The Polish pharmaceutical market has undergone many changes as a result of the new Reimbursement Act
I am a Principal Analyst for strategy at Datamonitor Healthcare. I have written varied analysis on several topics across the global pharmaceutical and biotech sectors, including a section on Indian pharmaceutical strategies in the book “Redefining Global Strategy” by Pankaj Ghemawat.

At Datamonitor Healthcare I am involved in a diverse range of disease areas and strategic issues relating to the Indian pharmaceutical industry. I have also represented the company at various trade conferences in India and have presented on the burgeoning issue of biosimilars.

If you have questions about the research, data, and findings within this document you can put your questions directly to the analysts. Simply email your questions to info@datamonitorhealthcare.com.

To find out more about Datamonitor Healthcare, contact us at:

email getcloser@datamonitorhealthcare.com
phone +44 20 7551 9430
Visit our website: www.datamonitorhealthcare.com
Or follow us on Twitter: @DatamonitorHC

DISCLAIMER
While every care is taken to ensure the accuracy of the information contained in this material, the facts, estimates, and opinions stated are based on information and sources which, while we believe them to be reliable, are not guaranteed. In particular, it should not be relied upon as the sole source of reference in relation to the subject matter. No liability can be accepted by Datamonitor, its directors, or employees for any loss occasioned to any person or entity acting or failing to act as a result of anything contained in or omitted from the content of this material, or our conclusions as stated. The findings are Datamonitor's current opinions; they are subject to change without notice. Datamonitor has no obligation to update or amend the research or to let anyone know if our opinions change materially.
Total pharmaceutical sales in Poland reached €5.0bn ($6.6bn) in 2012, with key drivers of the market being the country's growing economy, increasing life expectancy, and an increase in per capita physician visits, offering substantial market potential for pharmaceutical products. Moreover, Poland provides universal healthcare coverage, with 98% of the population covered by health insurance. However, the market for reimbursed medicines, which is a major contributor to the overall pharmaceutical market, has declined since 2012 due to the introduction of the new Reimbursement Act. The new act has led to many changes to the Polish pharmaceutical market and has tightened drug reimbursement regulation. The average drug price in Poland is among the lowest in the EU, mainly due to the high share of generic pharmaceuticals, low availability of innovative drugs, and high price pressure on reimbursed drugs.

The new Reimbursement Act has reduced National Health Fund spending on pharmaceutical reimbursement in Poland

The implementation of the Reimbursement Act of 2012 was a game-changer in the Polish pharmaceutical market. The changes introduced by the new act have impacted various stakeholders including patients, doctors, manufacturers, and the trade channel. The key objectives of the act are to tighten drug reimbursement regulation, to improve access to medicines, and to generate savings for the National Health Fund (NFZ; Narodowy Fundusz Zdrowia), which was running a considerable deficit. The last objective was very successfully met, with sales in the reimbursed market segment dropping by an astounding 14% in 2012 vs 2011.

One of the measures of the act was the requirement for all medicines to go through the new pricing and reimbursement process. This process, although more transparent than before, involves price negotiations, which together with the changes to the reference groups used by the internal reference pricing system have acted as key tools to minimize drug prices. Poland uses "jumbo" reference groups, whereby different molecules belonging to the same therapeutic group are grouped together with the same reimbursement limit. As a result, both branded and generic medicines may be included in the same jumbo reference group. Consequently, Polish pharmaceutical prices at ex-factory level are the lowest in the EU, which is a strong negative factor for pharmaceutical manufacturers.

Pharmaceutical sales in retail pharmacies have been hardest hit by the Reimbursement Act, and the introduction of a payback mechanism spells further potential dangers for the formerly most attractive segment of the market. Under the Reimbursement Act, NFZ spending on drugs is capped at 17% of overall guaranteed healthcare services expenditure. Should this be exceeded, manufacturers are obliged to pay back 50% of the overspend, proportional to the overspend per drug in a reimbursement group. While expenditure on all reimbursed medicines (hospitals, retail market, drug programs) is taken into account for the cap, payback is only applicable to medicines sold in retail pharmacies, potentially resulting in a disproportionate pressure on this segment. However, so far the payback mechanism has not been enforced, as the budget has not been exceeded.

While the changes made due to the Reimbursement Act have reduced NFZ expenditure on reimbursed drugs, there has been a growth in the sales of non-reimbursed prescription drugs and over-the-counter medicines. Consequently, many companies have turned to these areas in search of better growth prospects. Nevertheless, the reimbursed market segment will continue to play a major role, especially for high-cost medicines, and with 98% health insurance coverage, pharmaceutical companies will have no choice but to find ways to navigate new pricing and reimbursement conditions.
Inclusions of new innovative products on the reimbursement list have not matched industry expectations

The Polish healthcare system is underfunded, with the Ministry of Health being rather slow to add new medicines to the reimbursement list. Although one of the aims of the Reimbursement Act was to improve access to medicines, the rate of inclusion of new medicines on the reimbursement list so far has not matched industry expectations. As a result, patients in Poland continue to have restricted access to innovative therapies for many serious and chronic diseases, including cancer and multiple sclerosis, compared to other EU countries, as well as poor access to new biological therapies. For example, insulin analogs for type 2 diabetes became available to patients only in 2013. Moreover, there is a huge backlog of positive recommendations for innovative therapies made by the Agency for Health Technology Assessment in Poland to the Ministry of Health that have yet to be approved. However, it is expected that this situation will improve in 2014, as the Ministry of Health has recently been increasing the rate at which new innovative medicines and indications are added to the reimbursement list. This will in turn lead to better commercial prospects in Poland.

Risk-sharing agreements enable companies to introduce products in drug programs and chemotherapy programs

One of the key novelties of the new Reimbursement Act is the introduction of risk-sharing agreements (RSAs). Although not welcomed by the industry, these agreements nevertheless enable manufacturers to enter more expensive products into the reimbursement system. Moreover, under the new Reimbursement Act, products included in such schemes are excluded from the obligation to participate in the payback mechanism. The Ministry of Health has thus far only applied finance-based risk-sharing schemes (discount or payback schemes), and no outcome-based risk-sharing sharing schemes have been set up as most are not feasible in practice within the confines of the healthcare system. Pharmaceutical companies with expensive innovative drugs will stand to benefit from RSAs going forward as they will enable them to get their products included on the reimbursement list much more quickly.

So far, over 200 RSAs (for 200 international nonproprietary names) have been made, which have generated significant savings for the Ministry of Health. The majority of these agreements are related to products for drug programs and chemotherapy programs. In 2012, 51 drug programs were available for Polish patients, of which the top five drug programs in terms of NFZ spending were breast cancer, chronic myeloid leukemia, multiple sclerosis, hepatitis C, and renal cell carcinoma. These programs present the key market access route for high-cost innovative medicines in the country, and the NFZ’s spending on these drug programs has begun to increase, signaling a positive change for manufacturers of specialty medicines.
About us

Datamonitor Healthcare
Bringing you a clearer, richer and more responsive view of the pharma & healthcare market.

Complete market coverage
Our independent research and analysis provides extensive coverage of major disease areas, companies and strategic issues, giving you the perspective to identify opportunities and threats arising from shifting market dynamics and the insights to respond with faster, more effective decision-making.

Unique expert capabilities
With teams located across developed and emerging pharma markets, we are uniquely placed to understand local healthcare trends and provide accurate and reliable recommendations. By working closely with our partners at MedTrack, Citeline, SCRIP Intelligence and Informa Healthcare, our experts are able to share data and resources to produce the most authoritative and robust market intelligence.

Cutting-edge delivery
Available through single reports or via subscription to our state-of-the-art online intelligence service that features intuitive design and interactive capabilities, our analysis offers the definitive platform to enhance your product management, market assessment and strategic planning.

To find out more about Datamonitor Healthcare, please contact us at:

email info@datamonitorhealthcare.com
phone +44 20 7551 9430
website: www.datamonitorhealthcare.com
Twitter: @DatamonitorHC

We’ve just made strategic investments in Datamonitor Healthcare to give you the best of health.

Introducing The New Datamonitor Healthcare.

We’ve quadrupled our business intelligence which covers more than 90% of prescription medicines in the major markets. Our forecasts are tailored to your needs as events occur and are powered by a new forecasting tool built in collaboration with a leading analytics technology provider. We’ve increased our global analyst resources by 300%, and Live Support replies to your queries in real time, not hours, for the fastest support in the market.

Discover the best of health.
Visit www.BestofHealthDatamonitor.com to tour the new Datamonitor Healthcare with one of our representatives. Request a live demo and see how The Best of Health supports smarter, faster decision-making.