CEE Keynote

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AIPM®

Association of International Pharmaceutical Manufacturers

Ассоциация международных фармацевтических производителей

CENTRAL AND EASTERN EUROPE

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CEE region overview

•CEE represents a total market of 285 million people and a combined GDP of US$3.0 trillion in 2010

• CEE region has proven to be one of the Europe's fastest growing economies, pharmaceutical market is one of the most dynamic sectors of the economy in CEE and in the world

• 10 countries of the CEE region has been joined the EU by 2011:

Much of the pharmaceutical legislation within the region has therefore been harmonized with EU

The implementation of GMP is taking place across most of the region and this is inevitably improving the quality of overall production and leading to a rise in market values. Other countries such as Russia, Ukraine are on the way to harmonization.

• Developing or fundamentally changing healthcare systems

• Different IP protection levels

• Dominance of generic medicines

Russia, a potentially vast emerging market

Russia has the largest pharmaceutical market in the CEE region, followed by Poland and the Czech Republic.

Pharma market growth in 2010 :

Indicator	RUB	$	EURO	Packs
Value 2010, Bln.	544.0	17.86	13.39	5.10
Growth 2010/2009	▲5%	▲9%	▲14%	▲1%

The market environment remains challenging due to unpredictability, lack of IPR protection etc.

Despite of the financial crisis pharmaceutical industry has witnessed steady growth for the past 5 years.

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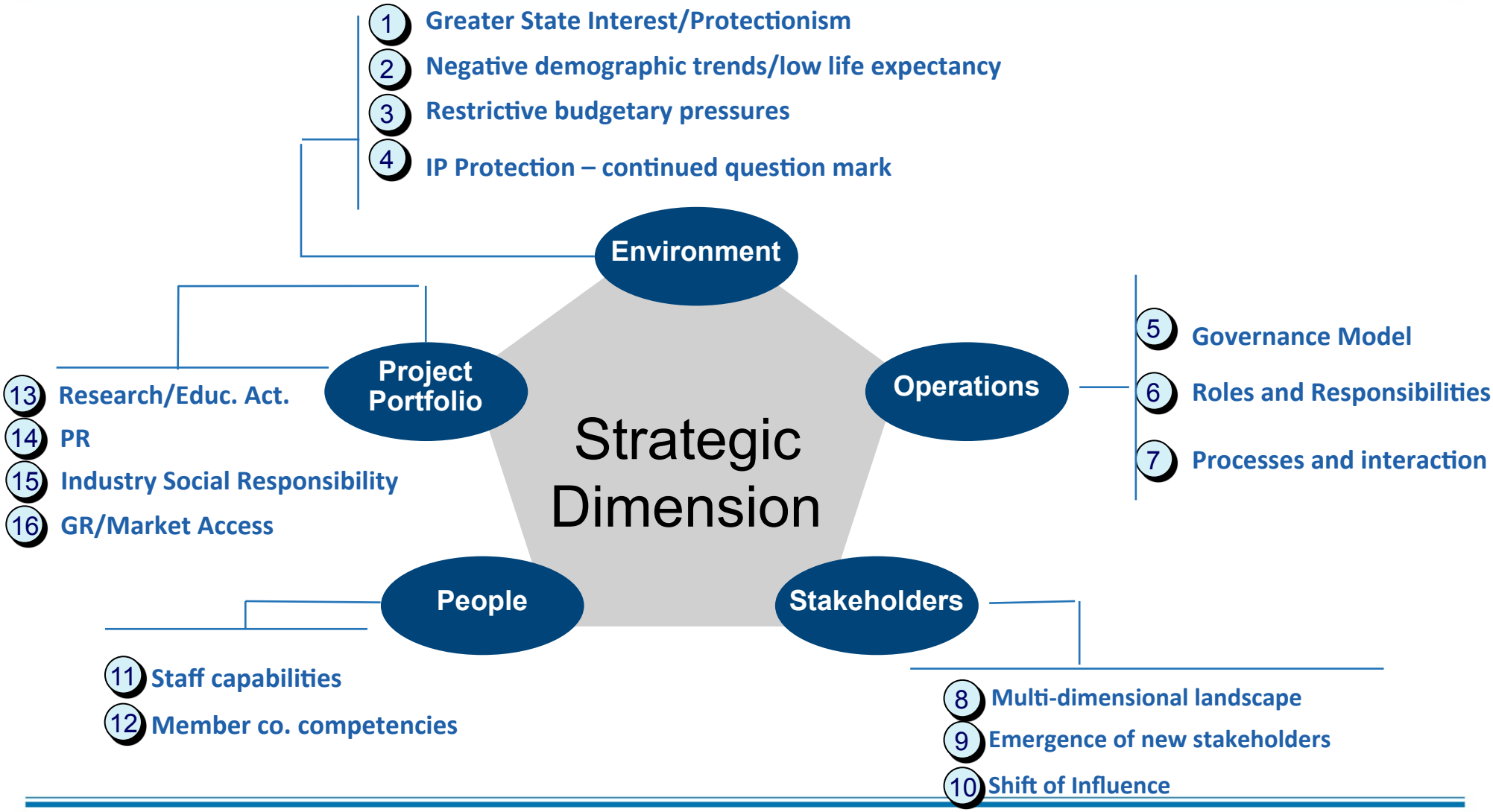
Russian pharmaceutical market snapshot



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Selected drivers of growth potential

- Focus by Federal government on improving healthcare
- Focus on local pharmaceutical development
- Increased demands on healthcare
- Strong growth in original brands and branded generics
- Economic growth prerequisites due to high prices on oil and gas
- Desire to access to innovative new products
- Development of Reimbursement system

Intellectual Property Rights Protection in Russia

DE update:

- ✓ Data Exclusivity is under discussion in the frame of the RU/EU/US WTO accession dialogue
- ✓ DE 6-year mechanism is now included into the Law on Drugs circulation amendments conditionally signed in December 2010
- ✓ Amendments will come into force upon Russia entering WTO

WTO accession:

- ✓ US/EU assessment is that up to 95% of pending questions are solved, there are still a few, IPR is one of them
- ✓ According to the first VP Igor Shuvalov the probability of Russia joining the WTO still this year is high: however it is a political issue so has an unpredictable manner

Much of IPR standarts are in force: the IPR protection norms were summarized in the Civil Code of the RF(part 4), the establishment of Patent Court and other initiatives are under discussion

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AIPM member companies

Abbott Laboratories
Abbott Products
Alcon
Amgen
Astellas
AstraZeneca
Bausch + Lomb
Baxter
Bayer Consumer Care
Bayer Schering Pharma
Berlin-Chemie
Boehringer Ingelheim
Bristol - Myers Squibb
Celgene
Dr. Falk
Egis
Eisai
Eli Lilly
EVER Neuro Pharma
F. Hoffmann-La Roche
Ferrosan
Fresenius Kabi
Galderma
Gedeon Richter
Genzyme
GlaxoSmithKline C.H.
GlaxoSmithKline Pharma
Grunenthal
Ipsen
Janssen Pharmaceutica
Johnson&Johnson
KRKA
Laboratories Boiron
MSD Pharmaceuticals
MEDA
Merck Serono
Merck Sharp & Dohme
Novartis C.H.
Novartis Pharma
Novo Nordisk
Nycomed
Pfizer HCP Corporation
Pierre Fabre
Polpharma
Ranbaxy
Reckitt Benckiser
Sandoz
Sanofi-aventis
Sanofi Pasteur
Servier
STADA CIS
Takeda Pharmaceuticals
Teva
UCB Pharma
Zambon Group

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AIPM

• **Association of International Pharmaceutical Manufacturers (AIPM)** is a non - profit organisation representing the interests of 55 international pharmaceutical companies operating in Russia. AIPM members manufacture approximately 80% of pharmaceuticals globally and more than 65% of pharmaceuticals imported into Russia, and more than 50% of pharmaceuticals consumed in Russia.

• **AIPM is a member** of IFPMA, American Chamber of Commerce and the Russian Union of Industrialists and Entrepreneurs.

•**The fundamental principles of the AIPM are**:

- *Supporting innovation through strong and transparent intellectual property rights legislation*

- *Adherence to ethical standards as set out in AIPM Code of Marketing Practices*

All AIPM members confirmed in written the adherence to ethical standards as set out in AIPM Code of Marketing Practices

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Development of the Code of Marketing Practices of the AIPM

- First version – 1998
- Second version – 2003
- Third version – 2006

Based on IFPMA, EFPIA Code

- The Code was revised twice in 2009, the latest version of December 10, 2009 is published, placed at the www.aipm.org and under distribution to the AIPM member companies and other interested parties

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AIPM Objectives: Ethics

- To continue harmonization of ethical standards with standards of other associations, including IFPMA/EFPIA, distribution of the given standards on other participants of the pharmaceutical market

- Assistance to approval and advancement of ethical standards at the various levels: state authorities, other stakeholders PR - campaigns in mass - media, public informing

- Examination of the current legislation: Federal Law “On Drug Circulation”, Draft law “On the Community Health Protection”, Federal Antimonopoly Service legislative initiatives

- To continue developing of the AIPM Code and online training in accordance with the legislation’s changes

- To continue promotion of the Code both internally and externally

- To continue sharing best practices

- Other kinds of activity

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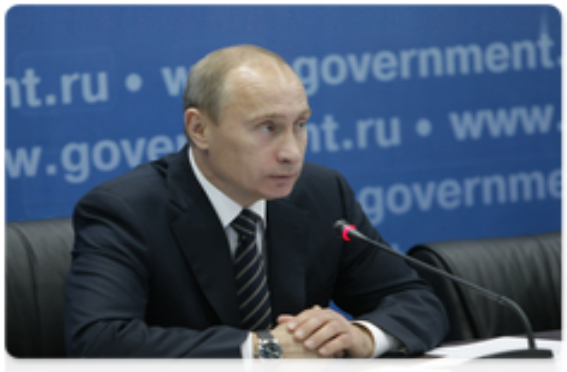
Turbulent environment



Meeting “On strategy of the development of Russian pharmaceutical industry till 2020 year” held on 9 October, 2009 in Zelenograd

Vladimir Putin, Prime Minister of the Russian Federation:

- *“ Last decades in Russia there was obviously abnormal practice of mutual relations between manufacturers, including, first of all foreign manufacturers and part of medical community”*

- *“It is unacceptable when pharmaceutical companies pay fees for prescription of medicines. Manufacturers sponsor corporate events, different seminars, including trips to the “warm seas”*

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Turbulent environment

Vladimir Putin, Prime Minister of the Russian Federation:

- *"In fact there are created echelon systems of lobbying of interests of the large pharmaceutical companies. This vicious practice is needed to be stopped"*

- *"It is necessary to get rid of Medical representatives. At the first stage should put this activity in certain frameworks and make it more transparent"*

"Should set up legislative bans for these kinds of activity and introduce more strict norms of medical ethics"

Following this statement the Russian Government prepared the amendments to the current legislation

Interactions with HCPs

The version of the Draft Law “On public Healthcare Protection in the Russian Federation”

It restricts significantly the interactions between HCPs and pharmaceutical companies.

- complete ban on receiving any gifts and payments provided by pharmaceutical company for anything if the amount is more than 3000 Rubles (appr. 100$) per year;
- ban to make written or oral agreement with company on prescription or recommendation of drugs, medical devices, medical equipment, nutrition;

- complete ban to get samples of drugs, medical devices, medical equipment, nutrition;
- it is prohibited to provide the patient with invalid or incomplete information on interchangeable drugs circulating on the market;
- complete ban on medical representatives visits during working hours;

- ban on prescription of drugs on the receipt blanks containing the advertising or trade name of drugs, medical devices, medical equipment, nutrition;
- complete ban on taking part of HCPs in any events sponsored by one pharma company (excluding events in the frame of clinical studies).

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- On 21st of April, 2011 the Federal Draft Law was submitted by the Government to the State Duma for consideration
- 19th of May, 2011 – Parliament hearing devoted to the Draft Law
- 23th of May, 2011 – Supposed 1st hearing date of the Draft Law at the State Duma
- The Law is supposed to enter in force on January 1, 2012.
- AIPM prepared the compromised version of the text and submitted it to the MoH, FAS, Administration of the President and other stakeholders with the results of National survey on interactions with HCPs.

- ***AIPM welcomes international pharma society and highly appreciate cooperation towards sharing best practice and establishing common approaches***

Other challenges

-Lack of transparency and predictability

-Registration procedures

-CTs: Multicentre clinical trials (if Russia did not participate) are not accepted for registration

- Orphan drugs

-Antitrust regulation

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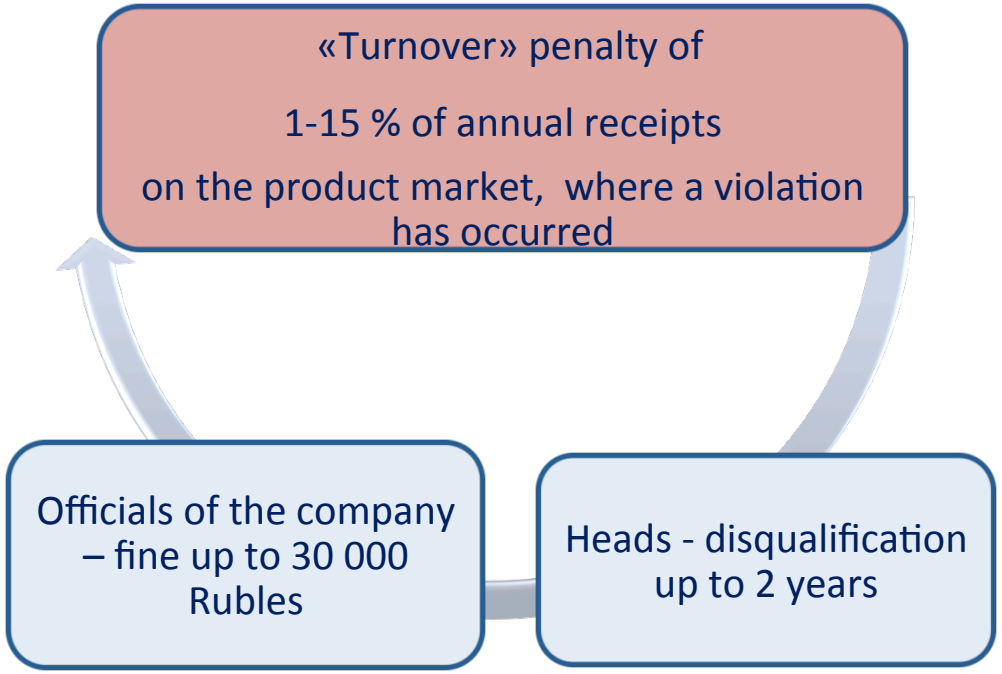
Sphere and methods of antimonopoly control are extending

Amendments to the Federal Draft law "On Public Health Protection"

Amendments to the Administrative Violations Code of the RF

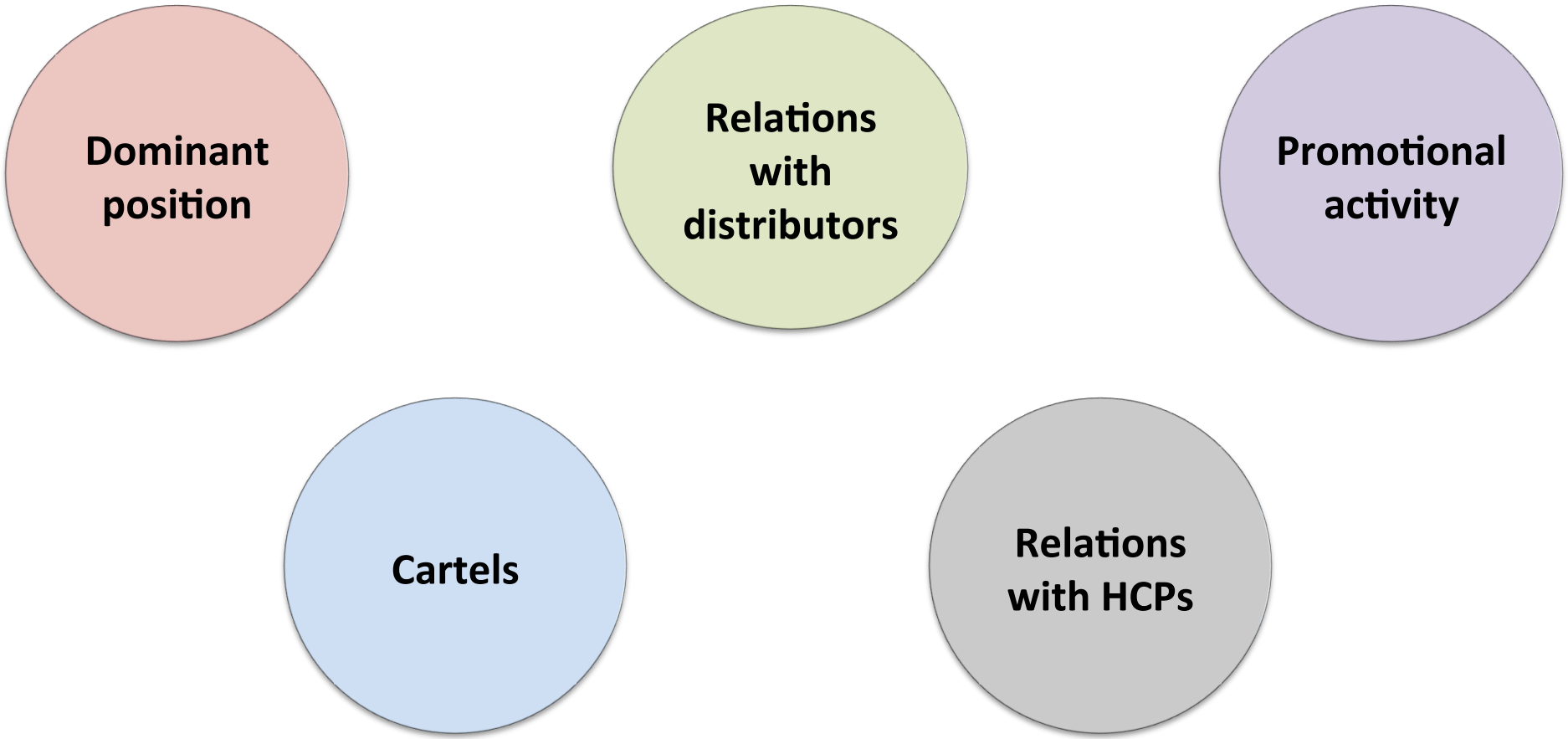
Responsibility of HCPs

Responsibility of pharmaceutical companies



Key learnings

Potential risk zones



Multi-stakeholder landscape