

THE NEW P&R REGULATIONS AND THEIR IMPACT ON HEALTH CARE SYSTEM IN POLAND

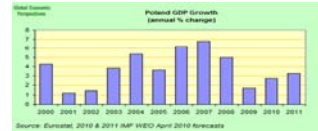
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 ISPOR Poland Chapter

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Global update on the country

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- Poland's economy should maintain a strong performance till the end of 2011, with an expected GDP growth of 4,0 %
 - Investment has expanded by 6 % in the first half of 2011
 - Domestic consumption and retail sales remain dynamic (+ 3%)
 - Export stays strong (+ 7 % vs 2010)



- The main source of risks today comes from the euro area uncertainties and a continuing historically high CHF level:
 - large Poland's external funding needs in € and strong links with the € banking sector
 - strong dependence on portfolio capital inflows (especially FD's)
 - 40 % of Poland's mortgage loans are denominated in CHF

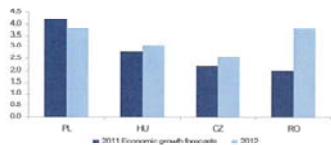
Global update on the country

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- In 2012, we expect Poland's economy to remain relatively strong, with an estimated GDP growth of **3.8 %**

- Every component of the GDP should contribute to this growth in similar proportions as in 2011:
 - Investments: + 6 %
 - Exports: + 8 %
 - Consumption: + 3,0 %

- Poland has chances to outperform its regional peers

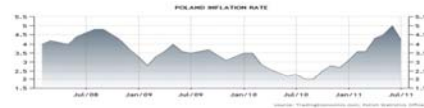


Global update on the country

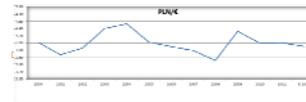
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- Inflation

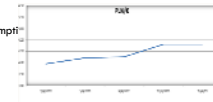
- There has been recently an acceleration of inflation, which rate is expected to reach 4.2 % in 2011. This might lead to some pressures on wages.



- Since mid-2010 the PLN has remained stable around 4.0 PLN/€...



- ...but it significantly weakened during the past weeks (- 4 %)



New rules on setting reimbursement limit and limit groups

- No clear definition of the limit groups
 - jumbo groups? (the same or different international names but similar therapeutic effect, if only they have the same therapeutic indications within which they are reimbursed and similar effectiveness)
- Reimbursement limit
 - Peculiar scheme of fixing the reimbursement limit: not the cheapest product, but „the product completing 15% of market volume“ 3 months before

• Very broad definition of the limit groups: very large limit groups (jumbo groups) which do not promote innovation,
 introducing the first substitute will automatically change the limit basis (with statutory ceiling price at the level of 24% of original product) and decrease the reimbursement limit;
 • Freezing level of reimbursement limits leads to uncertainty – impacting both patients and companies;
 • As a result of fluctuation of the reimbursement limits, the pharmacies may tend to avoid risk of holding a stock of products for which the reimbursement limit has changed.

Fixed prices and margins

Decrease in wholesaler and pharmacy margins

- Fixed statutory prices and margins in pharmacies
 - Wholesale margin %:
 - ✓ in 2012 – 7% of the official sales price (with VAT)
 - ✓ in 2013 – 6% of the official sales price (with VAT)
 - ✓ consecutive years – 5% of the official sales price (with VAT)
 - Retail margin: degressive (calculated from product wholesale price, constituting the basis of the limit in the respective limit group)

Drugs with the same dosage and package size have the same amount of margin

Product	Pharmacy price	Margin
DRUG A 2 mg 20 tab.	1,44	2,97
DRUG B 2 mg 20 tab.	1,19	2,97

- Introduction of fixed margins & prices will cause that the real market competition between competitors will take place at the level of MoH
- Lack of possibility to adjust price in the distribution channel / lower official price / introduction
- No price related incentive allowed: the patients' out-of-pocket may increase by 10–15%
- New way of calculating pharmacy margins – may support substitution and decrease pharmacy profitability

*Wholesale margin decreases from 5,78% compared to current regulation

Maximum prices & margins – in hospital

- Healthcare provider is obliged to purchase drugs at a price not higher than the official net selling price increased by margin not higher than official wholesaler
- Drugs available on the reimbursement lists may be purchased by healthcare provider only at a price which is no higher than the official sales price of the drug constituting the basis of the limit plus a margin of no more than the official wholesale margin

□ Example:

Market	Net selling price	Gross selling price	Wholesale price (margin 7% in 2012...)
Pharmacy (official price)	16,15 pln	17,44 pln	18,66 pln
Hospital (maximum price „wholesaler, limit)	4,90 pln	5,29 pln	5,66 pln

- Nature of maximum official price: possibility of lowering price at a hospital market; possibility of calling in a tender system
- „Reference pricing“ mechanism introduced to cap expenses at hospital may drive hospital prices down

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P&R Application contains:

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- the applicant's (company) name, address or place of business, forename and surname, telephone number, fax, e-mail and correspondence address of the person authorised to represent it with regard to this application; the description of the subject of the application; proof of the availability of the drug, special purpose dietary supplement or medical device on the market at the time of the submission of the application;
- the undertaking to ensure continuity of supply, together with an indication of the annual volume of supplies in event of inclusion in the reimbursement; data identifying the drug
- the name, form, method of administration or the method of use and the type of packaging; the authorisation number and a copy of the marketing authorisation decision, the EAN ID code or other code corresponding to the EAN code; the requested conditions for inclusion in the reimbursement
- the risk-sharing instruments
- the period of inclusion in the reimbursement; the draft description of the regimen programme, including: the name and objective of the regimen program; a description of the medical problem; regimen program, including: criteria for inclusion, dosage & method of administration, monitoring, including the monitoring of treatment and method of provision of reporting and settlement information, as well as criteria for exclusion;
- maximum & minimum net sales price, obtained on the territory of Poland during the year before the application submission for the proposed pack size & dose;
- maximum & minimum net sales price, obtained in the individual EU and EFTA countries within the framework of financing with public funds in those countries over the year before the submission of the application, converted into Polish zlotys at the mid exchange rate of the National Bank Polish in the month preceding the month of application and, in the case where the subject of the application is not financed with public funds in the given country, consideration is given respectively to the prices obtained on the open market, in the event that the applicant, being a parallel importer, specifies the net sales price from the country from which it is imported;
- the daily cost of therapy & average cost of standard therapy & the duration of standard therapy, separately for each indication; information on the expiry of patent protection, including the additional protection certificate, if applicable;
- information on the expiry of data exclusivity and market exclusivity period;

P&R Application contains:

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- justification of the application containing for a drug, special purpose dietary supplement or medical device which has at least one reimbursement counterpart in the given indication - **analysis of the impact on the budget of the entity responsible for financing benefits from public funds**,
 - for a drug, special purpose dietary supplement or a medical device which has no reimbursement counterpart in the given indication:
 - a **clinical analysis**, prepared on the basis of a systematic review compared with other medical procedures which can possibly be used in the given clinical condition with respect to the indication for which the application was submitted including, those financed with public funds, if any;
 - an **economic analysis** from the point of view of the entity obliged to finance benefits with public funds and the beneficiary;
 - **analysis of the impact on the budget** of the entity responsible for financing benefits with public funds;
 - **rationalisation analysis**, presented if the analysis of the impact on the budget of the entity obliged to finance benefits with public funds indicates an increase in the cost of reimbursement; this analysis should provide solutions for the reimbursement of drugs, special purpose dietary supplements and medical devices, the inclusion of which in the reimbursement will result in a release of public funds at an amount which corresponds to at least the increase in the costs arising from the analysis of the impact on the budget;
 - information on the applicant's scientific and research activities and investments related to healthcare on the territory of the Republic of Poland, as well as in other European Union Member States or Member States of the European Free Trade Association (EFTA);
 - proof of payment of the charge

HTA Guidelines in Poland

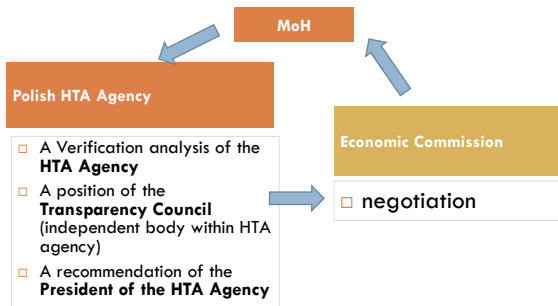
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- [Download Guidelines for conducting Health Technology Assessment \(HTA\) April 2009](#)
- http://www.ecfm.gov.pl/assets/Files/wytyczne_hta/2009/09.06.29_wytyczne_HTA_eng_MS.pdf

Decision of MoH

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Decision of MoH based on:

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The Agency's verification analysis includes the following, in particular:

- the assessment of the all HTA analyses
- a presentation of the reimbursement recommendations with regard to the drug, special purpose dietary supplement or medical device from other countries, together with an analysis of their justifications and the detailed conditions for inclusion in the reimbursement;
- the conditions for inclusion of a drug (...) in reimbursement in other countries with an analysis of the specific conditions of the reimbursement;
- the specification of the threshold net sales price at which the ratio of the costs of obtaining health effects is not greater than the threshold of the cost of obtaining an additional year of life adjusted for quality, and, in the absence of the ability to set this cost - the cost of obtaining an additional year of life.

Decision of MoH based on:

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The recommendation of the President of the Agency contains the following, in particular

- the establishment of whether the drug should be financed with public funds;
- the specification of the detailed conditions for the inclusion of the drug in the reimbursement with regard to:
 - the indications to be reimbursed; the suggested level of payment, suggestions on its inclusion into an existing or the establishment of a new limit group
- propositions of risk sharing instruments,
- a justification containing:
 - the specification of scientific evidence on the basis of which the recommendation was issued, including:
 - clinical and practical efficacy;
 - safety in administration;
 - the relationship between the costs to the health effects achieved by the drugs, special purpose dietary supplements or medical devices which have been reimbursed to date compared with that for which the application is being filed;
 - the relationship of the health benefits to the risk of administration;
- an indication of the existence of alternative medical technology and its clinical efficacy & safety in administration;
- a discussion of the impact on the spending of the entity obliged to finance benefits with public funds and beneficiaries;
- the indication & discussion of clinical recommendations, as well as recommendations on financing a given drug or special purpose dietary supplement with public funds in other countries;
- the indication of the threshold net sales price at which the relationship between the costs and the health effects achieved is no higher than the threshold of the cost of achieving an additional year of life, adjusted by the and, in the event of the inability to specify this cost – the cost of obtaining an additional year of life

New Reimbursement Bill – impact on market /stakeholders

Regulator (MoH)/ Payer (NMF)	<ol style="list-style-type: none"> 1. Estimated savings 5% of the reimbursement budget in the first year (in the next 4 years, more than 5 billion PLN.) 2. Sharing of financial burden with producers (drug budget more predictable for the payer)
Wholesalers	<ol style="list-style-type: none"> 1. Maintaining stock only for these drugs of manufacturers who can compensate potential impact of prices changes and provide services agreement and assistance in the management of drug prices 2. The deterioration of service to pharmacies: <ul style="list-style-type: none"> * prolongation payment terms * prolongation of drug's delivery time (currently average twice a day) 3. Adjusting downwards the prices of existing inventories of reimbursed drugs (to the end of 2011)
Pharmacies	<ol style="list-style-type: none"> 1. Significant decreasing in pharmacies profitability 2. Possibility of bankruptcy up to 20% pharmacies 3. Reduction in number of SKUs on pharmacies' shelves 4. Incentives for sell cheap generics (increase of substitution)
Patients	<ol style="list-style-type: none"> 1. Difficulties in drug availability in pharmacies 2. Limitation in drug availability in hospital (only the cheapest drugs) -> safety issues 3. Deterioration in access to innovative medicines - frozen budget for reimbursement caused to barriers for innovative drugs 4. Increasing patient co-payment (up to 50% for reimbursed drugs) 5. Increase patients expenditures on reimbursed drugs by more than 3 billion PLN (IMS data)
Producers	<ol style="list-style-type: none"> 1. Significant price reduction 2. Exposure to more frequent use of EU/EFTA reference pricing 3. Parallel export 4. Economic risk and increasing unpredictability of the business (necessity to strictly monitor the amount of reimbursements obtained by the company – payback system) 5. Necessity changes in operational model (ban on incentives aimed to increase reimbursement products sales) 6. Selling price definition – potential danger of 2nd margin case