

# Pharma Poland News

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## Flu drives growth of pharmacy market

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*Continued on page 2 ►*

## Changes to the Food and Nutrition Safety Act as pertaining to the marketing of dietary supplements

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*Continued on page 5 ►*

## Flu drives growth of pharmacy market

Consumer traffic at Polish pharmacies increased significantly in October. As a result, medicine sales were up in all the main categories. This was accompanied by a substantial increase in the value of reimbursement and a slight decline of prices and pharmacy margins.

### Overall market performance

An early outbreak of the flu season and mounting fears about swine flu led to a considerable increase in patient numbers

at Polish pharmacies in October<sup>1</sup>. This fed through into sales figures, which maintained robust growth for another straight month.

In October, the Polish pharmaceutical market (understood as retail pharmacy sales)

reached the value of PLN 2.31bn (€547m), up by 5.9% from September. In annual terms pharmacy sales grew 5.3%, a slight acceleration compared with the preceding month. Significantly, the strong result was achieved despite a high reference base (in September 2008 the pharma market grew by 9.4% y-o-y) and a lower number of working days than a year earlier.

Cumulatively in the first 10 months of the year the Polish pharmaceutical market rose by 7.9% y-o-y and amounted to nearly PLN 21.4bn (€4.9bn). In view of the rapid surge in flu cases observed in the past weeks,

<sup>1</sup> In the analysed month the number of patients visiting the average pharmacy was 3,940, an increase of 5.1% compared with September and up by 0.4% on a year earlier.

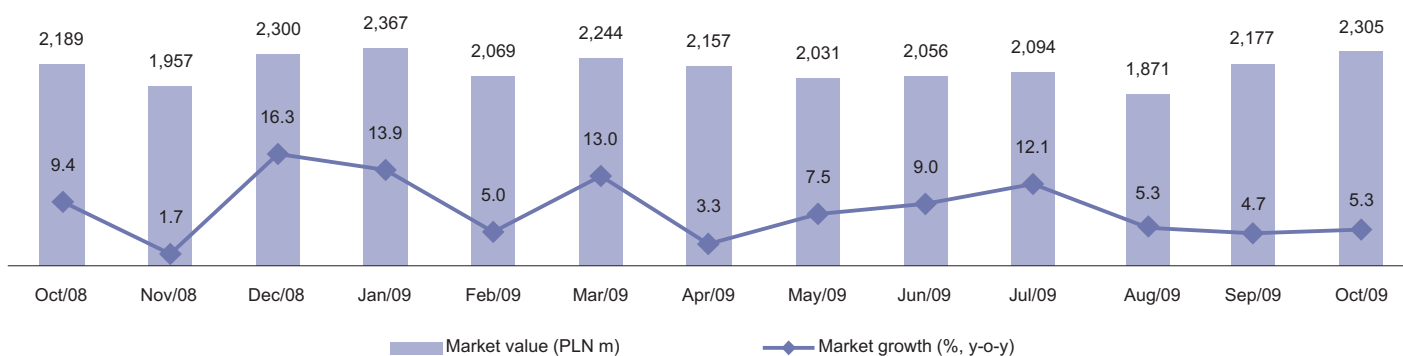
### Polish pharmaceutical market performance, October 2009

	October 2009	Change (m-o-m)	Change (y-o-y)	January-October 2009	Change (y-o-y)
<b>Total turnover, PLN '000</b>					
Average pharmacy	171.0	6.2%	5.6%	1,572.5	5.7%
Total pharmacy market	2,305,080	5.9%	5.3%	21,372,537	7.9%
<b>Value of reimbursed prescriptions, PLN '000</b>					
Average pharmacy	76.7	5.3%	1.2%	712.0	2.7%
Total pharmacy market	1,033,750	5.0%	0.9%	9,677,625	4.8%
<b>Value of fully-paid prescriptions, PLN '000</b>					
Average pharmacy	31.8	4.4%	-0.1%	301.5	4.6%
Total pharmacy market	429,162	4.1%	-0.3%	4,098,180	6.7%
<b>Value of non-prescription sales, PLN '000</b>					
Average pharmacy	61.5	8.2%	15.0%	550.5	10.5%
Total pharmacy market	828,901	7.9%	14.7%	7,481,835	12.8%
<b>Value of reimbursement, PLN '000</b>					
Average pharmacy	54.3	5.5%	5.9%	501.0	8.9%
Total pharmacy market	732,242	5.2%	5.7%	6,809,492	11.1%
<b>Share of reimbursement, %</b>					
In total pharmacy turnover	31.8	-0.6%	0.4%	31.9	3.0%
In reimbursement sales	70.0	0.1%	4.7%	69.6	6.0%
<b>Average price per package, PLN</b>					
Total	15.36	-0.1%	6.7%	15.05	6.0%
Of reimbursed medicines	27.41	0.0%	6.6%	26.64	5.6%
Of OTC medicines	9.27	1.3%	11.9%	8.96	8.6%
<b>Average pharmacy margin, %</b>					
Total	26.76	-0.5%	8.7%	26.0	8.2%
Of reimbursed medicines	20.47	-1.5%	7.9%	20.0	8.8%
Of remaining products	32.15	0.6%	8.2%	31.7	6.2%
<b>Number of patients per pharmacy</b>	3,940	5.1%	0.4%	37,012	-0.4%

Source: PharmaExpert, 2009

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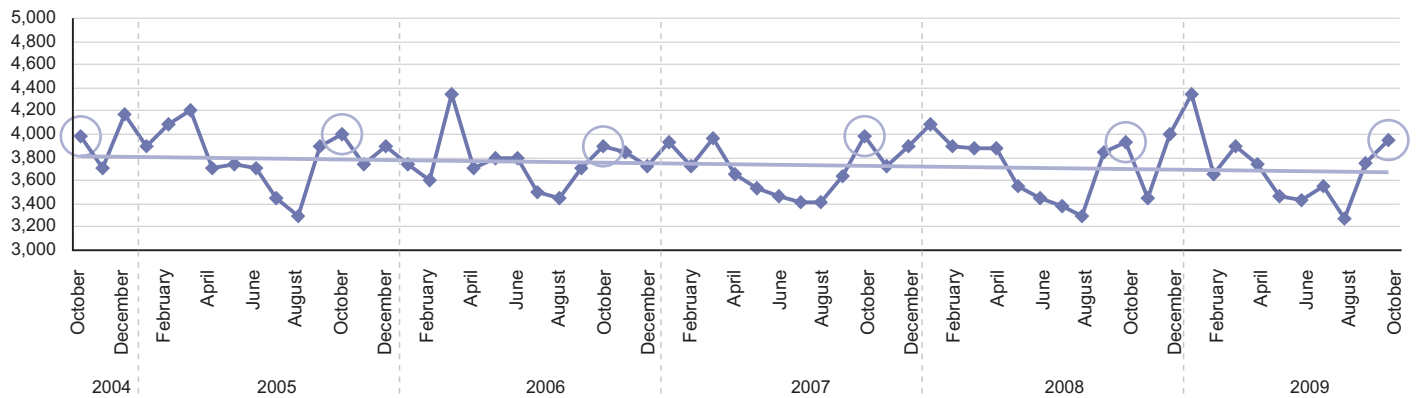
### Polish pharmacy market value and growth, October 2008-October 2009



Source: PharmaExpert, 2009

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## Average monthly number of patients in pharmacy in Poland, October 2004-October 2009



Source: PharmaExpert, 2009

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and given a markedly lower reference base, we expect a sharp rise in pharmacy sales in November, with a full-year forecast of 10% growth.

### OTC sales remain key growth engine

In comparison with September, pharmacy sales were significantly up in all the main product categories. As in previous months, the highest rate of market growth was observed in non-prescription sales, which rose by 7.9% in October and amounted to almost PLN 829m (€197m). Interestingly, on a year-on-year basis OTC sales posted an even more impressive growth (14.7%).

At the same time, sales of prescription medicines rose by 4.7% m-o-m and by 0.5% y-o-y, exceeding PLN 1.46bn (€347m). This was thanks chiefly to reimbursed sales, which registered growth of 5.0% m-o-m and 0.9% y-o-y, to PLN 1.03bn (€245m). Meanwhile, fully-paid prescription sales were up by 4.1% in monthly terms but down 0.3% on a year earlier, to over PLN 429m (€102m).

In the period under analysis, the value of reimbursement amounted to PLN 732m (€174m), which represents an increase of 5.7% against a year earlier (compared with annual growth of 5.6% in September). In

monthly terms the value of reimbursement rose less markedly in October (up by 5.2%). As a result, the share of reimbursement in total pharmacy sales amounted to 31.8%, which represents a drop of 0.2 p.p. in relation to September and a growth of 0.1 p.p. compared with October 2008.

### Slight drop of prices and margins

Following a marked increase in September (by 0.7%), in October the average price of a medicine sold in a Polish pharmacy edged down slightly (by 0.1%), due to a substantial decline in the average price of a fully-paid prescription medicine. At the same time, the average price of a reimbursed drug remained flat while OTC prices were up by 1.3% on average compared with September.

Despite the slight slowing of the upward trend, medicine prices in October were still significantly higher compared with a year ago. In the period under analysis, the average price of a medicine sold in a Polish pharmacy was PLN 15.36 (€3.6), up 6.7% y-o-y (compared with a growth of 7.1% y-o-y in September), while the price of a reimbursed drug reached PLN 27.41 (€6.5), up by 6.6% y-o-y (against 5.7% y-o-y in the previous month). At the same time, the average price of an OTC product was PLN 9.27 (€2.2), an increase of as much as 11.9% y-o-y (compared

to 10.7% y-o-y in September). As in previous months, the annual rate of price growth thus remained well ahead of inflation in all product categories (the consumer price index amounted to 3.1% y-o-y in October).

October also witnessed a marginal drop of the average pharmacy margin (by 0.1 p.p.). However, since this came after more than a year of increases, the average margin remains near its record levels. In the period under analysis, the average pharmacy margin was 26.8%, up by 2.2 p.p. compared with a year ago. Over the last 12 months, the reimbursed medicines margin increased by 1.5 p.p. to 20.5%, whereas the margin on the remaining products was up by 2.4 p.p. to 32.2%.

The data used in this article was sourced from PharmaExpert.

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# Polish dental services driving the private healthcare market

Polish citizens are increasingly often choosing private dental healthcare, rather than publicly funded services reimbursed by the National Health Fund (NFZ). At the moment it is estimated that the number of patients who would rather go private is already around 50%, and it is thought that they will spend more this year<sup>1</sup>.

## Private dental treatment worth almost PLN 4bn in 2008

According to our estimates, the private healthcare market in Poland is worth approximately PLN 26bn (€7.4bn) and is growing by more than 10% year on year. In 2008, Poles spent PLN 6bn (€1.7bn) on dental healthcare in total. The private subdivision is thought to be worth almost PLN 4bn (€1.1bn), with a 20-30% year-on-year growth rate. Forecasts suggest that in 2009 we can expect private spending on dental healthcare to increase by 10-20%<sup>2</sup>.

According to the Centrum Implantologii i Ortodoncji Dentim Clinic in Katowice, because of the increasing popularity of private dental healthcare, the market is doing very well during an overwhelming economic crisis. Last year the turnover of this practice increased significantly, and the number of patient appointments increased almost six-fold. In addition, the number of patients who chose to have one of the most expensive treatments, implants, is continuously increasing.

## Dental services in private hands

At present 80% of all dental treatment is provided by dental clinics which have contracts with the NFZ, and clinics therefore have certain dental procedures reimbursed by the NFZ. There is a long list of treatments which are reimbursed, and this includes not only general dentistry and surgical treatments, but also prosthetics and periodontics, along with the comprehensive dental care of preg-

nant women. However, patients cannot, for example, choose the kind of filling to have, apart from those specified by the NFZ, and patients of more than 13 years of age do not have their orthodontic treatment reimbursed at all<sup>3</sup>. Unlike NFZ funded dental healthcare, at a private practice one can choose the form of anaesthesia, including the new, painless, computer-controlled anaesthetic device – “The Wand”. These are just a few examples, of which there are many and which are the reason why an increasing number of patients are choosing to pay for dental treatment themselves.

It also follows from this that those who choose private, non-reimbursed practices are usually more affluent, more interested in more comprehensive treatments, and more well-informed, looking for access to the most recent and most innovative solutions introduced in the field of dental care.

## Small clinics preferred

With regard to the choice of dental healthcare provider, there is also an interesting mi-

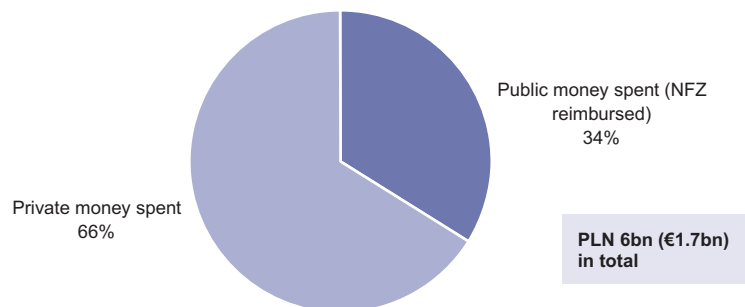
nor detail: the surveys suggest that, when choosing a private dental practice and a dental clinic, patients tend to favour small private dental practices, rather than large clinics. About 80% of local healthcare practices are now served by private companies and they usually rent equipment and premises.

The expectations of patients are growing in step with the value of the dental market. Today, a typical patient expects to receive comprehensive and professional treatment, which is not, however, always available. Patients tend to look for a dental healthcare provider which can offer all required services and treatments promptly and in one place. Of about 6,700 dental practices registered in Poland, 1,243 are located in the Slaskie voivodship, and of these only two have specialist computer-driven tomography equipment. In total only 10% of dental practices are equipped with modern RTG or tomography apparatus. This is associated with the trend mentioned previously – most private dental practices are too small to afford such medical devices.

## Promotions increasingly widespread

Private treatments are, in addition to being more luxurious, in a sense, obviously more expensive. Whereas a standard, one-off visit to the dentist costs approximately PLN 150 (€35), highly specialist treatments can be considerably more expensive. For this reason, many private practices, and clinics, have introduced the possibility of paying treatment fees in instalments, by signing an agreement with a bank, which offers the patient money specifically for dental treatment at a particular dental surgery. Such loans usually carry interest of about 1%, which makes them very attractive as a source of funding. The patient

## Amount spent on dental healthcare in Poland by public and private sectors (%), 2008



Source: Deloitte, 2009

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<sup>1</sup> According to a survey carried out by PBS DGA.

<sup>2</sup> All data on dental spending in this paragraph comes from Deloitte.

<sup>3</sup> In accordance with an August 2009 ordinance.

thus not only becomes loyal to the dental practice or clinic but can also afford essential treatment, which can sometimes cost as much as PLN 30,000 (€6,900), e.g., for an aesthetic.

Another way in which large dental clinics attract customers is to offer promotions for certain packages of treatments: for example, Enel-Med offers 60% off a consultation and 15% off the treatment. It is also becoming increasingly common to issue warranties for dental services, which require the patient to appear for regular check-ups, once again increasing customer loyalty. Such practices are used by other large clinics which offer dental treatment, including Lux-Med and Medcover.

## Polish dental services attractive to foreigners

Polish private dental practices and clinics are also very attractive destinations for foreign patients. Because of the location of Poland and its relative proximity (a flight of between two and two-and-a-half hours) to all other European countries, it is very common for German, Dutch and Swedish citizens to travel there to receive dental treatment. Surprisingly, the statistics show that Poland is also a popular “dental tourism” destination for nations such as Britain and Canada, which are further away. According to the Polish Information and Foreign Investment Agency, foreign patients spent more than

PLN 400m (€114m) on dental treatment in Poland in 2008. Experts expect numbers to rise by 25-30% on an annual basis.

# Changes to the Food and Nutrition Safety Act as pertaining to the marketing of dietary supplements

On 2 December 2009 the Sejm passed legislation amending the Food and Nutrition Safety Act and some other laws. The bill is now before the Senate, and it is highly likely that it will be enacted in its current form. The new legislation has important implications for the dietary supplements market.

The bulk of the changes approved by the Sejm concern dietary supplements. Indeed, the committee and subcommittee meetings that led to the passage of the bill showed just how complex and controversial the issues surrounding dietary supplements really are, raising the question whether this category of products would more properly be regulated by a separate act of parliament. Their closeness to medicines cannot be denied, particularly from the perspective of the average consumer. On the other hand, they are only allowed to contain ingredients that appear in food products, which from the legal viewpoint makes dietary supplements a subcategory of food. Whether this is a good solution is a difficult question. Obviously, it follows from relevant EU regulations, but that is not to say that it is necessarily right.

## Mutual recognition

Concerning EU law, we should note the introduction into the Food and Nutrition Safety Act of a new Article 6, which contains a reference to the mutual recognition clause. It stipulates that food products lawfully produced or marketed in another Member State of the European Union should be allowed to be marketed in Poland even if they do not meet requirements set forth in other parts of the Polish law that are not covered by the EU directive, provided that they do not constitute a danger to human health or life. A company that introduces a food product on the Polish market will be required to prove that the product is not harmful: the sanitary inspection may order the company to submit information confirming the product’s “com-

pliance with equivalent health standards, including documents issued by relevant authorities of the country of origin”.

Because the past record of Polish sanitary authorities in applying the mutual recognition clause as pertaining to dietary supplements has generated much controversy, the proposed changes could inject a degree of stability into the market in this respect.

## Investigation process

Under the proposed changes, a company that introduces (or is about to introduce) a food product (including a dietary supplement) on the Polish market for the first time, will be required to provide the following information in an official notification filed with the Chief Sanitary Inspectorate (GIS):

- full name of the product and of its manufacturer
- the form in which the product is introduced on the market
- a model of the product’s labelling in Polish
- classification of the food product, adopted by the company
- qualitative composition of the product, with data on its ingredients, including active ingredients
- quantitative composition of the product
- name and address of the company that is notifying authorities about the introduction of the product on the Polish market for the first time, as well as its tax identification number (NIP), if applicable.

The notification will have to be submitted in both electronic and written form. However, the written form will continue to be regarded as the “official” one, as the date of its submission will count as the official date of notification. Imposing an additional requirement to submit the notification in electronic form is hardly a simplification of the procedure.

In another important change, the amendment enlarges the scope of the investigation process that may be initiated by the Chief Sanitary Inspectorate in case of doubt over a product. A GIS investigation may now encompass product composition, properties of specific ingredients, and intended product use.

Furthermore, the GIS's investigative powers will now extend to the correctness of the product's classification, its compliance with the requirements pertaining to the relevant type of food product, and to establishing whether the product does not meet the requirements for other human products, in particular for medicinal products, cosmetics, or medical devices, as defined by relevant laws or regulations.

At the same time, the amended Act retains an existing provision whereby the GIS must notify the concerned company “immediately” about the launch of an investigation. Significantly, however, the Act does not specify when such an investigation should or could be initiated. Does it mean that it could be launched e.g. one year after the product has been introduced on the market?

### URPL's opinion

Under the amended Article 31, during the investigation process the Chief Sanitary Inspectorate may:

- demand the opinion of the Dietary Supplements Panel (...)
- order the (notifying) company to submit the opinion of a scientific institution (...)

Item 2 of this article stipulates that “in case the GIS resolves to conduct an investigation with a view to establishing whether the food product that is the subject of the notification procedure does not meet the requirements for medicinal products or for medical devices as defined by relevant laws and regulations, the Chief Sanitary Inspector is obliged to request the opinion of medicines registration office URPL”.

What is new and surprising, the amended Act stipulates that if the URPL concludes that the product in question does meet the re-

quirements for medicinal products or medical devices, it must express its opinion in the form of an official decision, subject to an appeal procedure. It appears that by including this provision, lawmakers have responded to calls by the industry for an appeal route against decisions that classify a product as a medicine. Nevertheless, such an arrangement is controversial, because it accords to an opinion – which by definition has an auxiliary character – the status of an administrative act.

The appeal route envisaged by the amended Act raises problems of its own. If it is the GIS that requests the opinion of the URPL, it begs the question whether it is not in fact the GIS that is also entitled to lodge an appeal against it. Obviously, the intent of the law is different, but the right of companies to appeal against URPL decisions is by no means expressly established in the amended Act. Furthermore, it is not clear which authority is competent to handle such an appeal. Is it the health minister, or should the appeal take the form of a request addressed to the URPL to reconsider the case?

Finally, we should also mention the standpoint of the Committee of the European Integration Office (UKIE). According to the Office, a failure by a company to submit the opinion of the URPL does not in itself constitute a basis for the removal of its product from the Polish market. That is because such a decision may be justified only on the grounds of health risk to the population; and it is incumbent upon sanitary authorities to prove that such a situation obtains in the case of a given product.

As with any legislative changes, only practice will tell whether the new bill lives up to expectations and contributes to a more stable market environment, or whether it only makes life more difficult for companies.

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## Central and Eastern Europe: an attractive and promising location for clinical trials

The Central and Eastern European (CEE) area is considered to be a very attractive location for clinical trials. This is because of the lower costs, the large population and the lack of patient access to innovative therapies in the CEE countries. Despite some similarities, the market is not homogeneous, and there are important differences between individual countries in the region. This was one of the main problems discussed at the 4<sup>th</sup> Annual Clinical Site Partnerships in Central & Eastern Europe and Clinical Outsourcing Alliances in Central & Eastern Europe conferences held recently in Budapest and Boston<sup>1</sup>.

### The East is cheaper and offers high quality...

One of the greatest advantages of carrying out a study in Central and Eastern Europe is the benefit of cost saving with no loss of quality of service. HungaroTrial, a CRO company, claims that the costs of monitoring a clinical trial are roughly only 60-70% of those which it would incur with a comparable study in the US. Salaries and investigation fees are still lower in the CEE than in Western Europe and the US, and because of the low salaries of doctors it is quite easy to take on qualified medical staff.

Furthermore, because of its large population and the small number of patients who have access to innovative therapies, recruitment for a clinical trial in the CEE region is usually faster than it is in other countries.

According to companies operating on the market whose representatives spoke at the conferences, clinical trials carried out in the CEE region are superior to those carried out in the Western European countries and the US, because clinical trials in the countries of the region are less widespread and because investigators and patients are more motivated. This is also supported by inspections carried out in the CEE area by the US Food and Drug Administration, which showed that, between 1994 and 2008, only 2% of trials in CEE required obligatory measures in order to

rectify inaccuracies (in Western Europe the figure was 6% during the relevant period).

### ... but some ethical problems may occur

A company carrying out clinical trials in the CEE region may encounter ethical problems. This was emphasised by many speakers at the conferences. As such countries have weaker democratic traditions, because of their past political situations, their professional traditions may not be as ethical as those of Western Europe.

Because of this, several problems may arise:

- the reporting of activities which have not been carried out (employees)
- having two conflicting jobs despite a non-competition agreement (employees)
- personal relationships instead of skills used as recruitment criteria (CROs)
- service provider selection not transparent (regional sponsors)
- hiding income and evading taxes (sites)
- corruption.

### CEE: similar but different

Although the CEE countries are similar to each other in terms of costs and the quality of trials, there are some important differences. For example, in Russia and Ukraine customs processes are long, complicated and very cost-

ly in comparison with the situation in other CEE countries. In addition, many unforeseen procedures may arise in these two countries, and the instigation of a trial is slower and less predictable than in other countries of the region. On the other hand, although Russia and Ukraine are not EU members, they adhere to most EU regulations. Patient recruitment is even faster than in other countries in the region, because of the widespread willingness of patients to take part in a clinical trial.

Furthermore, financial reward plays an important role on those emerging markets with less well-developed economies and health care systems, such as Russia, Ukraine and Bulgaria, but it is not as important in, for example, Poland and Hungary. In addition, the international prestige of an employer might be considered an important motivational tool in Russia or Ukraine, but not necessarily in other CEE countries.

### Poland: clinical trials to be regulated by a comprehensive law?

In 2008 there were 468 new clinical trials approved in Poland, in comparison with 449 in 2007 and 451 in 2006. The most widely discussed topic in the country in the area of clinical trials in the recent past was the possibility of adopting a new law which would provide a comprehensive legislative framework for clinical research. At present this area in Poland is regulated by several legal instruments, in pharmaceutical and civil law. The draft version of a new law was presented by the Health Ministry in mid-December, and the public consultation stage is to last until the beginning of January.

The law will change the current regulations pertaining to the insurance of a researcher and will limit the number of clinical studies lead by one researcher (this will be decided individually in each case by bioethics committees). Access to clinical trials is also to be easier. Sites which carry out clinical trials will have to announce this fact on their websites, with any patient, rather than just one chosen by a researcher, able to take part in a trial.

The Head of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL), and not the health minister, will issue the final decision on the approval or rejection of a clinical trial, if the law comes into force.

<sup>1</sup> The conferences were organised by NextLevel Pharma in September and October 2009.

## Russia: significant reduction in the number of new trials approved

In 2008, 615 new clinical trials were approved by RosZdravNadzor<sup>2</sup> in Russia, representing an increase in excess of 9% in the number of studies in comparison with 2007. In every quarter of 2009, however, the number of new clinical trials approved in Russia fell in comparison with the corresponding period of 2008. There was a decline of around 13% in Q1 2009, 26% in Q2 2009 and around 10% in Q3 2009, according to the Synergy Research Group. In total, therefore, the number of new trials approved fell by 17% in the first three quarters of 2009 in comparison with the corresponding period of 2008, from 474 to 395. This is probably a result of new strategies approved by many global pharmaceutical manufacturers, which decided to limit their spending on research and development during the economic crisis.

Close to half of the new clinical studies approved in Russia during the first nine months of 2009 were phase III trials. Only 6% of new trials are phase I.

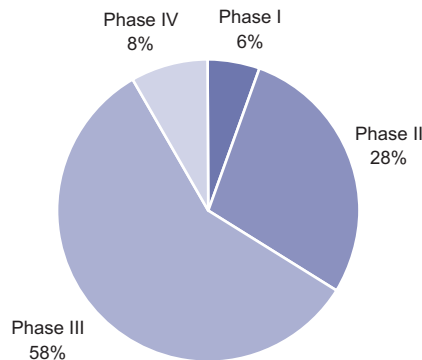
The clinical trials market in Russia is dominated by foreign companies. In Q3 2009, 67% of new clinical trials approved were sponsored by international companies. Furthermore, during the period analysed, as many as 61% of new approved clinical trials were multinational and multi-centre, and, despite the general reduction in the number of new trials approved, the proportion of multinational studies increased in Q3 2009 by 3 p.p. in comparison with Q3 2008. Leading international study sponsors in Russia in Q3 2009 included Novartis, Novo Nordisk, GlaxoSmithKline, Merck&Co. and Eli Lilly.

## Czech Republic: more clinical trials in oncology than in any other area

In 2008 some 61 new applications for clinical trial authorisation and 293 clinical trial notifications were submitted to the State Institute of Drug Control (SUKL) in the Czech Republic. There was a reduction of around 15% in the number of applications for approval/notification of a clinical trial in

<sup>2</sup> The Federal Healthcare Surveillance and Social Development Service of the Russian Federation

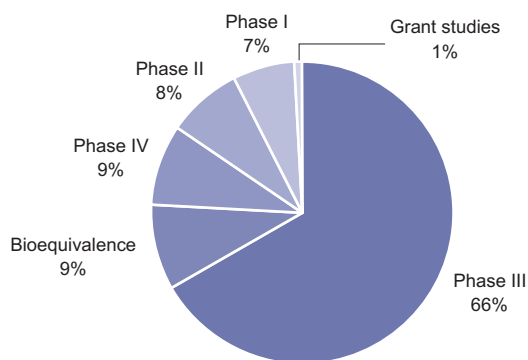
## Number of new clinical trials approved in Russia, by phase (%), Q1-Q3 2009



Source: Synergy Research Group, 2009

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## Number of clinical trial applications assessed by SUKL in the Czech Republic, by phase (%), 2008



Source: SUKL, 2009

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comparison with 2007. This could be because of a new Act on Pharmaceuticals which came into force in December 2007. This significantly changes the clinical trials arena in the Czech Republic. These are now governed not only by pharmaceutical law, but also by an Administrative Code. This has led to a major increase in the administrative work associated with the assessment of a clinical trial. Furthermore, given the planned changes in the reimbursement of clinical trial costs, companies have decided to speed up their clinical trial applications. As a result, some 60 new applications were submitted in December 2007 alone, twice the usual monthly average.

An application for the authorisation of a clinical trial is submitted for any clinical trial in which the relevant medicinal product is obtained by biotechnological processing or which contains substances of human or animal origin not authorised in the Czech Republic or in the other EU Member States (regardless of whether or not they are authorised in third jurisdictions). Clinical trial no-

tification is granted for, among other things, a medicinal product obtained by means of biotechnological processing and substances of human or animal origin authorised in the Czech Republic or in the European Union states by means of a centralised procedure but which is not used within the scope of the marketing authorisation decision.

Most of the clinical trial applications assessed by the SUKL in 2008 pertained to phase III trials (around 66% of the total) and bioequivalence studies. The most substantial number of applications for approval/notification of a clinical trial submitted in 2008 were in the areas of oncology (20% of the total) and neurology (13%).

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## Drug withdrawals in Poland, November 2009

	Date	Marketing authorisation holder	Product	Pharmaceutical form	Pack size	Series
<b>Withdrawals</b>	5 November 2009	Nuticia Cuijk	Bebilon Sojowy 2	powder	400 g	231966
	19 November 2009	Stiefel Laboratories	Isotrexin	gel	30 g (20 mg/g Erythromycin + 0.5 mg/g Isotretinoinum)	586L
	26 November 2009	Phytopharm Kleka	Intrctum Visci Phytopharm	oral liquid	100 ml	090205

Source: Main Pharmaceutical Inspectorate (GIF), 2009

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## Bans on drug advertising in Poland, November 2009

Date	Manufacturer*	Product	Media Form
12 November 2009	Novartis Poland	Femara	Advertisement addressed to distributors and people entitled to issue prescriptions, in the form of a leaflet with the identification number 05/09/FEM/DET/0623; advertisement in the May, 2009 issue of "Magister Farmacji" magazine; advertisement in the March/April, 2009 issue of "Onkologia info" magazine, volume 6, no 2 (28).
18 November 2009	US Pharmacia	Gripex Noc	Advertisement addressed to the public in the form of an audiovisual ad with the following message: „You are invited to view this programme by the maker of Gripex Noc medicine. Gripex Noc combats all symptoms of flu and cold. It allows you to sleep the night through,” and lighted words: „Running nose”, „Cough”, „Fever”, „Pain”, „Combats all symptoms of cold and flu”, „Allows you to sleep the night through”.
18 November 2009	Worwag Pharma GmbH & CO.KG	Milgamma	Advertisement addressed to the public in the form of a brochure.

\* Marketing authorisation holder

Source: Main Pharmaceutical Inspectorate (GIF), 2009

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## Drugs approved for trading in Poland, October 2009

No	Drug name	Commonly used drug name	Pharmaceutical form	Dose	Pack size	Availability category	Marketing authorisation holder	Manufacturer	Country of manufacturer
1	Alendronat Bluefish	Acidum alendronicum	Tablets	70 mg/ tabl.	4 tablets 12 tablets	Rx	Bluefish Pharmaceuticals AB	Laboratorios Belmac S.A.	Spain
2	Aqua Pro Iniectione Kabi	Aqua pro iniectione	Solvent for parenteral drugs	-	20 ampoules 5 ml 20 ampoules 10 ml 20 ampoules 20 ml 50 ampoules 5 ml 50 ampoules 10 ml	Rx	Fresenius Kabi Polska Sp. z o.o.	Fresenius Kabi Espana S.A.	Spain
3	Azimax	Azithromycinum	Coated tablets	500 mg	3 tablets	Rx	Apotex Europe B.V.	Apotex nederland B.V.	Netherlands
4	Belepar	Levodopum + Benserazidum	Tablets	100 mg + 25 mg 200 mg + 50 mg	30 tablets 50 tablets 60 tablets 100 tablets	Rx	Teva Pharmaceuticals Polska Sp. z o.o.	Teva Sante SA Teva UK Ltd. Teva Pharmaceutical Works Private Limited Company Teva Pharmaceutical Works Private Limited Company Pharmachemie B.V.	France Great Britain Hungary Hungary Netherlands
5	Bicalutamide medac	Bicalutamidum	Coated tablets	50 mg 100 mg	5 tablets 7 tablets 10 tablets 14 tablets 20 tablets 28 tablets 30 tablets 40 tablets 50 tablets 56 tablets 80 tablets 84 tablets 90 tablets 98 tablets 100 tablets 140 tablets 200 tablets 280 tablets	Rx	medac Gesellschaft fuer klinische Spezialpraeparate mbH	Synthon Hispania S.L. Synthon BV Synthon BV	Spain Netherlands
6	Bleomycin Teva	Bleomycini sulfas	Injection solution powder	15000 IU/phial	1 phial 10 ml 10 phials 10 ml	Lz	Teva Pharmaceuticals Polska Sp. z o.o.	Pharmachemie B.V.	Netherlands
7	Candepres	Candesartanum cilexetilum	Tablets	4 mg 8 mg 16 mg 32 mg	28 tablets 30 tablets in blisters 30 tablets in bottle 56 tablets 60 tablets	Rx	Sandoz GmbH	Lek Pharmaceuticals d.d. Lek S.A. Salutas Pharma GmbH	Slovenia Poland Germany
8	Co-Valsacor	Valsartanum + Hydrochlorothiazidum	Coated tablets	80 mg + 12.5 mg 160 mg + 12.5 mg 160 mg + 25 mg	28 tablets 56 tablets 98 tablets	Rx	Krka d.d., Novo mesto	Krka d.d., Novo mesto TAD Pharma GmbH mibe GmbH	Slovenia Germany
9	Donemed	Donepezili hydrochloridum	Coated tablets	5 mg 10 mg	28 tablets 56 tablets 98 tablets	Rx	Sun-Farm Sp. z o.o.	Arzneimittel Sun-Farm Sp. z o.o.	Germany
10	Doreta	Tramadoli hydrochloridum + Paracetamolium	Coated tablets	37.5 mg + 325 mg	10 tablets 20 tablets 30 tablets 60 tablets	Rx	Krka d.d.	Krka d.d.	Slovenia

No	Drug name	Commonly used drug name	Pharmaceutical form	Dose	Pack size	Availability category	Marketing authorisation holder	Manufacturer	Country of manufacturer
11	<b>Ebetrexat</b>	Methotrexatum	Solution for injections with pre-filled syringes	20 mg/ml	1 single-dose pre-filled syringe 1 ml 1 single-dose pre-filled syringe 1.25 ml 1 single-dose pre-filled syringe 1.5 ml 4 single-dose pre-filled syringes 1 ml 4 single-dose pre-filled syringes 1.25 ml 4 single-dose pre-filled syringes 1.5 ml 5 single-dose pre-filled syringes 1 ml 5 single-dose pre-filled syringes 1.25 ml 5 single-dose pre-filled syringes 1.5 ml	Rx	Ebewe Pharma Ges.m.b.H Nfg. KG	Ebewe Pharma Ges.m.b.H Nfg. KG	Austria
12	<b>Epinorm</b>	Oxcarbazepinum	Coated tablets	150 mg 300 mg 300 mg	50 tablets 100 tablets 200 tablets	Rx	Teva Pharmaceuticals Polska Sp.z o.o.	Ivax Pharmaceuticals s.r.o. Teva Sante SA Teva UK Ltd. Teva Pharmaceutical Works Private Limited Company Teva Pharmaceutical Works Private Limited Company Pharmachemie B.V. Dragenopharm Apotheker Pueschl GmbH Egis Pharmaceuticals PLC	Czech Republic France Great Britain Hungary Hungary Netherlands
13	<b>Escitil</b>	Escitalopramum	Coated tablets	5 mg 10 mg 15 mg 20 mg	14 tablets 28 tablets 56 tablets	Rx	Egis Pharmaceuticals PLC	Egis Pharmaceuticals PLC	Germany Hungary
14	<b>Evertas</b>	Rivastigminum	Hard capsules	1.5 mg 3 mg 4.5 mg 6 mg	30 capsules	Rx	Zentiva k.s.	Zentiva k.s.	Czech Republic
15	<b>Eztom</b>	Mometasoni furoas	Ointment	1 mg/g	30g tube	Rx	Glenmark Generics (Europe) Ltd.	Medicamenta, a.s.	Czech Republic
16	<b>Fluxemed</b>	Fluoxetinum	Hard capsules	20 mg	30 capsules	Rx	PROMED.CS Praha a.s.	Morningside Pharmaceuticals Ltd.	Great Britain
17	<b>Fosinopril Actavis</b>	Fosinoprilum natriicum	Tablets	5 mg 10 mg 20 mg	14 tablets 20 tablets 28 tablets 30 tablets 50 tablets 98 tablets	Rx	Actavis Group PTC ehf.	Actavis hf.	Iceland
18	<b>Gabagamma 600</b>	Gabapentinum	Coated tablets	600 mg 800 mg	20 tablets 100 tablets	Rx	Wonwag Pharma GmbH & Co. KG	Zambon S.p.A. Dragenopharm Apotheker Pueschl GmbH	Italy Germany
19	<b>Galpamol</b>	Paracetamolum	Tablets	500 mg	6 tablets 8 tablets 12 tablets 24 tablets 48 tablets	OTC	APC Instytut Sp. z o.o.	Galpharm International Limited	Great Britain

No	Drug name	Commonly used drug name	Pharmaceutical form	Dose	Pack size	Availability category	Marketing authorisation holder	Manufacturer	Country of manufacturer
20	Granegis	Granisetronum	Coated tablets	1 mg 1 mg	5 tablets 10 tablets 100 tablets	Rx	Egis Pharmaceuticals PLC	Actavis hf. Actavis Ltd.	Iceland Malta
21	Imipenem/Cilastatin Teva	Imipenemum + Cilastatinum	Powder for solution for intravenous infusion	250 mg + 250 mg 500 mg + 500 mg	1 phial 5 phials 10 phials	Rx	Teva Pharmaceuticals Polska Sp. z o.o.	Facta Farmaceutici	Italy
22	Irbesartan Sandoz	Irbesartanum	Coated tablets	75 mg 150 mg 300 mg	28 tablets (4 x 7) 28 tablets (2 x 14) 30 tablets 60 tablets	Rx	Sandoz GmbH	Lek Pharmaceuticals d.d. Lek S.A. Salutas Pharma GmbH	Slovenia Poland Germany
23	Iricam	Irinotecani hydrochloridum trihydricum	Concentrate for solution for infusion	20 mg/ml	1 phial 2 ml 1 phial 5 ml 1 phial 15 ml	Lz	US Pharmacia Sp. z o.o.	Haupt Pharma Wolftratshausen GmbH	Germany Slovakia
24	Irinotecan Accord	Irinotecani hydrochloridum trihydricum	Concentrate for solution for infusion	20 mg/ml	1 phial 2 ml 1 phial 5 ml	Rx	Accord healthcare Ltd Accord healthcare Ltd	hameln rds a.s. Cemelog BRS Ltd.	Great Britain Hungary
25	Isoptin SR 180	Verapamilli hydrochloridum	Extended release tablets	180 mg	30 tablets 60 tablets	Rx	Abbott GmbH & Co.KG	Abbott GmbH & Co.KG	Germany
26	Izepox	Indapamidum	Extended release tablets	1.5 g	30 tablets	Rx	Ozone Laboratories BV	Ozone Laboratories SRL	Romania
27	Kvelux	Quetiapinum	Coated tablets	25 mg 50 mg	30 tablets 60 tablets 90 tablets	Rx	Sandoz GmbH	Salutas Pharma GmbH Lek Pharmaceuticals d.d. Lek S.A. S.C. Sandoz S.R.L. S.C. Sandoz S.R.L.	Germany Slovenia Poland Romania Romania
28	Latanoprost Actavis	Latanoprosom	Eye drops, solution	50 mcg/ml	1 bottle 2.5 ml	Rx	Actavis Group PTC ehf.	Hoechst-Biotika spol. s.r.o. Pharma Stulln	Slovakia Germany
29	Lofradyk	Clopidogrelum	Coated tablets	75 mg	14 tablets 28 tablets 28 tabl. (4 x 7) 28 tabl. (2 x 14) 30 tabl. (3 x 10) 30 tabl. (2 x 15) 60 tabl. (6 x 10) 60 tabl. (4 x 15) 90 tabl. (9 x 10) 90 tabl. (6 x 15)	Rx	Zaklad Farmaceutyczny Adamed Pharma S.A.	Adamed Sp. z o.o.	Poland
30	Losartan HCT - 1 A Pharma	Hydrochlorothiazidum + Losartanum kalicum	Coated tablets	50 mg + 12.5 mg 100 mg + 25 mg		Rx	1 A Pharma GmbH	Salutas Pharma GmbH Salutas Pharma GmbH Lek S.A. Lek Pharmaceuticals d.d.	Germany Germany Poland Slovenia
31	Miflexin	Clopidogrelum	Coated tablets	75 mg 75 mg	14 tablets 28 tablets	Rx	Zaklad Farmaceutyczny Adamed Pharma S.A.	Adamed Sp. z o.o.	Poland
32	Monotop	Topiramatum	Coated tablets	25 mg 50 mg 100 mg 200 mg	28 tablets in blisters 28 tablets in container 60 tablets in blisters 60 tablets in container	Rx	Nycomed Danmark ApS	Pharmathen S.A. Nycomed SEFAAS	Greece Estonia
33	Natrium chloratum 0.9 %Kabi	Natrii chloridum	Solvent for parenteral drugs	0.9 g/ml	20 ampoules 5 ml 20 ampoules 10 ml 20 ampoules 20 ml 50 ampoules 5 ml 50 ampoules 10 ml	Rx	Fresenius Kabi Polska Sp. z o.o.	Fresenius Kabi Espana S.A.	Spain
34	Nebilet HCT	Nebivololum + Hydrochlorothiazidum	Coated tablets	5 mg + 12.5 mg 5 mg + 12.5 mg	7 tablets 14 tablets 28 tablets	Rx	Menarini International Operations Luksemburg SA	Berlin-Chemie AG	Germany
35	Nofardom	Clopidogrelum	Coated tablets	75 mg	14 tablets 28 tablets	Rx	Zaklad Farmaceutyczny Adamed Pharma S.A.	Adamed Sp. z o.o.	Poland

No	Drug name	Commonly used drug name	Pharmaceutical form	Dose	Pack size	Availability category	Marketing authorisation holder	Manufacturer	Country of manufacturer
36	Omeprazol Stada	Omeprazolium	Intestinal capsules, hard	10 mg 20 mg 40 mg	14 tablets 28 tablets	Rx	Stada Arzneimittel AG	Laboratorios Liconsa S.A.	Spain
37	Pantoprazol Technimede	Pantoprazolum	Intestinal tablets	20 mg 40 mg	10 tablets 14 tablets 28 tablets 56 tablets 60 tablets	Rx	Technimede - Soc. Technico - Medicinal S.A.	West Pharma - Producoes de Especialidades Farmaceuticas S.A.	Portugal
38	Paracetamol APC	Paracetamolium	Tablets	500 mg	6 tablets 8 tablets 12 tablets 24 tablets 48 tablets	OTC	APC Instytut Sp. z o.o.	Galpharm International Limited	Great Britain
39	Parnassan	Olanzapinum	Coated tablets	2.5 mg 2.5 mg 2.5 mg 2.5 mg	30 tablets	Rx	Grodziskie Zakłady Farmaceutyczne "Polfa" Sp. z o.o.	Grodziskie Zakłady Farmaceutyczne "Polfa" Sp. z o.o.	Poland
40	Quemed	Quetiapinum	Coated tablets	25 mg 100 mg 150 mg 200 mg 300 mg	30 tablets 60 tablets 90 tablets 100 tablets in blisters 100 tablets in container 250 tablets	Rx	Medis ehf.	Actavis hf. Actavis Ltd.	Iceland Malta
41	Quetiapine Medis	Quetiapinum	Coated tablets	25 mg 100 mg 150 mg 200 mg 300 mg	30 tablets 60 tablets 90 tablets 100 tablets in blisters 100 tablets in container 250 tablets	Rx	Medis ehf.	Actavis hf. Actavis Ltd.	Iceland Malta
42	Quetiapin Sunfarm	Quetiapinum	Coated tablets	25 mg 25 mg/100 mg 100 mg 150 mg 200 mg 300 mg	10 tablets 20 tablets 50 tablets 100 tablets	Rx	Sun-Farm Sp. z o.o.	Nycomed Pharma Sp. z o.o. mibe GmbH Arzneimittel	Poland Germany
43	Queftilis	Quetiapinum	Coated tablets	25 mg 100 mg 150 mg 200 mg 300 mg	30 tablets 60 tablets 90 tablets 100 tablets in blisters 100 tablets in container 250 tablets	Rx	Medis ehf.	Actavis hf. Actavis Ltd.	Iceland Malta
44	Risperlept Quicklet	Risperidonum	Disintegrating tablets	3 mg 4 mg	28 tablets 56 tablets	Rx	Janssen Farmaceutici S.p.A.	Janssen Farmaceutici S.p.A.	Italy
45	Sciefic	Riluzolum	Coated tablets	50 mg	30 tablets 56 tablets	Rx	Actavis Group PTC ehf.	Actavis hf.	Iceland
46	Setinin	Quetiapinum	Coated tablets	25 mg 100 mg 150 mg 200 mg 300 mg	30 tablets 60 tablets 150 mg 200 mg 300 mg	Rx	Actavis Group PTC ehf.	Actavis hf. Actavis Ltd.	Iceland Malta

No	Drug name	Commonly used drug name	Pharmaceutical form	Dose	Pack size	Availability category	Marketing authorisation holder	Manufacturer	Country of manufacturer
47	<b>Spiriva Respimat</b>	Tiotropium	Inhalation solution	2.5 mcg/ measured dose	30-dose cartridge (60 measured doses) + 1 Respimat inhaler	Rx	Boehringer Ingelheim International GmbH	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany
48	<b>Synapamid SR</b>	Indapamidum	Extended release tablets	1.5 mg	30 tablets 60 tablets 90 tablets	Rx	SymPhar Sp. z o.o.	SymPhar Sp. z o.o.	Poland
49	<b>Targin</b>	Oxycodoni hydrochloridum + Naloxoni hydrochloridum	Extended release tablets	5 mg + 2.5 mg 10 mg + 5 mg 20 mg + 10 mg 40 mg + 20 mg	30 tablets 60 tablets	Rpw	Norpharma A/S	Mundipharma GmbH BARD Pharmaceuticals Ltd.	Germany Great Britain
50	<b>Terbinafine Aurobindo</b>	Terbinafinum	Tablets	125 mg 250 mg	7 tablets 8 tablets 12 tablets 14 tablets 28 tablets 42 tablets 56 tablets	Rx	Aurobindo Pharma Limited	Pfizer Service Company BVBA Pfizer PGM Zone Industrielle-29 route des Industries Milpharm Limited	Belgium France Great Britain
51	<b>Tesamol</b>	Paracetamolum	Tablets	500 mg	6 tablets 8 tablets 12 tablets 24 tablets 48 tablets	OTC	APC Instytut Sp. z o.o.	Galpharm International Limited	Great Britain
52	<b>Trandolapril Galex</b>	Trandolaprilum	Hard capsules	2 mg 4 mg	28 capsules 30 capsules 56 capsules 60 capsules	Rx	Galex, d.d.	Pharmathen S.A. Galex, d.d.	Greece Slovenia
53	<b>Trandox</b>	Trandolaprilum	Hard capsules	0.5 mg 1 mg 2 mg 4 mg	28 capsules	Rx	Apotex Europe B.V.	Pharmathen Pharmaceuticals S.A.	Greece
54	<b>Trylan ODT</b>	Olanzapinum	Disintegrating tablets	5 mg 5 mg 5 mg 5 mg	7 tablets 14 tablets 28 tablets 30 tablets in blisters 30 tablets in container 56 tablets 100 tablets	Rx	Medis ehf.	Actavis Group PTC ehf. Actavis Ltd.	Iceland Malta
55	<b>Vigamox</b>	Moxifloxacinum	Eye drops, solution	5 mg/ml	1 bottle 5 ml	Rx	Alcon Polska Sp. z o.o.	Extended release tablets Alcon Cusi S.A.	Belgium Spain
56	<b>Woda utleniona</b>	Hydrogenii peroxidum 3%	Skin care liquid applied to oral cavity	8.57 g	1 pack 100 g	OTC	Jaroslawn Szczepanczyk Laboratorium Farmaceutyczne	Jaroslawn Szczepanczyk Laboratorium Farmaceutyczne Famar S.A.	Poland
57	<b>Xaloptic</b>	latanoproszum	Eye drops, solution	0.05 mg/ml	1 bottle 2.5 ml	Rx	Zakłady Farmaceutyczne Polpharma S.A.	Farmaceutyczne Polpharma S.A.	Greece Poland
58	<b>Zeldox</b>	Ziprasidonum	Oral suspension	10 mg	1 bottle 60 ml 1 bottle 240 ml	Rx	Pfizer Polska Sp. z o.o.	Pfizer Manufacturing Deutschland GmbH	Germany

LZ – hospital use

Rpw – available on special prescription only (eg. narcotics)

Source: Office for the Registration of Medicinal Products, Medical Devices and Biocides (URPL), 2009

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### Advancing Biologics from the Lab to the Clinic

<b>EVENT:</b>	<b>Advancing Biologics from the Lab to the Clinic</b>
<b>VENUE:</b>	Brussels, Belgium
<b>DATES:</b>	11-12 January 2010
	NextLevel Pharma Phone.: +421 232 662 621 Fax: +421 232 662 622
<b>ORGANISER:</b>	E-mail: erika@nextlevelpharma.com URL: <a href="https://www.nextlevelpharma.com/events/view/advanced_biologics_from_the_lab_to_the_clinic">https://www.nextlevelpharma.com/events/view/advanced_biologics_from_the_lab_to_the_clinic</a>

### 5th Annual Pricing, Reimbursement & Market Access in Pharma & Medical Devices

<b>EVENT:</b>	<b>5th Annual Pricing, Reimbursement &amp; Market Access in Pharma &amp; Medical Devices</b>
<b>VENUE:</b>	Barcelona, Spain
<b>DATES:</b>	20-21 January 2010
	Jacob Fleming Conferences Phone.: + 420 257 222 800
<b>ORGANISER:</b>	E-mail: david.polak@jacobfleming.com URL: <a href="http://www.jacobfleming.com/conferences/life-science/5th-pricing-reimbursement-market-access-in-pharma-medical-devices-1">http://www.jacobfleming.com/conferences/life-science/5th-pricing-reimbursement-market-access-in-pharma-medical-devices-1</a>

### 13th Annual Competitive Intelligence in Pharma

<b>EVENT:</b>	<b>13th Annual Competitive Intelligence in Pharma</b>
<b>VENUE:</b>	Nice, France
<b>DATES:</b>	27-28 January 2010
	Arena International Phone.: +44 207 936 6672 Fax: +44 207 915 9773
<b>ORGANISER:</b>	E-mail: emanhauari@arena-international.com URL: <a href="http://www.ciinpharma-events.com/">http://www.ciinpharma-events.com/</a>

### Market Access Europe 2010

<b>EVENT:</b>	<b>Market Access Europe 2010</b>
<b>VENUE:</b>	Regents Park Marriott, London
<b>DATES:</b>	2-3 March 2010
	eyeforpharma
<b>ORGANISER:</b>	E-mail: jstanta@eyeforpharma.com URL: <a href="http://www.eyeforpharma.com/marketaccesseurope">http://www.eyeforpharma.com/marketaccesseurope</a>

### BioForum 2010

<b>EVENT:</b>	<b>BioForum 2010</b>
<b>VENUE:</b>	New Business Centre Manufaktura, Lodz, Poland
<b>DATES:</b>	19-21 May 2010
	Bio-Tech Consulting /Ltd. Phone.: +48 42 299 60 83 Fax: +48 42 678 01 28
<b>ORGANISER:</b>	E-mail: bioforum@bioforum.pl URL: <a href="http://www.cebioforum.com">http://www.cebioforum.com</a>

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