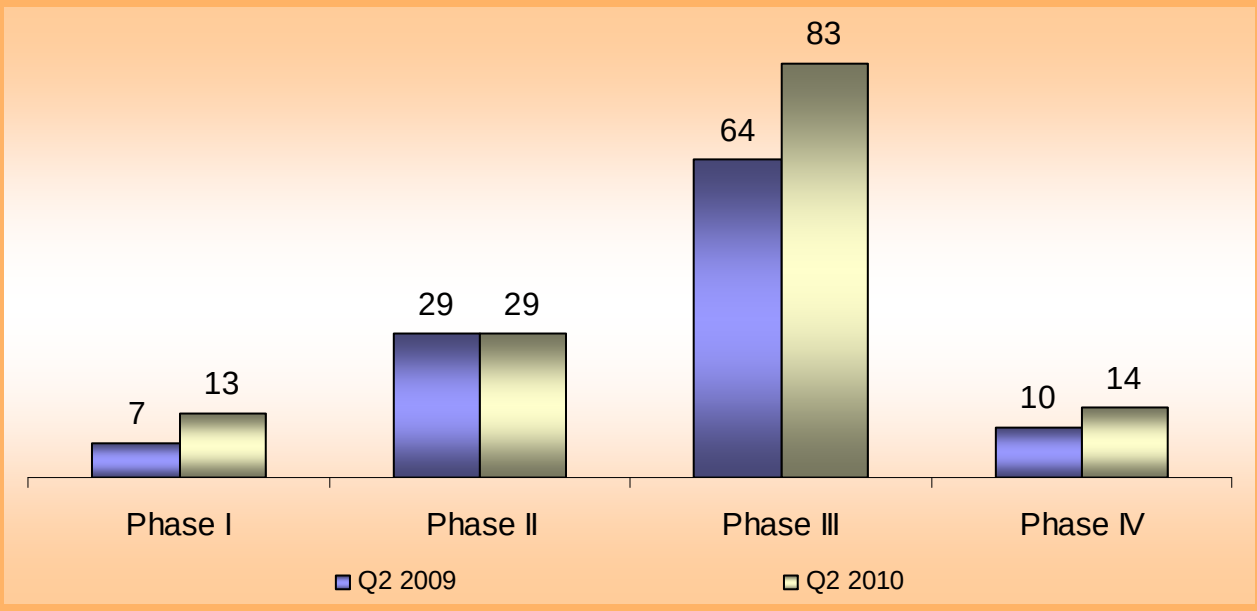


France, Austria, Israel, Spain, Hungary, Kazakhstan, Canada, Netherlands, and Japan are represented among others.

Clinical trials by Phase

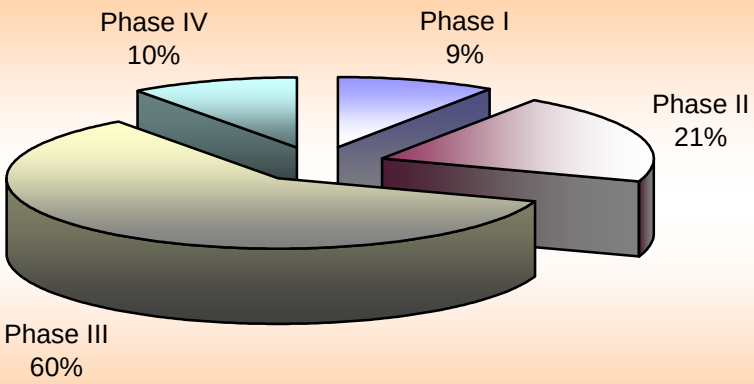
Thirteen new Phase I clinical trials were launched in the second quarter of 2010; six trials up over the corresponding quarter of last year. The number of the Phase II remained the same as in the second quarter of 2009 (29). The number of Phase III trials demonstrated a significant 30% increase over last year number, up from 64 to 83 studies. The number of Phase IV trials also notably increased from 10 in Q2 2009 to 14 in Q2 2010.

Figure 5. Clinical trials in Russia in Q2 2010 by phase



As shown in Figure 6, the share of Phase III trials in Q2 2010 stood at 60% of the total number of studies, the share of Phase II trials accounted at 21%, Phase IV trials stood at ten per cent, while the share of Phase I studies stood at nine per cent.

Figure 6. The proportions between study phases in Russia in Q2 2010



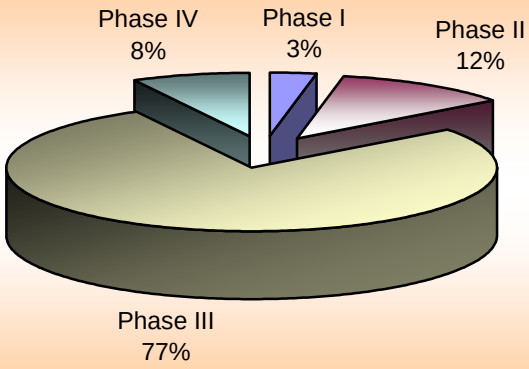
The number of patients which are planned to be enrolled in the Phase I-IV trials launched in the second quarter of 2010 stood at 15,287 patients, 24% up over the last year number of 12,338 patients.

Four hundred and sixty three subjects will be recruited in Phase I trials; 1,800 patients – in Phase II trials; 11,844 subjects – in Phase III studies and 1,180 patients will be enrolled in Phase IV studies.

The minimal number of subjects in a single study is six, the maximum number is 2,032.

The proportions of the number of patients between different Phases is shown on the Figure 7.

Figure 7. The number of patients in Q2 2010 by study phase



The duration of the shortest trial is three months, the longest one will take five years.

Rating of international sponsors

The Swiss *Novartis* sponsoring eleven new studies is on the top of the heap in the second quarter of 2010. *GlaxoSmithKline* with six new trials in Q2 2010 took the runner-up place. It is followed by *Johnson & Johnson* sponsoring five new studies, and *Teva* with four new studies, but with greater number of patients and sites. The top five is concluded by *Novo Nordisk* also with four new studies.

Top five international sponsors by the number of new studies in Q2 2010 are presented in Table 1.

Table 1. Top-5 international study sponsors in Q2 2010

№	Sponsor	No. of trials	No. of patients	No. of sites
1	Novartis	11	2032	117
2	GlaxoSmithKline	6	1600	86
3	Johnson & Johnson	5	473	50
4	Teva	4	644	68
5	Novo Nordisk	4	190	23

Rating of Russian sponsors

The Russian pharmaceutical company ZAO *Rafarma* sponsoring four new clinical trials enrolling 400 patients in four sites, ranked number one among domestic pharmaceutical manufacturers by the number of new studies in the second quarter 2010.

OOO *Materia Medica* with three new trials and 494 subjects in 20 sites, took the runner-up place. It is followed by ZAO *Biocad,* OAO *Nizhpharm* with the same number of studies (3), but different number of patients and sites. ZAO *Firn M* takes the 5th place with two studies and 160 subjects in 6 sites.

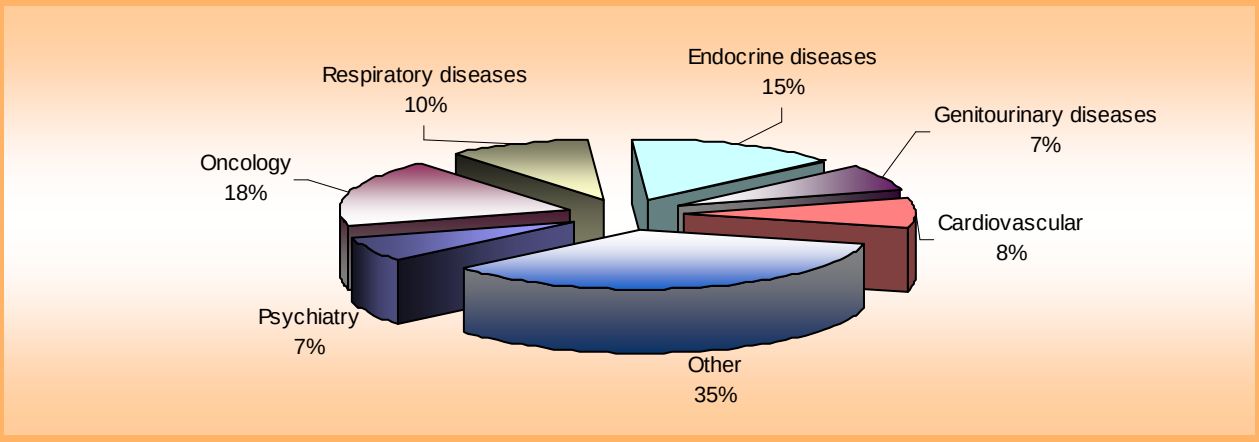
Table 2. Top-5 Russian study sponsors in Q2 2010

№	Sponsor	No. of trials	No. of patients	No. of sites
1	Rafarma	4	400	4
2	Materia Medica	3	494	20
3	Biocad	3	300	15
4	NIzhpharm	3	240	6
5	Firn M	2	160	6

Therapeutic areas of clinical trials in Russia in Q2 2010

Sixty four per cent of the new studies in Q2 2010 were conducted in the six leading therapeutic areas. The maximum number of trials (24) were initiated in Oncology; 20 clinical trials in Endocrine diseases; 13 new studies in Respiratory diseases; 11 new studies in Cardiovascular, 10 in Genitourinary diseases and 9 in Psychiatry were initiated in Q2 2010. The proportions between different therapeutic areas are shown in Figure 8.

Figure 8. Clinical trials in Russia in Q2 2010 by therapeutic area



Clinical trials results

The Center for Drug Evaluation and Research (CDER) of the FDA approved 26[1] new drugs during Q2 2010; four of them are new molecular entities (NME); others are the new dosages, manufacturers or indications of the already marketed drugs. The Table 3 represents three of the drugs which were tested in clinical trials in Russia.

Table 3. New Drugs approved by FDA in Q2 2010 and tested in Russian sites

Approval date	Drug	Manufacturer
04/20/2010	Vimpat (Lacosamide)	Schwarz Biosciences
06/01/2010	Prolia (Denosumab)	Amgen
06/17/2010	Staxyn (Vardenafil hydrochloride)	Bayer Hlthcare
Source: CDER FDA http://www.fda.gov/cder		

During the period from April 1 to June 30 2010 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMEA) reviewed 14[2] applications to market drugs in the EU. No negative opinion was adopted for any of the drugs which had been approved earlier. Eight of the drugs which received positive opinions were (or are being) tested in clinical trials in Russia (see Table 4).

Table 4. New Drugs approved by EMEA in Q2 2010 and tested in Russian sites

Approval date	Drug	Manufacturer
22/04/2010	Votrient (Pazopanib hydrochloride)	Glaxo Group Ltd
22/04/2010	Reyataz (Atazanavir)	Bristol Myers Squibb Pharma EEIG
22/04/2010	RoActerma (Tocilizumab)	Roche Registration Ltd
20/05/2010	Ozurdex (dexamethasone)	Allergan Pharmaceuticals Ireland
20/05/2010	Orencia (Abatacept)	Bristol Myers Squibb Pharma EEIG
20/05/2010	Taxotere and Docetaxel Winthrop (Docetaxel)	Aventis Pharma S.A.
24/06/2010	Vpriv (Velaglucerase alfa)	Shire Pharmaceutical Ireland Ltd
24/06/2010	Byetta (Exenatide)	Eli Lilly Nederland B.V.
Source: CHMP EMEA http://www.emea.europa.eu/index/indexh1.htm		

[1] CDER FDA http://www.fda.gov/cder
[2] CHMP EMEA http://www.emea.europa.eu/index/indexh1.htm

FDA inspections

According to the FDA data, there were no FDA inspections conducted in the Russian investigative sites during Q2 2010.