WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

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Abstract Book

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Strand 1 –
Pricing and reimbursement of medicines

Submitted and accepted abstracts (sorted by last name of the first author)

Challenges when introducing policies to engineer lower prices for generics: experiences from Abu Dhabi

Poster

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Problem Statement: Perverse incentives may prevent health authorities from fully realising savings from generics. HAAD introduced a ˜Unified Prescription Form' in March 2009 mandating INN prescribing. This combined with further policy interventions sought to increase generic uptake in Abu Dhabi. However (a) Pharmacists still free to dispense either originator or the generic and be fully reimbursed (although 20-30% co-payment for some patients) as well as receive appreciable bonuses from manufacturers, (b) originator manufacturers not mandated to lower prices for reimbursement and patients do not have to pay the price difference for a more expensive molecule and (c) limited demand side measures directing physician prescribing.

Objective(s): Analyse the outcome of recent generic policies; secondly, determine possible reasons behind the findings; lastly, suggest potential reforms HAAD could implement to enhance savings from generic availability.

Policy/ies targeted: Policies to achieve low prices for generics and increase their utilisation.

Stakeholder(s) involved: Payers, physicians, pharmacists and generic manufacturers

Region covered: Middle East and Europe

Study design: Pre and post policy analysis of the impact of recent generic policies for 5 of top 8 pharmaceutical expenditure areas (ATC Level 4) in ambulatory care through analysing changes in expenditure (IMS) 12 months to Nov 2009 versus 12 months to Nov 2008 for chosen classes.

Time period: 12 months to Nov 2009 vs. 12 months to Nov 2008

Setting: Ambulatory care

Intervention(s): Unified generics policy to enhance prescribing of generics once multiple sources available.

Result(s): Expenditure in the 5 ATC Level 4 drug classes increased by 34.4% to $59.21mn in 2009 vs. 2008 helped by (a) Statins - increased utilisation of rosuvastatin and atorvastatin (87.5% of total statins on a Defined Daily Dose basis in 2010), (b) Proton Pump Inhibitors (PPIs) - increased utilisation of patented PPIs including esomeprazole versus a reduction in multiple sourced omeprazole, (c) Oral fluoroquinolones - increased utilisation of levofloxacin and moxifloxacin versus reduced prescribing of multiple sourced ciprofloxacin. Potential reasons for changes in expenditure versus expectations include concerns that patients prescribed multiple sourced drugs may be dispensed different branded generics each time with complaints about their effectiveness and safety versus originators. Prescribing of single sourced products alleviates this.

Conclusions: Anticipated savings from the generic policies have not been realised in HAAD. Polices to address this are being explored based on experiences in other countries. These include patient education and possibly reference pricing for the molecule with higher co-payments for more expensive products.

Lesson(s) learned and success factor(s): Health authorities need to ensure comprehensive reforms with physicians, pharmacists and patients to enhance the prescribing and dispensing of generics at low prices. Failure to co-ordinate these will appreciably reduce potential savings from the availability of generics.

Keywords: generics, Abu Dhabi, supply and demand side reforms
Funding Source(s): Funded with grants from HAAD

Croatian P&R model adjusted and implemented in Macedonia

Poster

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Problem Statement: P&R policy in Croatia introduced model of external referral as comparative drug prices (2001) and internal referral as reference price per pharmaco-therapic groups (2006). Croatian model was adapted for Macedonia (2009).

Objective(s): Croatian model provided systematized approach, enabling authorities with realistic projections of drugs expenditures, market control and rational drug use.

Policy/ies targeted: Defined model facilitated transparent P&R, estimation of costs and drug expenditures.

Stakeholder(s) involved: MoH of Croatia, Croatian HII, MoH of Macedonia, Macedonian HIF.

Region covered: EURO

Study design: Study evaluates revision of Croatian model and its application in Macedonia, points out why and how Croatian model was adjusted to Macedonian's needs.

Time period: Time covered is 2001-2009 (Croatia) and 2009-2010 (Macedonia).

Setting: Implementation was by National health insurances of Croatia and Macedonia.

Intervention(s): Completely implemented system in Croatia was based on external referral to 3+2 countries. Comparison was determined for generics and originators. Negotiations for specific drugs were introduced. Internal referral system was placed through 41 therapeutic groups for prescription drugs (drugs with same/ similar pharmacotherapic effect, up to fourth ATC level). Additional criteria for defining reference price included share of consumption, based on expenditures for previous year. Same model was used in Macedonia where four countries of reference were selected. Internal referring was used for 5 pharmacotherapic groups for prescription drugs.

Result(s): Implementation of the system stopped continuous increase of expenditures for prescription drugs. In Macedonia, the model enabled decrease of total drug expenditures for the patients (in terms of decreased co-payment) for same expenditures for National health insurance.

Conclusions: Best practice of this model was seen as increasing transparency for drug expenditures and rational drug utilization. Overall overview of the expenditures was established with realistic estimation of planned costs. In addition, model enabled the National health insurances to obtain more available effective drugs for the population within same expenditures.

Lesson(s) learned and success factor(s): Systems were set as benefit for the states and patients, but they need a "close look" and fine tuning, regarding the needs of the population, countries' financial capacities and developments of pharmaceuticals' markets.
Keywords: P&R policy, external referral, internal referral, comparative prices, pharmacotherapic groups
Funding Source(s): Partially, some of consultancies were funded by the WB.

The Political Economy of the Reimbursement Policy for Prescription Medicines in South Korea

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Problem Statement: In Korea, under the policy reimbursing medicines based on the notified price preset by the government, healthcare providers were inclined to profit from price markup between wholesale price and reimbursement price. This reimbursement policy contributed to overuse and misuse of medicine by increasing the amount of medicines. Pharmaceuticals account for 25% of Korea's total health expenditure and have rapidly increased since the introduction of the National Health Insurance (NHI) in 1989.
Objective(s): 1. to identify factors determining policy output during implementation process 2. to provide a better understanding of the political economic dynamics in reimbursement pricing policy.
Policy/ies targeted: The new policy introduced in November1999 changed the reimbursement price from the notified price preset by the government to the purchase price reported by healthcare facilities. Taking price mark-up from medicines became an illegal income for healthcare facilities.
Stakeholder(s) involved: The implementors are the Ministry of Health and Welfare and Health Insurance Review Agency. The target group are healthcare facilities. The third parties are pharmaceutical companies and wholesalers. The end beneficiaries are the public.
Region covered: WPRO. A national policy in Korea
Study design: a policy analysis based on a framework combining political analysis and policy implementation process analysis.
Time period: From November 1999 to September 2010
Setting: Prescription medicines in both outpatient and inpatient sectors, which are both covered by the public NHI
Intervention(s): Semi-constructive interviews
Result(s): All three implementation process indicators (number of surveys, compliance rate, and pharmaceutical expenditure) indicate the poor implementation of this new reimbursement policy. These results were driven by five determinants: 1) poorly designed policy structure to achieve a large change with low consensus, 2) a lack of the implementors' willingness to obtain the desired policy outputs, 3) implicit cartel between target groups (healthcare facilities and pharmacies) and the third parties (pharmaceutical companies), 4) low support from the general public, and 5) low media attention because of the introduction of separation between dispensing and prescribing in 2000.
Conclusions: This study suggests that the political economic relationship among policy participants heavily influence the implementation process of a policy and that the five factors--policy contents, implementors, target groups, beneficiaries, and the socioeconomic environment--should be considered in designing and implementing a reimbursement pricing policy.
Lesson(s) learned and success factor(s): Under a single-payer insurance system, the process for setting the reimbursement price for prescription medicine is a critical factor in determining the size of total pharmaceutical expenditure. The poor implementation of this policy was mainly caused by the strong cartel between healthcare facilities (target group) and pharmaceutical companies (third party). Korea's experience in reimbursement policy will provide valuable lessons to countries with a single-payer insurance system.
Keywords: Reimbursement pricing policy, policy implementation, implementation process analysis
Funding Source(s): None to declare

Reimbursement policy is not health economics

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Problem Statement: Pharmaceutical reimbursement decisions are often associated with health economics, but the international reimbursement landscape clearly shows that policy-level decisions on the public purchasing drugs are only partly associated with cost-effectiveness analyses. New trends reflect upon a diversion from quantitative methodologies. Health economists, who pursue the ideal of objective decision-making in reimbursement, sometimes misunderstand this trend as a threat to transparency. This leads to an increasing confusion regarding the nature and role of decision-making.
Objective(s): Interpreting reimbursement policy as a separate domain in public policy-making based on health economics, clinical pharmacology, decision theory and institutional sociology, the seemingly theoretical but in fact very practical presentation sets out to explain that fully objective decision-making is an illusion, but asserts that this is not necessarily a problem. It proposes a way to differentiate reimbursement policy and market access from health economics. It defines what goals sustainable reimbursement policy should follow, and provides an integrative, structured and transparent decision framework in which collective judgement has a pivotal role and which reimbursement policy should follow in everyday practice.
Policy/ies targeted: Reimbursement policy, reimbursement decisions
Stakeholder(s) involved: Regulators, payers, pharmaceutical companies, HTA agencies
Region covered: General presentation which builds on a synthesis of reimbursement decision-making practice in 8 EU markets, Canada, Japan, Australia, and New Zealand, as well as the authors' former personal experiences as payers
Result(s): Cost-effectiveness should stay the guiding principle for decisions on the reimbursement and disreimbursement, but neither cost-utility analyses nor explicit or implicit ICER thresholds are an adequate means to determine cost-effectiveness in a valid and socially acceptable way. To overcome methodological difficulties, a transparent procedure based on comprehensive drug assessment should lead to a new drug being designated as "cost-effective" in a decision of collective judgement. In cases where cost-effectiveness is a necessary but not sufficient criterion for decisions, therapeutic value-added, budget impact, explicitly formulated ethical considerations and, under circumstances, secondary effects can only be taken into consideration.

Conclusions: This approach integrates positive experiences from countries which apply either health technology assessment or qualitative (classification or scoring) methodologies upon the admission of new drugs into the reimbursement formulary and upon reimbursement review. It can also be shown that collective decision-making bodies supported by dedicated agencies can provide superior decision quality to quantitative methodologies, and there exists a possibility to compose decision-making rules in these bodies in a way which enables sustainable and socially responsible reimbursement decisions.
Keywords: pharmaceutical reimbursement, reimbursement policy, formulary management
Funding Source(s): none

The right to access drugs: a tool to address national pharmaceutical pricing and reimbursement rules

Stéphanie Dagron (Institute of Biomedical Ethics, Switzerland, dagron@ethik.uzh.ch)
Problem Statement: National pharmaceutical pricing and reimbursement policies are very difficult to approach and to compare from a legal perspective. They follow the same objectives in most countries, at least in most industrialized countries offering their citizens universal health coverage. These include the containment of health and particularly pharmaceutical costs, the availability and accessibility of the best possible pharmaceuticals for the population covered by the universal system and for some countries maintaining the attractiveness for pharmaceutical businesses and R&D activities. The multiplicity of the instruments used and the complexity of the mechanisms and interactions at stake render it difficult to analyse and compare pricing and reimbursement rules.
Objective(s): The research aims at defining a methodology based on the analysis of legal sources. This methodology will provide the framework for a comparison across countries offering their citizens universal health coverage.
Policy/ies targeted: Pricing and reimbursement policies in health insurance systems with universal coverage.
Stakeholder(s) involved: The instruments studied are directed at different stakeholders playing a role with regard to drug supply (pharmaceutical industries, pharmacies, wholesalers) or with regard to drug consumption (dispensing doctors, patients).
Region covered: Europe
Study design: The compared countries (Switzerland, Germany, and France) do all recognise a right to health as a fundamental right, which includes a (limited) right to access drugs. The focus of the analysis is therefore on the constitutions and statutes recognizing this right. Since these texts contain only general provisions it is indispensable to look also into judicial decisions in order to determine the content of the right to access drugs and of the general principles grounding the health insurance system.
Time period: Not applicable
Setting: Health insurance systems with universal coverage. Examples Switzerland, Germany and France.
Intervention(s): Not applicable.
Result(s): The difficulty in comparing national regulations does not only lie within the problem of obtaining information on the different prices of an original product. The coherent analysis and classification of the multiple regulation instruments employed poses an even bigger challenge. The legal methodology proposed for analysis allows a better understanding of the policies adopted and permits the identification of the most important instrument for pricing and reimbursement with regard to the legal understanding of the founding principles of the health insurance system. For instance in France the right to access drugs is not unlimited. The interpretation given by the judge to the principle of solidarity on which the social security system is grounded allows the legislator to decide which medical therapy is to be reimbursed by the solidary health insurance system. Accordingly the determination of the drugs which are to be reimbursed by the health insurance is the fundamental regulatory instrument in France. In Germany on the contrary the interpretation given by the statutes and the judges to the principle of solidarity and the fundamental right to health is broader. The system of fixed prices has to be interpreted as the most important price regulatory instrument.
Conclusions: The determination of the content of the right to access drugs can be fruitfully utilized in order to understand, classify and compare the national instruments used in the field of pharmaceutical regulations.
Lesson(s) learned and success factor(s): This methodology allows a legal approach of the different systems and a comparison accross countries with similar health insurance scheme.
Keywords: Right to health, right to access drugs, health insurance system, comparative law
Funding Source(s): Swiss National Science Foundation (Ambizione)

A taxonomy of approaches to value based pricing

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Problem Statement: Many payers relate reimbursement decisions and/or prices to an assessment of medicines 'value'. This is done in numerous ways and to varying degrees. The resulting global pricing and reimbursement landscape is confusing. E.g. the UK government is currently trying to distil global lessons for its plan to introduce 'value based pricing' of branded medicines. A taxonomy of the options for P&R systems would increase understanding, aid comparative analysis and clarify the lessons for improving P&R systems internationally.
Objective(s): To set out a concise, comprehensive descriptive taxonomy of the range of approaches that might be taken to value based pricing. We: identify and describe the full range of alternative means by which 'value' might be measured and valued, identify and describe the options available for aggregating the different components of value and converting them into a maximum price, and note the challenges and relative advantages associated with these approaches.
Policy/ies targeted: Value based approaches to regulating maximum reimbursed medicines prices
Stakeholder(s) involved: Payers, industry, health care providers, governments
Region covered: International
Study design: Review of relevant economic theory, review of approaches to value assessment in P&R and health technology assessment systems internationally, and analysis
Time period: 2011
Setting: Focus on Australia, Canada, France, Italy, Japan, Sweden, UK, but general international relevance

Intervention(s): Value based approaches to reimbursement and maximum reimbursement price decisions
Result(s): The taxonomy has five stages, each comprising a number of options. The combination of options across the five stages describes any given approach to value based pricing. The stages are: (1) the chosen elements of 'value' , (2) how each element is measured, (3) how each measured element is then accorded a value, based on whose values, (4) how the different elements are aggregated, (5) how that is converted into a price.
Conclusions: Which approach is taken depends on an underlying normative view of what is valued and which opportunity costs are relevant. There are three main approaches to aggregating the chosen elements into a single overall assessment of the 'value' of a medicine: weighted QALYs, multi-criteria decision analysis (MCDA), and net benefit. All approaches require the conversion of 'value' , however assessed, into a money price. All approaches face technical challenges in terms of the availability of evidence about the cost effectiveness threshold, regardless of whether 'value' is defined and measured as weighted QALYs, benefit points or any other numeraire. But whatever approach is taken, benefit foregone must be measured and assessed in those same terms. All stages of value based pricing are imprecise. The pragmatic response to that inevitability is to build in a stage of negotiation at the end of any value based pricing system. We observe that negotiation is the final stage of price setting in many countries but not (yet) the UK.
Keywords: value based pricing, taxonomy
Funding Source(s): The Office of Health Economics (OHE) received an unrestricted grant for this research from Celgene

WHO Pharmaceutical Situation Assessment (Level II) and HAI/WHO Medicines Prices and Availability surveys: a proposal for integration

Poster

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Problem Statement: Considering the challenges for ensuring access to affordable, quality, safe and efficacious medicines, the possible combination of the "WHO Pharmaceutical Situation Assessment Level II" and the "HAI/WHO Medicine Prices and Availability Survey" - provides valuable information to policy makers, optimizing time and resources.
Objective(s): Combine "WHO Pharmaceutical Situation Assessment Level II" and the "HAI/WHO Medicine Prices and Availability" surveys methodologies and its strengths.
Policy/ies targeted: Outcomes of pharmaceutical policies related to access to, quality and rational use of medicines
Stakeholder(s) involved: Professionals from PAHO-WHO CC on Pharmaceutical Policies in Brazil and PAHO'-HQ officials
Region covered: American Region
Study design: In order to make possible a combination, both methodologies were compared and reviewed regarding to sampling size and strategies, survey forms, training process and materials, data collection, database and template report.
Some limitations of the existing methodologies were considered, namely the sampling size and representativeness, mainly in big territories and equal nomenclature for different indicators obtained from different calculations were specially addressed.
Time period: 2010-2011
Setting: Academic (pilot in three countries, data not available yet)
Intervention(s): Statistical calculations, revision on materials, group discussion
Result(s): Six geographical areas are selected according to demographic density and geographical characteristics. The total number of health facilities is defined according to the accepted sampling error and total population referred to each one of them. A spreadsheet was developed and is provided to national coordination team, allowing this calculation and facilitating the decision on the acceptable sampling error. The number of health facilities in each area is now dependent on the population density. Three new indicators are proposed: availability of primary health care medicines, patient satisfaction with pharmaceutical services and % of facilities with expired medicines. The forms were combined in order to facilitate data collection, considering each data collection site for both surveys. Slides set were combined in five files (introduction, methods, data collection procedures, field work and data entry).
Conclusions: The combination of the surveys provides a broader range of information allowing keeping the strengths of the original ones. One negative aspect is eventually the increase in the cost and the time for countries more density populated depending on the error value decided. Nevertheless, the maintenance of the strength and representativeness are important positive aspects for big countries. A better harmonization between the two databases is still necessary in order to facilitate the work at country level and standardize the modus operandi.
Lesson(s) learned and success factor(s): The combined methodology was piloted in three countries. Nevertheless, the results are still being processed and validated and are not authorized by national authorities to be disseminated yet. The combine methodology showed to be feasible.
Keywords: Methodology, Validity, Reliability, Pharmaceutical Situation Assessment, Price
Funding Source(s): PAHO

Evidence on the impact of managed entries on payers, patients, and manufacturers

Poster

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Problem Statement: The launch of new a drug is often associated with uncertainties related to its clinical and cost effectiveness and budget impact. In an attempt to ensure patients access to innovative, high-cost drugs while protecting the payer from the risk due to uncertainties, and potentially rewarding the manufacturer, managed entries have been introduced in a number of countries worldwide.
Objective(s): 1. To review evidence on the impact of managed entries on: - Protecting the payer against the risk surrounding clinical and cost effectiveness and budget impact related to the introduction of innovative and high-cost drugs. - Patients access to innovative treatments - Rewarding the manufacturer for its R&D efforts; 2. To analyse emerging trends in managed entries at international level
Policy/ies targeted: Pharmaceutical pricing and reimbursement
Stakeholder(s) involved: Governments, health insurance agencies, drug manufacturers, patient organisations

Region covered: EURO, AMRO, WPRO, international level
Study design: Analytical. Systematic literature review (grey and peer reviewed) combined with selective interviews of decision-makers in a number of European countries
Time period: 1994 - 2011
Setting: Out-patient sector and in-patient sector, Public and private sector
Intervention(s): Managed entries represent a diverse group of innovative pricing and reimbursement mechanisms for pharmaceuticals. They range from purely financially based to health-outcome based agreements. Patient eligibility, discounts and/or reimbursement arrangements, monitoring and evaluation requirements and their duration can vary considerably.
Result(s): Impact of managed entries on: Payers: MEs have the potential of achieving better cost-effectiveness and lower drug prices. Evidence from Sweden illustrates how TLV was able to achieve a better cost-effectiveness and a lower price for Levodopa/Carbidopa, through a coverage with evidence development scheme. Price-volume agreements are widely used in France to address uncertainties regarding the budget impact of new drugs. In 2004, the savings from such agreements led to rebates totalled around three per cent of the overall drugs bill in France. Patients: In terms of patient access, findings from Italy show that authorization with a risk-sharing agreement was associated with more rapid patient access in comparison to authorization without such an agreement. Manufacturers: It is unclear whether managed entries constitute a reward for manufacturers, however, various benefits such competitive advantage over cheaper generic alternatives and coverage for drugs which initially received a negative recommendation such as Trabectedin in the UK have been reported. Not to mention the possibility of granting discounts while leaving list prices untouched. Health care staff: Evidence from the UK shows that the daily management of MEs schemes is hampered by the complexities of retrospective reimbursement systems, administrative burden, and the lack of management capacity at current staff levels.
Conclusions: Research is ongoing and the final conclusion will be available before the conference in September.
Lesson(s) learned and success factor(s): Research is ongoing and lessons learnt will be available before the conference in September.
Keywords: Managed entries, Performance-based agreements, Risk-sharing, Patient access, Innovative drugs
Funding Source(s): LSE Health and European Commission

Performance of drug reimbursement systems: a comparison of the Austrian, Belgian, Dutch, French and Swedish systems

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Oral presentation
(Fri, 30 Sept, 12:00-12:15, Festsaal)

Problem Statement: Quality and sustainability of drug reimbursement systems is continually tested by rising health care expenditures.
Objective(s): The aim of our study is to compare European drug reimbursement systems to obtain insight into their strengths and weaknesses and formulate policy recommendations.
Policy/ies targeted: European drug reimbursement systems (entire process from reimbursement request to the final decision).
Stakeholder(s) involved: Interviews with policymakers, patients and representatives of the pharmaceutical industry.
Region covered: Austria, Belgium, France, the Netherlands and Sweden.
Study design: We investigated policy documents, explored literature and conducted 57 interviews with relevant stakeholders. We used the analytical Hutton Framework to analyse in detail five European drug reimbursement systems. We compared systems' objectives, institutions, processes (distinguishing assessment, appraisal and decision making), reimbursement criteria, and output and implementation in real life.
Time period: Research took place from April 2008 until December 2010.
Setting: Desk research and interviews (performed by mail questionnaire, phone or face-to-face).
Result(s): All systems aim to balance three main health policy objectives: system sustainability, equity and quality of care. System impact, however, is mainly assessed by drug expenditure. A centralised reimbursement agency evaluates reimbursement requests on a case-by-case basis. The minister has discretionary power to alter the reimbursement advice in Belgium, France and the Netherlands. All systems make efforts to increase transparency in the decision-making process but none uses formal hierarchical reimbursement criteria. Various attempts have been made to operationalise the equity objective in relevant decision criteria. The reimbursement level depends on disease severity in France and Belgium. All countries but France consider cost-effectiveness in decision making but none is explicit about its importance or applies a threshold value. Although case-by-case revisions are embedded in some systems for specific groups of drugs, systematic group revisions are limited, resulting in uncertainty about reimbursed drugs' value for money.
Conclusions: While there is convergence in assessment processes, important differences in appraisal and decision making remain between the Austrian, Belgian, Dutch, French and Swedish drug reimbursement systems. All countries recognise that cost-effectiveness is relevant but experience difficulties in defining its weight in the decision-making process, next to quality of care and equity.
Lesson(s) learned and success factor(s): We identified two common areas for improvement: i) transparency in the appraisal process and appraisal criteria, ii) evaluating drugs throughout their life cycle, including systematic (group) revisions. To obtain more value for money, countries could explore a shift towards a demand driven system in which reimbursement authorities indicate the type of drugs that address societal needs for which they are prepared to pay a premium price.
Keywords: Drug reimbursement, pharmaceutical economics, health policy, decision making, country comparison
Funding Source(s): This study was partly performed in the context of the Escher project (T6-202), a project of Top Institute Pharma, Leiden, the Netherlands.

Potential impact of policy regulation and generic competition on sales of cholesterol lowering medication, antidepressants and acid blocking agents in Belgium

Poster

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Associated Authors: Van Hal, Guido; De Loof, Hans; Remmen, Roy; De Meyer, Guido; Beutels, Philippe

Problem Statement: Pharmaceutical expenditures are increasing as a proportion of health expenditures in most rich countries. Antidepressants, acid blocking agents and cholesterol lowering medication are major contributors to medicine sales around the globe.
Objective(s): We aimed to document the possible impact of policy regulations and generic market penetration on the evolution of sales volume and average cost per unit (Defined Daily Doses and packages) of antidepressants, acid blocking agents and cholesterol lowering medication.
Region covered: Belgium
Time period: 1995-2009
Intervention(s): We extracted data from the IMS health database regarding the public price and sales volume of the antidepressants (selective serotonin reuptake inhibitors (SSRI's), monoamine oxidase inhibitors (MAOI's) and tricyclic and remaining antidepressants (TCA's)), acid blocking agents (proton pump inhibitors (PPI's) and H2 receptor antagonists) and cholesterol lowering medication (statins and fibrates) in Belgium between 1995 and 2009. We describe these sales data in relation to various national policy measures which were systematically searched in official records.
Result(s): Our analysis suggests that particular policy regulations have had immediate impact on sales figures and expenditures on pharmaceuticals in Belgium: changes in reimbursement conditions, a public tender and entry of generic competitors in a reference pricing system. However, possible sustainable effects seem to be counteracted by other mechanisms such as marketing strategies, prescribing behaviour, brand loyalty and the entry of pseudo-generics. It is likely that demand-side measures have a more sustainable impact on expenditure.
Conclusions: Compared with other European countries, generic penetration in Belgium remains low. Alternative policy regulations aimed at enlarging the generic market and influencing pharmaceutical expenditures deserve consideration. This should include policies aiming to influence physicians' prescribing and a shared responsibility of pharmacists, physicians and patients towards expenditures.
Keywords: Pharmaceuticals, Generics, Pharmacoeconomics, Belgium, National Policy
Funding Source(s): Grants from the Special Research Fund (Bijzonder Onderzoeksfonds, BOF) of the University of Antwerp assisted the initiation of this research. BOF is currently funding this research under terms of an InterDisciplinary Doctoral scholarship (ID).
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European countries with small populations cannot obtain appreciable price reductions for generics: Lithuania as a case history to contradict this

Poster

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Problem Statement: Recent publications have suggested smaller European countries have difficulties negotiating low prices for drugs including generics. As a result, limiting the potential to enhance prescribing efficiency as more standard drugs lose their patent.
Objective(s): Assess whether this happens in practice based on the situation principally in Lithuania. Lithuania chosen in view of its population size coupled with appreciably lower utilisation of anti-depressants, PPIs and statins (DDDs/ TID) than Western European countries.
Policy/ies targeted: Generic pricing policy
Stakeholder(s) involved: Health authorities/ health insurance agencies, generic manufacturers and physicians
Region covered: Lithuania
Study design: Observational study involving all 3.3 million ambulatory care patients contained within the compulsory health insurance system in Lithuania with a particular focus on generics.
Time period: 2000-2009
Setting: Analysis of reductions in reimbursed expenditure/ DDD (2010 DDDs) assessed for generic PPIs, statins, ACEIs, and SSRIs in 2009 vs. 2000 or 2001 originator prices, as well as a range of European countries. Description of generic pricing policies and their impact among selected European countries with smaller populations also based on published papers by the co-authors.
Intervention(s): Data on other European countries taken from published papers by the co-authors.
Result(s): Appreciable reductions seen in reimbursed expenditure/ DDD for generics in each drug class in Lithuania in 2007 or 2009 vs. 2000/ 2001 originators, e.g. 56% reduction for generic omeprazole, 73% for generic sertraline, 83% for generic simvastatin, 87% for generic atorvastatin and 92% for generic fluoxetine. These reductions in generic prices vs. originators similar to those seen among a range of Western European countries.
Conclusions: European countries with smaller populations can obtain appreciable reductions for generics vs. originators. In addition in Lithuania, no apparent difference between classes with high or low utilisation volumes. As a result, helping fund increased volumes alongside mandated budget cuts. Consequently, providing an example to other European countries seeking to enhance prescribing efficiency.
Lesson(s) learned and success factor(s): Same as conclusion
Keywords: Generic prices, Lithuania
Funding Source(s): The work in part supported by grants from Karolinska Institutet

Trends in generic pricing policies in Europe: implications for sustaining equitable and comprehensive healthcare

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Poster

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Problem Statement: Generic prices can vary up to 36 fold depending on the molecule. These differences are unsustainable with continuing resource pressures and more drugs losing their patents. Consequently, countries need to learn from each other.

Objective(s): Document different pricing policies for generics in over 20 European countries/ regions in an understandable format and assess their impact to provide future guidance.

Policy/ies targeted: Policies to obtain low prices for generics to enhance future prescribing efficiency

Stakeholder(s) involved: Health Authority and Health Insurance Companies, physicians and patients

Region covered: Europe

Study design: Retrospective observational CNC study using administrative databases in over 20 European countries/ regions for generic PPIs, statins, ACEIs and SSRIs to determine price reductions over time in 2007/ 2008 versus principally 2001 prices (expenditure/ Defined Daily Dose – 2010 ATC/ DDDs), i.e. typically before patent loss. Reimbursed expenditure as health authority perspective. Generic pricing policies documented and validated with payers and their advisers in each country. Policies subsequently grouped into 3 categories for comparison.

Time period: 2001 to 2007/ 2008

Setting: Ambulatory care

Intervention(s): Supply side measures to help lower generic prices.

Result(s): It is possible to group generic pricing approaches into 3 categories for comparative purposes: (i) Prescriptive pricing (PP) – established reductions for reimbursement, e.g. up to 85% reduction (Norway), 33% below for first generic (Turkey), (ii) market forces (MF) – no fixed amount – however mechanisms to enhance utilisation, (iii) mixed approach (MA) – PP for first generic(s) followed by MF. Expenditure/ DDD for generic simvastatin in 2007 97% below 2001 levels in England (MF), 96% below in Sweden (MF), and 79% below in Lithuania (MA) vs. just over 50% in France (PP). Typically, less marked reductions for omeprazole. Similar situation for generic ACEIs and SSRIs. Differences more attributable to conditions to enhance generic utilisation than population sizes.

These differences, plus differences in generic utilisation, resulted in considerable differences in reimbursed expenditure for PPIs and statins when adjusted for populations.

Conclusions: Categorisation system works and easily understandable. Important for countries to lower generic prices as well as enhance their utilisation to maximise efficiency. Examples of both identified to help European countries learn from each other to help maintain European ideals.

Lesson(s) learned and success factor(s): Countries can learn from each other to reduce the price of generics. Potential reductions are independent of the size of the country.

Keywords: Generics, pricing, pharmaceuticals, reforms

Funding Source(s): In part with funds from the Karolinska Institutet

Risk sharing arrangements – an opportunity or threat to fund new medicines

Poster

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Problem Statement: Risk sharing schemes are increasingly part of P & R negotiations across Europe as pharmaceutical companies seek reimbursement and funding for their new premium priced drugs within growing resource pressures. These include price:volume arrangements (PVAs), value based pricing, outcome guarantee and patient access schemes. However, there are concerns with multiple definitions, the administrative burden and transparency.

Objective(s): Provide a workable definition for "risk sharing" and review current schemes to provide future guidance.

Policy/ies targeted: Pricing, reimbursement and funding of new premium priced medicines

Stakeholder(s) involved: Payers (health authorities, health insurance agencies, etc.), hospital pharmacies, physicians and pharmaceutical companies

Region covered: Mainly EURO as well as US and Canada

Study design: (a) Develop an acceptable definition based on logic and validate this with key payers and their advisers across Europe, (b) Undertake a literature search of published schemes combined with unpublished/ grey data known to payers and advisers across Europe involved with assessing such schemes, (c) ascertain whether schemes can be classified according to the definition, (d) appraise the schemes including costs and concerns to provide future guidance

Time period: 2000 to 2010

Setting: All sectors

Intervention(s): Assessment of current risk sharing arrangements.

Result(s): Risk sharing schemes should be "considered as agreements concluded by payers and pharmaceutical companies to diminish the impact on payers' budgets for new and existing schemes brought about by uncertainty and/ or the need to work within finite budgets". They can be broken down into financial-based and performance-based/ outcomes-based models. The "risk" varies by situation, with in some

cases companies providing “free” drug to secure reimbursement. There are concerns though with a number of existing schemes including high administration costs and whether HAs will end up funding an appreciable proportion of a drug’s development costs.
Conclusions: There are only a limited number of situations where risk-sharing schemes should be considered apart from traditional PVAs. These include (a) where responses can be determined within a short time and reduce uncertainty, (b) high unmet need with a new technology showing benefit, (c) lowering drug costs in targeted patients will enhance reimbursement having factored in administration costs, (d) price: volume schemes limiting the budget impact of new drugs and (e) limited time frame.
Schemes should be rejected where (a) effective/ low cost standards already exist, (b) high administration costs/ burden limiting savings in practice, (c) concerns with access/ data ownership (d) HAs end up significantly funding drug development costs.
Lesson(s) learned and success factor(s): There is current confusion regarding the terminology of risk sharing arrangements with administration costs typically not taken into consideration by payers in their assessments. Most risk sharing schemes are a means by which pharmaceutical companies can gain reimbursement/ funding as well as potentially limit budget exposure (PVAs, price caps and free drugs).
Keywords: pharmaceuticals, risk sharing, reimbursement
Funding Source(s): Funded in part with a grant from Karolinska Institutet

Reimbursement restriction moderately decreases Benzodiazepine use in general practice

Poster

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Problem Statement: On January 1st 2009, benzodiazepines were excluded from the Dutch positive reimbursement list when used as anxiolytic, hypnotic or sedative, to limit misuse and for cost savings. Thus far, the (un)intended effects of this reimbursement restriction are unknown.
Objective(s): To assess the impact of the reimbursement restriction on benzodiazepine use in patients newly diagnosed with anxiety or sleeping disorder.
Policy/ies targeted: Reimbursement restriction and general practice.
Stakeholder(s) involved: General practitioners.
Region covered: The Netherlands
Study design: Drug utilization study
Time period: January 2007 - July 2009
Setting: Netherlands Information Network of General Practice, a network of general practices across the Netherlands
Intervention(s): Reimbursement restriction
Result(s): In the first two to three quarters after the policy change, the incidence of anxiety and sleeping disorders decreased by almost 10% and 12%, respectively. The proportion of patients being prescribed a benzodiazepine following a diagnosis was lower in 2009 compared to 2008 for both anxiety (33.7% vs. 30.0%, $p<0.05$) and sleeping disorder (67.0% vs. 59.1%, $p<0.05$) as was the proportion of patients with more than 1 benzodiazepine prescription for both anxiety (42.6% vs. 36.4%, $p<0.05$) and sleeping disorder (42.6% vs 35.0%, $p<0.05$). A shift to or an increase in initiation of alternative treatment for anxiety with SSRIs was not found. Patients with sleeping disorder had a lower risk of discontinuation in 2009 compared to 2008 (HR 0.63 95%CI 0.52-0.76), this was not observed for patients with anxiety.
Conclusions: The reimbursement restriction has resulted in a moderately positive effect on the use of benzodiazepines, as initiation of benzodiazepine use slightly decreased in patients newly diagnosed with anxiety or sleeping disorder. Besides, no unwanted negative effects, such as shifts to alternative treatment with SSRIs, have been observed.
Lesson(s) learned and success factor(s): Careful attention is needed before implementing a new policy and afterwards, when determining the effects of regulatory changes. The outcomes of policy changes should be seen in broader perspective. A regulatory change may lead to public cost savings, but may increase private expenditures or may lead to under-treatment of certain populations.
Keywords: benzodiazepines, reimbursement, anxiety, sleeping disorder, policy change
Funding Source(s): none declared.

Comparison on two pricing methodologies in relation to affordability and availability of medicines in the republic of Macedonia

Poster

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Background: In the Republic of Macedonia, the procurement of medicines from the Positive List (PL) was carried out by the Health Insurance Fund (HIF) through centralized international tenders until 2005. The main criterion for selecting the best tender offer was the medicine price, which determined its reimbursement cost. The last international tender took place in 2005 and it was valid until the agreed quantities of medicines were consumed. The external reference pricing system was established in 2007. Its latest methodology uses the comparative analysis of the prices of generic medicines in the reference countries in the region. The reference price is the maximum amount that HIF reimburses for the PL medicines, and it takes into consideration the Purchasing Parity Power. The unified medicines prices were also established in 2007 based on ex-factory price, wholesale mark-ups and pharmacy mark-ups.
Objectives and methodology: This study explores what impact the reference pricing (RP) methodology has on the affordability and availability of medicines in comparison with the international tender (IT). It includes the financial affordability, defined in the WHO/HAI Medicines Prices Manual as a price of predetermined regimens of treatment for selected six chronic and two acute diseases (eight in total). It can be related to either national average monthly wages or working hours needed to purchase a month of treatment in January 2010 (RP) vs. January 2005 (IT). The availability is measured as a range (number) of same INN (generics) of the above medicines available on the market in 2010 vs. 2005. The study also calculates out-of-pocket money that patients need to pay as difference between reference prices and average market prices for all available generics for the selected treatments.

Results

Table 1: Clinical conditions, their average treatment costs in Macedonian denars (MKD) and working hours

Condition	Medicine name (INN) and dosage form	Average treatment cost in 2005 (MKD*)	Average treatment cost in 2010 (MKD*)	Average income/cost 2005 (working hours)	Average income/cost 2010 (working hours)
Diabetes	Glibenclamid 5mg tabl	139.20	91.20	4	1
Hypertension	Atenolol 50mg tabl	90.51	66.90	2	0,75
Adult respiratory infection	Amoxicillin 500mg caps	93.66	114.87	2	1,25
Gonorea	Ciprofloxacin 500mg tabl	24.99	13.69	0,5	2
Arthritis	Diclofenac 50mg tabl	130.20	181.80	2,7	2
Depression	Amitriptylin 25mg tabl	244.62	198.00	5	2,20
Asthma	Salbutamol inhaler 0.1 mg/dose	30.93	23.00	0,65	0,25
Ulcer	Omeprazol 20 mg tabl	643.50	355.50	15,53	4

* MKD = 61,5 Euros

The absolute costs of treatment for eight selected clinical conditions are lower in six and higher in two conditions in 2010 vs 2005 (Table 1). Table 2 shows that there is no significant difference in the average cost of all eight treatments in 2005 and 2010 (2,84 € vs. 2,12€, Wilcoxon Matched Pairs Test: Z=1,120, p=0,2626).

Table 2: Average cost of treatment in MKD 2005 vs 2010

Year	Average cost in MKD	Standard deviation	Minimum	Maximum
2005	174.30	201,66	24,99	643,50
2010	130,62	122,65	13,69	355,50

The average number of working hours needed to purchase a month of treatment decreased from 227,87min in 2005 to 94,12min in 2010 (Wilcoxon Matched Pairs Test: Z=2,240, p=0,0250).

Table 3: Average values of working hours (in minutes) needed to purchase treatment for certain conditions in 2005 vs 2010

Year	Average cost in working hours (minutes)	Standard deviation	Minimum	Maximum
2005	227,87	253,26	30,00	812,00
2010	94,12	70,08	15,00	240,00

The number of medicines with the same INN (generics) for the eight selected clinical conditions increased significantly in 2010 compared to 2005 (total INN 51 vs. 17, Mann-Whitney U Test: Z =-2,607, p=0,0091).

Table 4: Generic medicines on the Positive list available on the market 2005 vs 2010

Medicine name (INN)	Number of generics 2005	Number of generics 2010
Salbutamol 0.1 mg/dose inhaler	1	1
Glibenclamide 5 mg cap/tab	2	3
Atenolol 50 mg cap/tab	2	2
Amitriptyline 25 mg cap/tab	1	2
Ciprofloxacin 500 mg cap/tab	1	6
Amoxicillin 500 mg cap/tab	3	10
Diclofenac 50 mg cap/tab	3	11
Omeprazole 20 mg cap/tab	1	7
Total	17	51

The difference between reference price and average market price of all available generics for each of the eight selected treatments in 2010 represents the out-of pocket money. It can be paid for seven out of eight treatments in the range 0,4-3,27 times of the reference price per unit of the treatment.

Table 5: Difference between reference price and average market price of all available generics for each of the eight selected treatments in 2010

Medicine name (INN)	2010		
	Av. market price per unit (MKD)	Av. reference price per unit (MKD)	Difference (MKD)
Salbutamol 0.1 mg/dose inhaler	153,72	110,00	43,72
Glibenclamide 5 mg cap/tab	1,52	0,70	0,82
Atenolol 50 mg cap/tab	2,23	0,85	1,38
Amitriptyline 25 mg cap/tab	2,20	2,45	-0,25
Ciprofloxacin 500 mg cap/tab	13,69	3,20	10,49
Amoxicillin 500 mg cap/tab	5,47	2,63	2,84
Diclofenac 50 mg cap/tab	3,03	0,85	2,18
Omeprazole 20 mg cap/tab	11,85	6,93	4,92

Lessons learned: In comparison with the international tender in 2005, the reference price system in 2010 generally decreased the prices of reimbursed medicines at reference prices levels. That helps save HIF finances for other healthcare activities. The advantages of RP also include improved availability of same INN, which means bigger choice for both patients and prescribers. However, the difference between reference price and market price result in high out-of-pocket expenses, as no additional health insurance exists nationally. The analysis also confirms that better financial affordability of medicines in 2010 is only partly a result of lower medicines prices, but it is predominantly a result of higher monthly wages.

Analysis of price levels of prescription drugs and determinants of international price differences between the United States and selected European countries

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Associated Authors: Alessandra Ferrario and Sotiris Vandoros
Problem Statement: As governments in OECD countries undertake a programme of extensive health reforms, a key issue remains how to contain the growing cost of prescription drugs. Spending on prescription drugs in key OECD countries has increased by 50% or more in the last ten years, raising questions about overall system sustainability.
Objective(s): The study analyses possible reasons for differences in prices and volumes consumed across key OECD countries, taking into account national differences in pharmaceutical policy and regulatory mechanisms. In so doing, the study compares pharmaceutical price levels and utilisation between the US, selected European countries, Australia and New Zealand and investigates determinants of international price differences in both originator and generic prescription medicines in these countries.
Policy/ies targeted: Pricing and reimbursement (P&R) regulations, drug promotion, drug use, and competition
Stakeholder(s) involved: Governments, health insurers, and manufacturers
Region covered: AMRO and EMRO. International level.
Study design: Panel data modelling is used to investigate the effect of pharmaceutical P&R regulations, drug promotion, drug use, and competition on price levels. The data analysed are from IMS Health and the US Federal Supply Schedule and include top-50 selling on patent and generic prescription drugs used in the study countries. Regulatory variables are included as dummy variables in the model.
Time period: 2006-2010 on a quarterly basis
Setting: The study analyses out-patient pharmaceutical markets and covers the insurance (public and private) market.
Result(s): Preliminary results suggest that: a) cross-country price comparisons are only meaningful if the right prices are compared in each case. Here, we demonstrate how significant price differences are when ex-factory prices are compared and how these differences narrow down significantly when public prices are compared across countries, b) It seems that price differences of originator brands between the US and Europe have been exaggerated, generic prices are very often significantly lower in the US than in other countries. c) Cross-country public price differences and cross-country ex-factory price differences are not the same across the study countries. This highlights the importance of distribution as a key contributor to public prices of prescription medicines, by default, as a contributor to the cost incurred by health insurance. d) Off-patent originator brands account for a significant proportion of the price variation between US and the other study countries, differences in generic policies between the two and more intensive intervention in some European countries plus Australia and New Zealand, can explain the significant increase in the price spread between the US and other study countries. e) Pricing regulation accounts for a considerable proportion of the variation in prices across the study countries. f) Distribution and taxation can contribute significantly to the total cost of prescription medicines that health insurers pay.
Conclusions: Research is ongoing and the final conclusion will be available before the conference in mid-September.
Lesson(s) learned and success factor(s): Research is ongoing and lessons learnt will be available before the conference in September.
Keywords: Price levels, price determinants, promotion, competition
Funding Source(s): Commonwealth Fund

Prices and affordability of medicines in Armenia

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Festsaal)

Irina Kazaryan (National Institute of Health/ Pharmacy Department, ikazaryan@yahoo.com)
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Problem Statement: Lack of access to medicines is an important challenge for the Armenian pharmaceutical policy. Due to lack of Government funding patents forced to purchase the majority of medicines out-of-pocket. Reimbursement system covers only some vulnerable groups (some social groups and patients with certain diseases). Approximately one third of the households surveyed in 2008 did not get a recommended service after they contacted the health system, for medicines, 35% of those who did not get a recommended service said they failed to do so (because of finances). In August 2009, 21% of households reduced or stopped buying the medicine they required. High prices are one of the main reasons of a low affordability of medicines and treatment.
Objective(s): The objective of this study was to measure and evaluate prices of some essential medicines as well as to assess the cost of treatment for some patients with wide-spread diseases (adult respiratory infection, hypertension, diabetes, asthma and so forth) in Yerevan.
Policy/ies targeted: At present there is no any price regulation in Armenia and prices are set by the private sector - pharmaceutical producers, wholesalers, pharmacies.
Stakeholder(s) involved: Prices for medicines intended for the population in whole were studied.
Region covered: Yerevan - the capital of Armenia.
Study design: Survey, analysis, price comparisons.
Time period: Data on prices for more than 50 medicines were collected for June and December 2009, June and December 2010.
Setting: Data were collected from 30 community pharmacies located in different regions of Yerevan.
Intervention(s): No intervention has been implemented.
Result(s): The prices of the great majority of products increased from June 2009 by December 2010, despite price fluctuations were observed for some medicines during this period of time. Significant price rising was identified for certain pharmaceuticals, in particular, prices have increased by 25% and more for such products as Unidox Solutab, Corinfar retard, Adalat retard, Ciprobay. There are very large differences in the affordability of originator brand products (and brand name generics) and the lowest-priced generics. The number of days the lowest-paid government worker needs to work in order to be able to pay for a standard course of treatment for Asthma (salbutamol, one inhaler of 200 doses) are 2.8 days if originator brand product is used, and 0.85 day for the lowest-priced generic, for Arthritis (diclofenac, 50 mg capsule or tablet, a 30-day course) - 10.8 and 0.78 day. The originator brand product of amitriptyline was not available, but the number of days for the lowest-paid government worker to pay for treatment of Depression with the lowest-priced generic (25 mg capsule or tablet, three times daily, a 30-day course) are about 1.7.
Conclusions: Thus, there is a clear trend of medicines prices increase in Armenia. Treatment is often not affordable, especially taking into account that brand products are mainly prescribed by physicians and selected by patients. Introducing price regulation and/or other strategies intended for reducing medicines prices could be useful for improving the situation.
Keywords: medicines prices, affordability of treatment, Armenia
Funding Source(s): No funding

Income Concentration and Price Differentiation in Low and Middle Income Pharmaceutical Markets

Oral presentation
(Fri, 30 Sept, 11:45-12:00, Festsaal)

Eric Keuffel (Fox School of Business (Temple University), USA, ekeuffel@temple.edu)

Problem Statement: Prior international comparisons of pharmaceutical prices generally show that firms price discriminate at the country-level in high income countries. In the limited cases where middle or low income country prices have been examined (e.g. Mexico relative to US), the private sector prices are relatively high in relation to GDP/capital in part since firms and distributors are likely focus on the upper tier of the income distribution in these countries. Low and middle income markets are of increasing importance to branded and generic manufacturers, but little empirical work has been generated on these markets where most purchasing occurs out-of-pocket rather than via government insurance purchasing.
Objective(s): Estimate the extent to which income concentration (or inequality) affects private sector prices for generic and originator products in low and middle income markets.
Policy/ies targeted: Firm (and Distributor) Pricing Behavior
Stakeholder(s) involved: Regulators, Manufacturers, Distributors, individuals
Region covered: Global
Study design: I regress originator product private-sector median price ratios (MPRs relative to MSH international prices) for each country-survey-year unit on relevant covariates including a measure of income concentration. Similar analyses are conducted for generics. A positive coefficient on the income concentration term indicates that prices are higher in countries with more skewed income concentration.
Time period: 2000-2010
Setting: Lower Income Markets, n=69
Intervention(s): Observational data is from HAI/WHO Pricing Database. Country-level income concentration data and other covariates from World Bank.
Result(s): The mean private-sector patient-level MPRs for originator medicines (16.85) is 3 times the MPRs for lowest price generics (5.58) although the basket of goods differs between these two forms. For each 1% increase in the share of income earned by the top 10% of the population, prices of originator products in the private sector increase approximately 3.5% (p=.02). There is no significant shift in pricing among generics as income concentration increases. Results are robust across different measures of income concentration. Much of the effect for private-sector originator markets occurs at the upper end of the price distribution (the effect of income concentration on the 75th percentile product bundle is significant and large, the effect of the 25th percentile bundle is not significant).
Conclusions: This result is consistent with a model in which manufactures (or distributors) price discriminate in those low and middle income markets where income concentration is skewed. Price discrimination is not uniformly negative from a welfare perspective (especially if higher prices are concentrated on higher income customers and greater revenue potential may invite greater dynamic entry by manufacturers)

Lesson(s) learned and success factor(s): This result is consistent with a model in which manufactures (or distributors) price discriminate in those low and middle income markets where income concentration is more heavily skewed. The results suggest that high-income individuals perhaps pay more for medicines, but prices are not necessarily increasing proportionally as much for the products targeted toward lower income individuals. Future analyses will be conducted at the product (rather than country level) to help tease out the product selection vs. pure pricing effects. Initial analyses use private-sector patient-level prices from the HAI data (supply chain mark-ups included), but future analyses will also examine public sector patient-level and public sector procurement prices.
Keywords: Pharmaceuticals, Price Differentiation, Low and Middle Income Markets
Funding Source(s): None

Access to innovative anticancer drugs in the outpatient setting in Latvia

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Festsaal)

Marta Kipena (The Centre of Health Economics Latvia, marta.kipena@vec.gov.lv)
Associated Authors: Viksna Anita (The Centre of Health Economics, Latvia),
Baltina Dace (Riga East Clinical University Hospital, Latvia), Behmane Daiga (The Centre of Health Economics, Latvia)
Problem Statement: The trend towards greater patient demand and higher prices for innovative anticancer drugs present a significant challenge for regulatory authorities and payers in health care system.
Objective(s): To review the clinical and pharmacoeconomic data on selected cancer drugs submitted for the inclusion in the positive list and to review the strategies used to raise patient access to new anti cancer agents.
Policy/ies targeted: Reimbursement with conditions, external price referencing, negotiations, cost-effectiveness evaluation.
Stakeholder(s) involved: Regulatory authorities, pharmaceutical companies, cancer patients
Region covered: Latvia
Study design: A retrospective analysis of clinical and pharmacoeconomic information submitted by the holders of marketing authorization for decision making and strategies used by the Centre of Health Economics of Latvia to either support or refuse the reimbursement of innovative cancer drugs for the treatment of head and neck, breast and colorectal cancer.
Time period: 2008-2010
Setting: Outpatient
Intervention(s): Cetuximab, Trastuzumab, Bevacizumab
Result(s): Monoclonal antibody Cetuximab was reimbursed in 2008 for the treatment of patients with head and neck squamous cell carcinomas in combination with irradiation. The incremental cost effectiveness ratio (ICER) per life year gained was 6 250 EUR. A recombinant humanized monoclonal antibody Trastuzumab was included in the Positive list in 2010 for the treatment of patients with HER2 positive (IHC 3+), Grade II/III early breast cancer following surgery and within six weeks after adjuvant chemotherapy. ICER per life year gained was estimated within 19 500 and 35 100 EUR, depending on the model used for obtaining overall survival data. Bevacizumab, a VEGF receptor inhibitor, was submitted for inclusion in the Positive list in 2010 for the treatment of patients with metastatic colorectal cancer in combination with fluoropyrimidine-based chemotherapy. Because of cost-ineffectiveness (ICER per life year gained was more than 81 500 EUR) the appraisal was negative and inclusion of Bevacizumab was rejected.
Conclusions: The decision about clinical and economic value of the new drugs was based on overall survival data from randomized, comparative phase III studies, as well as on pharmacoeconomic studies carried out by the holder of marketing authorization, the incremental cost-effectiveness ratio and price negotiations. The incremental costs have to be considered in context with gains in overall survival.
Lesson(s) learned and success factor(s): In the era of healthcare budget restrictions reimbursement with conditions does not solve the problem of patient access to new therapies because only a limited number of patients who meet the pre-set conditions will be able to receive therapy with the treatment.
Keywords: Cancer, drugs, reimbursement
Funding Source(s): The Centre of Health Economics Latvia

Drug procurement cooperation Norway tender for a -TNF/biologicals - recommendations and results

Poster

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Problem Statement: LIS TNF/BIO specialist group has made recommendations for choices of a-tnf/biological pharmaceuticals within rheumatology, gastroenterology and dermatology.
Objective(s): The 4 health trusts have decided that a specialist group will decide what are the preferred choices of a-tnf/biological pharmaceuticals within the indications rheumatoid arthritis, Bekhterevs disease, Crohns disease, Ulcerus colitis, psoriasis arthritis and psoriasis.
Policy/ies targeted: The use of biological treatment has increased by 61 % since the 4 regional health trusts started financing these pharmaceuticals in June 2006. Hospital expenditure for pharmaceuticals will probably be doubled in the next five years.
Stakeholder(s) involved: All hospitals in Norway
Region covered: Procurement of tnf/ biologicals For 2011 the 4 health trusts received offers for abatacept (Orencia®), adalimumab (Humira®), certolizumab pegol (Cimzia®), etanercept (Enbrel®), golimumab (Simponi®), infliximab(Remicade®), ustekinumab(Stelara®), rituximab (MabThera®), and tocilizumab (RoActemra®).
Study design: Procurement
Time period: 1.2.2011-31.1.2012
Setting: National procurement agency
Intervention(s): The 4 health trusts have decided that a specialist group representing the hospitals will decide what are the preferred choices of a-tnf/biological pharmaceuticals. The recommendations are to be followed when starting or switching a patient on biological treatment. In addition to the recommended choice the estimated cost of one year's treatment is presented.
Result(s): The recommendations are to be followed when starting or switching a patient on biological treatment. In addition to the

recommended choice the estimated cost of one year's treatment is presented. The lowest calculated price per patient per year is based on the recommendations even though there is no clearly documented difference in effect and adverse effects shown by head to head comparative studies. There might be special conditions in the individual patient which can affect the choice of product.
Conclusions: Recommendations are implemented and the costs for tnf/biological is reduced. More patients can be treated.
Lesson(s) learned and success factor(s): National procurement and recommendations works and are followed.
Keywords: TNF/ biologicals, tenders, reduced costs, treatment recommendations

Literature Review on Patient Access Schemes, Flexible Pricing Schemes and Risk Sharing Agreements

Poster

Ruth Puig-Peiro (Office of Health Economics, UK, jmestre-ferrandiz@ohe.org)
Associated Authors: Jorge Mestre-Ferrandiz, Jon Sussex and Adrian Towse, Office of Health Economics
Problem Statement: Risk sharing schemes, and variants thereof, are increasingly being used in many countries to determine the price and/or reimbursement status of pharmaceuticals. There is a need to understand what are the costs and benefits of such schemes.
Objective(s): To identify existing knowledge about the costs and benefits, assessed either quantitatively or qualitatively, of performance based reimbursement, risk sharing (RS) schemes, patient access schemes (PAS), and flexible pricing (FP) schemes for pharmaceuticals.
Policy/ies targeted: Drug pricing policy. performance based reimbursement, risk sharing (RS) schemes, patient access schemes (PAS), and flexible pricing (FP) schemes for pharmaceuticals
Stakeholder(s) involved: patients, providers, payers and industry
Region covered: International
Study design: review and analysis
Time period: 2008-2011
Setting: Interface; public and private sector
Intervention(s): performance based reimbursement, risk sharing (RS) schemes, patient access schemes (PAS), and flexible pricing (FP) schemes
Result(s): Four main results have been identified, based on our literature review. First, more than 40 per cent of the publications referred to the Multiple Sclerosis Risk Sharing Scheme (MS RSS) implemented in the UK since 2002. Second, the review did not identify any cost benefit analysis evaluating the overall economic impact of schemes in monetary terms. All included studies discussed costs and benefits qualitatively and in some cases, when known, some costs were reported. Third, key stakeholders participating in the schemes (patients, payers, providers and industry) bear different costs and benefits and conflicting incentives may arise. Fourth, costs and benefits widely vary depending on the characteristics of the scheme. Financially based schemes are easier and faster to implement than outcome based schemes which are more complex and therefore suffer from higher uncertainty around the overall balance of costs and benefits.
The costs most commonly cited in the reviewed publications were: Transactional/implementation costs (costs of negotiation, contracting, monitoring and data collection and analysis); Specific administrative burdens for the health system; Complexity of the methodology to generate the evidence; and Regarding the MS RSS, additional challenges identified were: problems of governance of the scheme, enforceability of the contract, time delays generating the evidence, and impact on NICE future decisions when evaluating drugs for the same indications
Cited benefits include: Increase in access to new treatments; Paying a price closer to the value of the drug (a 'value-based' pricing approach); Potential to improve the efficiency of the pharmaceutical market; Rewarding innovation; and Reducing uncertainty in the payer's decision making process
Conclusions: There is lack of consensus on the welfare consequences of the schemes and their social desirability, partly explained by the scarce evidence available. Some authors recommend outcome-based agreements only in exceptional cases given their complexity and high costs, in line with the recommendations in the PPRS (2009). Identified benefits are countered by significant costs and challenges and therefore the overall balance remains unclear, despite strong opinions regarding one specific scheme (the MS RSS).
Lesson(s) learned and success factor(s): Important lessons are to be learned from the existing experience but further objective research is necessary for two main reasons: a) to assess in a transparent way to what extent the transactional costs and administrative burden of the schemes are shared between the payers and the pharmaceutical companies as they constitute an important barrier for the implementation of the schemes; b) to aid design of a successful Value Based Pricing (VBP) system for new drugs in the UK in the next few years, given the similar principles that underpin outcome-based schemes where prices are set to match "real world" NHS value in practice
Keywords: drug price survey, drug price comparison, drug price monitoring, median price ratio performance based reimbursement, risk sharing schemes, patient access schemes and flexible pricing schemes
Funding Source(s): The Office of Health Economics (OHE) receives research funding and consultancy income from the Association of the British Pharmaceutical Industry (ABPI). No separate funding was received for this paper. The views expressed in this abstract are the authors and do not represent those of either the OHE or the ABPI

A Pitfall interpretation of Thailand Medicine Price Survey in 2006 and 2010

Poster

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Associated Authors: Siriwat Suwattanapreeda MSc, Petcharat Pongcharoensuk PhD
Problem Statement: Medicine prices should be monitored regularly to inform policy makers of its magnitude and trends. Changes in drug prices can impact financial management of the Thai health care system which provides basic health services to the majority of Thai citizen.
Objective(s): 1. To compare the changing of Thailand public procurement prices in relative to the changing of MSH prices between the year 2006 and 2010, 2. To compare the median price ratio of public procurement prices between the year 2006 and 2010
Policy/ies targeted: Drug pricing policy.
Stakeholder(s) involved: Health policy maker
Region covered: Public hospitals in Thailand

Study design: The design of this study was adapted from the 2008 edition manual workbook of WHO, HAI, Medicine Prices: A new approach to measurement.
Time period: January – June 2010
Setting: 36 public hospitals with more than 60 beds all over Thailand were surveyed
Intervention(s): The 14 core medicines from Medicine Prices: A new approach to measurement (WHO/HAI, 2008), were surveyed. Price from hospital data base were recorded and mailed back to the researcher. Price data were entered into the workbook provided as part of the WHO/HAI methodology. Data entry was checked by the 'double entry' and 'data checker' functions of the workbook. Median Price Ratio, MPR was a parameter for each medicine, calculated from Thai median price divided by median of MSH reference price. Prices were compared with a previous survey by Sooksriwong C. http://www.haiweb.org/medicineprices/surveys/200610TH/sdocs/survey_report.pdf
Result(s): There are 11 drugs listed in 2010 survey matched with those in 2006 survey. The result reveals that in 2010, the median prices of 3 generic drugs procured by public hospitals remain the same and the rest are less than the prices procured in 2006 at the range (–) 17.65% to (–) 39.76%. It implies that generic drug prices in Thailand are decreasing. These percentages decrease are less than changing of the lowest MSH prices at (–) 5.41% to (–) 82.32. For changing of the median price ratio, the figures were in the opposite direction. The MPR of 11 drugs in 2010 increase from 2006 at (+) 3.29% to (+) 415.38%, only one MPR of procurement price decreases at (–)–26.67%. Interpretation of the price ratio suggests that drug prices in Thailand are getting more expensive. In 2006, 7 from 11 drugs (64%) had MPR from 1.16 to 3.15, and in 2010, 10 from 11 drugs (91%) had MPR from 1.37 to 4.64 when compared to MSH prices.
Conclusions: The major cause of this interpretation owed to the differences of the rate of money exchange and the MSH prices of the year 2006 and 2010. Rate of exchanged in the 2010 survey was based on 3 February 2010 with selling rate from bank of Thailand = 32.9528 baht per US dollar, while in the 2006 survey the rate was 36.7456 baht per US dollar, nearly 10% different.
Lesson(s) learned and success factor(s): The trend of drug price monitoring could be tricky if we look at one parameter, median price or median price ratio only. The interpretation of a price survey should be careful especially in countries under high economics fluctuation.
Keywords: drug price survey, drug price comparison, drug price monitoring, median price ratio
Funding Source(s): Thai Drug System Monitoring and Development Program

The comparative description of pharmaceutical pricing and reimbursement policies in the selected Latin-American and European countries

Paola Stefan Oliveros (paolastefan@gmail.com)
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Poster

Problem Statement: Pharmaceutical pricing and reimbursement policies are being established all over world but. There is a lack of information on the operation of the pharmaceutical pricing and reimbursement policies in Colombia, Brazil and Poland.
Objective(s): To describe and compare the differences and similarities of the pharmaceutical pricing and reimbursement policies in Brazil, Colombia, the United Kingdom and Poland.
Policy/ies targeted: Pharmaceutical pricing and reimbursement policies. Positive list, economical evaluations and reference pricing were studied within the reimbursement policies.
Stakeholder(s) involved: The main stakeholders are the ministry of health in each country, pharmaceutical manufacturers, health technology assessment agencies, commissions or comities taking part in the decision making process for the pricing and/or reimbursement decisions.
Region covered: EMRO and PAHO. National level in Brazil, Colombia, the United Kingdom and Poland.
Study design: Descriptive study
Time period: January – May 2011
Setting: Out-patient sector. Public sector
Intervention(s): A questionnaire was handed out to national experts in the field of pharmaceutical pricing and reimbursement policies. A documental review searching for legal documents, governmental reports and scientific articles was performed
Result(s):

PRICING				
	BRAZIL	COLOMBIA	POLAND	UK
Frequency of the updates of the official documents	According to regulation every year but not in practice.	Updated recently due to irregularities in reimbursed priced	Currently being updated due to major policies reform	Every 5 years or monthly for generics
Ministry taking the pricing decisions	Minister of health	Ministry of commerce Industry and Tourism	Ministry of Health	Department of health
Sectors applying the pricing policy	All sectors	All sectors	Public –reimbursed drugs	Public – reimbursed drugs

REIMBURSEMENT				
	BRAZIL	COLOMBIA	POLAND	UK
Frequency of the updates of the official documents	Reference price program every 2 years. Essential drug list unknown	Not according to law requirements, but according to orders from the judicial branch	Currently being updated due to major reform	Every 3–5 years
Practices used for reimbursement	Positive list, reference pricing	Positive list	Reference pricing, positive list, economic evaluations	Negative list, economic evaluations
Number of product publicly reimbursed	Between 39 to 135 pharmaceutical presentations	Between 600–660 pharmaceutical presentations	Around 4700 formulations.	All the products in the market except for the negative list.

Conclusions: All the countries included in this study have official pharmaceutical pricing and reimbursement policies.

The updates of the official documents on reimbursement and pricing policies are not performed as frequently as the law establishes it in Brazil and Colombia. The criterion used for the updates is not well known. Brazil and Colombia have similar behaviour regarding the policy making, this can also be extended to Latin America. Stakeholder pressure is a main factor in the decision making of reimbursement policies in Colombia. There is a lack of information in English about the studied policies in Poland.
Lesson(s) learned and success factor(s): The information gathered by questionnaire has better results when is administrated by an interview. The best response in filling out the questionnaire came from Brazil, while Colombia was the country with the lowest response even when the number of people contacted was the larger. Similar situations are described in previous researches.
Keywords: Pharmaceutical pricing, reimbursement of pharmaceuticals, pharmaceutical policy
Funding Source(s): Jagellonian University-Europubhealth program

The comparative analysis of the impact of pharmaceutical pricing and reimbursement policies on drug access and cost containment in the selected Latin American and European countries

Poster

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Problem Statement: What is the impact of the pharmaceutical pricing and reimbursement policies in terms of access to drugs and cost containment in Brazil, Colombia, The United Kingdom and Poland?
Objective(s): To analyze the impact of the pharmaceutical pricing and reimbursement policies in terms of access and cost containment for each country.
Policy/ies targeted: Pharmaceutical pricing and reimbursement policies. Positive list, economical evaluations and reference pricing were studied within the reimbursement policies.
Stakeholder(s) involved: The main stakeholders are the ministry of health in each country, pharmaceutical manufacturers, health technology assessment agencies, commissions or comities taking part in the decision making process for the pricing and/or reimbursement decisions.
Region covered: EMRO and PAHO. National level in Brazil, Colombia, the United Kingdom and Poland.
Study design: Review
Time period: January - May 2011
Setting: Out-patient sector. Public sector
Intervention(s): The review was performed in International, Latin American, Colombian, Brazilian and Polish databases: Medline, The Cochrane Library, Embase, LILACS, CSPCol, SUS, CIDSaude, Polska Bibliografia Lekarska and Farmakoekonomika. The limits were articles in English, Spanish, Polish, Portuguese.
Result(s): 6303 articles were found. 7 articles were selected. 4 articles were from Brazil, 2 from Colombia and 1 from the UK.
In terms of cost containment a research studied the effects of NICE negative or positive with major restrictions recommendations, on prescribing and net ingredient costs of drugs in the National Health Service in the UK. No decline in the prescription rates and net ingredient cost were found after the publications recommendations appraisal. In Brazil popular pharmacy program, drug prices were compared between the public pharmacies and the private. Higher prices were found in the public pharmacy. The Brazilian government control drug prices in the public pharmacies. Drug access in the family health program in Brazil was around the 51% in a study performed in 2009. An important proportion of the drugs prescribed were not sought in the public pharmacies. This is related with lack of confidence from the population on the drug availability in the public facilities. Higher availability of drugs included in the national essential drug list was found in the private pharmacies. In 1997 the World health Organization assessed the access to the drugs included in the National positive list and the pricing policy in Colombia. The result was 4 of 5 points. In 2002 a study showed 51% of access to antidiabetic drugs included in the national essential drug list in Colombia.
Conclusions: There is no evidence implying that the reimbursement and pricing policies in the UK has improved drug access or cost containment. In Brazil there is a lack of access to the reimbursed drugs included in the essential drug lists. A study performed in Colombia showed lack of access to drugs included in the national positive list. No study was found assessing the impact of the pharmaceutical pricing and reimbursement policy in Poland.
Keywords: Pharmaceutical pricing, reimbursement of pharmaceuticals, pharmaceutical policy, Review studies.
Funding Source(s): Jagellonian University-Europubhealth program

Assessment of Pharmaceutical Expenditure Trends in Portugal - Pricing and Reimbursement Policy

Poster

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Problem Statement: In Portugal several measures have been adopted in recent years aiming at controlling the National Health Service (NHS) medicines expenditures. The Stability and Growth Pact approved by the Portuguese Government in 2010 limits the annual growth of public expenditure in 1% for drugs reimbursed in outpatient sector.
Objective(s): Considering the 5.6% increased in pharmaceutical expenditure from the NHS in 2010 and the 1.5% increased in volume, this study aims to identify the main factors of expenditure growth and implications of legislative modifications in Portugal.
Policy/ies targeted: Ambulatory Pharmaceutical Expenditure
Stakeholder(s) involved: Pharmaceutical Sector
Region covered: Portugal
Study design: Descriptive study
Time period: 2008-2011
Setting: We have considered the policy changes concerning pricing and reimbursement and analyzed the database that includes sales from Portuguese community pharmacies and drugs prescription data. The statistical analysis of monthly data by product was performed with Statistical Analysis System (SAS), version 8.2.
Intervention(s): Market research and impact simulations

Result(s): As in most European countries, the pharmaceutical market is highly regulated in Portugal. The new legislation approved in June 2009, that establishes generics reimbursement at 100% for pensioners whose income is below the national minimum wage and withdrawn in June 2010, was responsible for more 26.8 million euros of NHS spending in 2010. Nevertheless 117.1 million euros are explained by the new molecules (branded drugs) recently reimbursed, in the last three years. After July 2010 and due to the 1% increase in the VAT rate of medicines, the NHS expenditure had increased 7.5 million euros in six months. The Health Subsystems (special Social Security schemes for certain professions) had also contributed positively for this trend: in December 2010 about 7.4 million euros were transferred from the 'ADSE' (primarily civil servants Health Subsystem) for the NHS. At the end of 2010, the Government adopted further measures to control the public expenditure in pharmaceuticals, such as 6% discount in reimbursed prices and several reductions in the pharmaceuticals reimbursement levels. Immediately the NHS expenditure on medicines decreased 21.2% only in the four first months of 2011, with a huge effect to the stakeholders.
Conclusions: The legal framework has a high impact in pharmaceuticals expenditures trends, and consequently in public financial burden and patient co-payments.
Lesson(s) learned and success factor(s): Besides price and reimbursement reductions, with limited impact in the short run, it would be important to consider prescribing guidelines linked to conditional reimbursement for certain innovative medicines and promotion of generics, just to name a few measures. The different policy measures adopted in Portugal should be assessed on a periodic basis in order to monitor the market dynamics and to identify the strategies that support the sector sustainability.
The policies required to accomplish in the coming years by the Authorities (European Commission, the ECB and the IMF), also predict major changes in the expenditures trends in Portugal and a huge impact on the pharmaceutical sector.
Keywords: Pharmaceuticals, Expenditure, NHS
Funding Source(s): CEFAR / ANF

Cost containment interventions introduced on the community drug schemes in Ireland - evaluation of expenditure trends using a national prescription claims database

Oral presentation
(Fri, 30 Sept, 11:30-11:45, Festsaal)

Cara Usher (National Centre for Pharmacoeconomics, cusher@stjames.ie)
Associated Authors: Lesley Tilson, Kathleen Bennett & Michael Barry
Problem Statement: An important policy objective for healthcare decision makers in the current economic climate is to obtain value for money from pharmaceuticals during pricing and reimbursement negotiations. In Ireland, prices of pharmaceuticals are regulated at manufacturer level. Between 2006 and 2010 a range of cost-containment interventions were introduced after negotiations between the healthcare payer (i.e. the Health Service Executive, HSE) and the pharmaceutical industry. The outcome of the negotiations had a direct impact on the future pricing of patented, patent-expired (off-patent) and generic medicines in Ireland.
Objective(s): The aim of the present study was to examine expenditure of pharmaceuticals according to class (i.e. generic, off-patent and patented) following the various cost-containment interventions on the Community Drug Schemes in Ireland from 2005 to 2010.
Policy/ies targeted: A price reduction was applied to all off-patent medicines which had a generic equivalent available and took the form of a two-stepped price cut, whereby the price to the wholesaler was reduced initially by 20%, and by a further 15%, 22 months later. The first 20% price cut (or phase 1) was introduced in March 2007 and a subsequent 15% (or phase 2) was implemented in January 2009. In July 2009 further cost-containment measures were introduced for wholesaler and pharmacy margins, whereby the wholesaler margin was reduced from 17.66% to 10% and the pharmacy mark-up on the Drug Payment Scheme was reduced from 50% to 20%. In February 2010, the pharmaceutical industry reduced further the price of off-patent products by 40%, and finally in October 2010, industry renegotiated the price of generic products.
Stakeholder(s) involved: The Irish healthcare payer, (i.e. the Health Service Executive, HSE).
Region covered: Ireland.
Study design: Retrospective observational study using a national prescription claims database. Drugs are classified into three classes on the database: generics, off-patents and patented products. Total expenditure was determined for drugs dispensed in each class on the Community Drug Schemes from 2005 to 2010 and the impact of the following interventions on expenditure in March 2007, January 2009, July 2009 and February 2010 was determined. To compare the different interventions throughout the time period (January 2005 to October 2010), segmented regression analysis was performed.
Time period: 2005 - 2010
Setting: Primary Care
Intervention(s): March 2007 (15% reduction in price of off-patents); January 2009 (20% reduction in price of off-patents), July 2009 (wholesale margin reduced from 17.66% to 10%, pharmacy mark-up also reduced from 50% to 20%), February 2010 (40% further reduction in price of off-patents), October 2010 (price realignment of generics with off-patents).
Result(s): An increase in expenditure was noted across all schemes up to 2009 and declined thereafter to the end of the study period (October 2010). Significant reductions in expenditure were noted following the introduction of a 20% price-cut to patent-expired products (off-patents) ($p<0.001$). In July 2009, pharmacy and wholesale margins were reduced, resulting in significant reductions in expenditure for patented (GMS, $p<0.05$ and DP scheme, $p<0.001$) and generic (DP scheme only, $p<0.01$) products. No significant reductions in expenditure were noted for off-patent products at this time. Furthermore, no significant reductions in expenditure were noted for off-patents following a 15% price reduction in January 2009 and a further 40% price reduction in February 2010.
Conclusions: Results from the study indicate that reductions in the wholesale margin and pharmacy mark-up had the largest impact on reducing pharmaceutical expenditure during the study period. This analysis of national expenditure trends over a 6 year period provides valuable information for the healthcare payer on the impact of the cost-containment interventions and may provide a benchmark for future negotiations with the pharmaceutical industry.
Lesson(s) learned and success factor(s): Expenditure on pharmaceuticals has shown a downward trend in the last 2 years and can be attributed to the pricing control mechanisms first introduced in 2007. While price controls are important, the question still remains on whether their impact will be sustainable. Price control needs to be supplemented with volume control in order to (i) constrain overall

spending but also to (ii) promote efficiency in the use of pharmaceuticals. Only when costs and benefits are evaluated together, can the best use be made of scarce resources.
Keywords: pharmaceutical expenditure, community drug schemes, cost-containment, time series.
Funding Source(s): No funding was provided for this study.

Cost-containment measures on medicines prices in European countries during a global financial crisis year

Poster

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Associated Authors: Nina Zimmermann, Christine Leopold, Bettina Schmickl, Friederike Windisch (all Gesundheit Österreich GmbH – GÖG / Austrian Health Institute)
Problem Statement: Several European countries were hit by the global financial crisis. As a consequence countries introduced several measures to contain costs in the pharmaceutical sector (e.g. emergency price cuts).
Objective(s): To survey the development of the prices of selected medicines in some European countries, including those countries strongly targeted by the crisis
Policy/ies targeted: pricing policies, in particular price cuts, price reviews, distribution remuneration, taxes and external price referencing
Stakeholder(s) involved: competent authorities for pricing
Region covered: 15 European countries (Austria – AT, Belgium – BE, Bulgaria – BG, Cyprus – CY, Czech Republic – CZ, Finland – FI, France – FR, Greece – EL, Hungary – HU, Ireland – IE, Poland – PL, Portugal – PT, Romania – RO, Spain – ES, Slovakia – SK)
Study design: Price survey of 3 medicines and time-line analysis of price data and policy measures
Time period: January 2010 to January 2011, update for June 2011 planned
Setting: Focus on out-patient sector. Price analysis at all price types (ex-factory, wholesale, pharmacy retail price gross and net)
Result(s): In the analysis period Spain and Greece, among the countries hardest hit by the crisis, undertook cost-containment measures on medicines prices. In spring '10 ES cut the prices of generics by 30%. Prices of original products and of orphan medicines were reduced by discounts of 7.5% and 4% respectively which were borne by all stakeholders. The pharmacy margin, however, was increased for some expensive medicines. EL reformed its pricing system in '10, with price cuts, a reduction of the wholesale margin and twice an increase in VAT on medicines. Price cuts were also undertaken in CZ. The pharmacy remuneration was changed in BE and PT. Increases in VAT rates on medicines took place in the CZ, FI, FR, PT & PL. The changes in the distribution remuneration and VAT rates were reflected in the prices of the surveyed products. At manufacturer price level, the prices in EL decreased for the 3 medicines, while for ES there was no change of the manufacturer price according to official medicine price lists. The manufacturer prices of the surveyed products remained rather stable during the research period, but for some products price increases could be observed in RO & FI in 2010 and in CZ in 2011, and price decreases in IE, SK and BG.
Conclusions: Changes in the VAT rates proved to be a much more common policy measure than price cuts at manufacturer level. Some price cuts were "hidden" in the form of discounts which were then not reflected in the price data bases.
Lesson(s) learned and success factor(s): For the analysis of prices several factors need to be taken into consideration: the manufacturer prices as well as other price components (e.g. distribution costs, taxes). It is sometimes difficult to get the full picture due to discounts, rebates and further "hidden" price elements. As a consequence, countries referencing to discount countries might not fully take advantage of the price cuts in the reference countries.
Keywords: price analysis, price cuts, discounts, distribution remuneration, crisis
Funding Source(s): No specific funding for this research which was done in the framework of the WHO CC activities funded by the Austrian Federal Ministry of Health

Impact of medicines price reductions in Greece and Spain on other European countries applying external price referencing

Poster

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Problem Statement: Several European countries apply external price referencing (EPR), i.e. comparing to the prices in other countries as a basis for their pricing decision. A price decrease in a reference country, as this was the case for Greece and Spain in 2010 in reaction to the financial crisis, might have an impact on the prices in the other countries.
Objective(s): To assess if price reductions in Greece and Spain were translated in the prices in other European countries applying EPR
Policy/ies targeted: external price referencing and further pricing policies (e.g. price cuts, price reviews, changes in distribution margins, taxes)
Stakeholder(s) involved: competent authorities for pricing
Region covered: 15 European countries (Austria – AT, Belgium – BE, Bulgaria – BG, Cyprus – CY, Czech Republic – CZ, Finland – FI, France – FR, Greece – EL, Hungary – HU, Ireland – IE, Poland – PL, Portugal – PT, Romania – RO, Spain – ES, Slovakia – SK)
Study design: Pharmaceutical policy analysis including a price survey of 3 medicines
Time period: January 2010 to January 2011, update for June 2011 planned
Setting: Focus on out-patient sector. Price analysis at all price types (ex-factory, wholesale, pharmacy retail price gross and net)
Result(s): While there were decreases in the ex-factory prices of the selected medicines in EL and ES, they were seldom "translated" in lower prices in other European countries which refer to them. In the months following the price cuts in EL and ES, the ex-factory prices of Olanzapin and Trastuzumab remained stable in AT, BE, BG, FR, HU and SK, while for Abacavir prices went down in BG, IE and SK. There were even increases in the ex-factory prices for some or all of the three selected products in FI, RO and CZ. IE had reductions in the ex-factory

prices for two medicines which is attributable to their price cuts to manage the financial crisis. At the level of wholesale and pharmacy retail prices, more changes, in particular increases, were observed which were mainly a consequence to increases in the VAT rates on medicines in several European countries during 2010.
Conclusions: We identified two major reasons for the low impact of the price reductions in reference countries on the EPR countries: 1. Missing regular price reviews which would allow learning about the price reductions. 2. Some price reductions were hidden, in particular the price decreases on original products in Spain, which was implemented as discounts and are not reflected in the price databases. It is recommended to assess the potential full savings which European EPR countries would achieve in case of regular price reviews and/or transparency about discounts.
Lesson(s) learned and success factor(s): For making best use of EPR, an effective price monitoring system is needed, which keeps track of the changes in the reference countries. The functionality of EPR is distorted by intransparency like "hidden" price cuts in the form of discounts or rebates.
Keywords: external price referencing, price analysis, price cuts, discounts, crisis
Funding Source(s): No specific funding for this research which was done in the framework of the WHO CC activities funded by the Austrian Federal Ministry of Health

Recent policies to reduce the drug costs and the budget deficit in Croatia: impact and example to others for sustainable healthcare

Poster

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Problem Statement: Croatia has recently introduced a number of reforms to reduce their budget deficit. These include measures to enhance transparency of new drug decision making and reference pricing for existing drugs.
Objective(s): Document the reforms that have recently been introduced and their impact to provide examples to other countries.
Policy/ies targeted: Potential supply and demand side reforms that could be introduced to reduce the budget deficit in Croatia
Stakeholder(s) involved: Physicians, health insurance personnel and pharmaceutical companies
Region covered: Europe - Croatia
Study design: Documentation of recent reforms and their impact on ambulatory care drug expenditure using data from the Croatian Institute for Health Insurance.
Time period: First 6 months of 2010 compared with the first 6 months of 2009
Setting: Ambulatory care in Croatia
Intervention(s): Principally supply side measures regarding the pricing of new originator drugs, me-toos and generics, as well as measures to curb pharmaceutical company activities.
Result(s): Recent reforms included:

a) Maximum price for new generics - up to 90% of the price of last bioequivalent product. First generic up to 70% of the originator
b) Maximum price for original breakthrough products up to 100% of average price in these 3 countries.
c) Maximum price for original me-too products up to 90% of average price of equivalent drugs in Croatia.
d) New reference pricing system for existing drugs (ATC Levels 3 to 5) principally based on DDDs. Reference prices (Levels 3 and 4) based on the lowest price of products with a market share of at least 5% by expenditure during the preceding 12 months, with patients paying the price difference for a more expensive product. Manufacturers can opt to lower prices of their other products if problematic, e.g. limited opportunities for substitution such as antiepileptic drugs.
e) Prices recalculated annually to make sure stay within established price limits.
f) Strict controls of marketing activities including mandatory recording of all promotional expenses and financial transactions with physicians, limiting representative activity.
g) Pay back, claw back, payment for performance and cross product agreements
h) Health insurance expenditure decreased by 13% from 1.7bn Kuna to 1.5bn Kuna (-0.2bn) first 6 months 2010 vs. similar period in 2009 enabling reduction of Fund's arrears to pharmacies from 1.3 bn Kuna (-173 million) to 1bn Kuna (-137 million).

Conclusions: Recent reforms have reduced costs providing guidance to other countries facing similar pressures.
Lesson(s) learned and success factor(s): Supply side reforms to influence the prices of new and existing drugs can be successfully introduced even in European countries with small populations to reduce budget deficits. As a result, provide guidance to others.
Keywords: Croatia, pricing reforms, generics, reference pricing
Funding Source(s): None - although principal authors employed by the Croatian Institute of Health Insurance

Development of benchmarks to improve price negotiations of antiretroviral medicines for low and middle income countries

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Festsaal)

Veronika J. Wirtz (National Institute of Public Health Mexico, veronika.wirtz@insp.mx)
Associated Authors: Yared Santa Ana-Tellez, Warren A. Kaplan
Problem Statement: Large differences of public procurement prices for high cost medicines between countries have been identified over the last decade partly caused by inefficiencies in the procurement process.
Objective(s): To design different price benchmarks to improve price negotiation of ARVs and to discuss their relevance in different country contexts
Policy/ies targeted: Public procurement of high cost medicines
Stakeholder(s) involved: Social security institutions, ministry of health, pharmaceutical industry as well as patient interest groups
Region covered: Global

Study design: Cross-sectional data
Time period: 2008
Setting: The Global Price Reporting Mechanism (GPRM) was used as the data source for analysis
Intervention(s): Five different reference points or benchmarks were developed in order to illustrate what procurement agencies could do to evaluate efficiency of procurement: lowest and highest manufacturing cost, lowest generic price, lowest innovator price and median procurement price (MPP) by income level for four, first line combinations and three, second-line ARV combinations. To illustrate opportunity costs (i.e., the annual savings if ARVs were procured at benchmark or below) potential saving scenarios were developed in which countries paid benchmark prices, for those countries which paid lower procurement prices than the benchmark prices, the current procurement price was used.
Result(s): In total, 2395 procurements of 16 different ARV dosages forms from 85 countries (36 low-income, 39 lower-middle and 11 upper middle income) were included in the analysis. For first line combinations, the MPP stratified by income group was higher than the lowest generic procurement price in that income group but below the lowest innovator price in that income group (except in two out of twelve cases). Contrastingly, for second-line combinations the MPP was higher than lowest innovator prices but lower than the lowest generic prices. Even if countries were only able to negotiate the MPP of their income group, the annual savings using the MPP price/ total amount spent for ARV procurement from the GPRM price would be between 8.7 and 32.4% for lower-middle and 50.3 to 69.2% for upper-middle income countries.
Conclusions: Using benchmark methods should provide policy makers with relevant information to optimize allocation of scarce resources. Different benchmarks provide complementary information. The median procurement price indicates the country's performance against other countries in the same income group whereas the lowest generic or lowest innovator prices provides information about the possible further price reduction and hence, savings. The production cost benchmark might have particular importance in highlighting the minimum expected prices for an ARV which is more feasible to achieve for generic ARV than innovator ARV.
Lesson(s) learned and success factor(s): Defining price benchmarks can provide relevant information to detect inefficient procurement procedures. There is currently no agreement on best practice of defining benchmarks, transparency in procurement prices is a pre-requisite, however, there are currently a lack of incentives to individual countries or agencies to report transaction prices which jeopardize data availability.
Keywords: Medicines price benchmarks, public procurement, price transparency, antiretroviral medicines, Global Price Reporting Mechanism
Funding Source(s): Ford Foundation

Strand 2 –
Rational use of medicines

Multiple demand side measures needed to enhance prescribing of generics: experiences from Abu Dhabi

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[1]Division of Clinical Pharmacology, Karolinska Institutet, Sweden; [2]Health Authority Abu Dhabi (HAAD), UAE,

Oral presentation
(Fri, 30 Sept, 12:00-12:15, Theatersaal)

Problem Statement: Potential savings from generics will be reduced if there are only limited demand side measures combating industry pressures once multiple sourced products are available. Health Authority - Abu Dhabi (HAAD) recently introduced the "Unified Prescription Form" (March 2009) mandating INN prescribing alongside a comprehensive Generic Drug Policy (August 2009). However, currently limited demand side measures directing physician prescribing to generics.
Objective(s): Document the outcome of the recent generic policies in HAAD. Subsequently suggest potential reforms that could be introduced in HAAD to achieve desired results based on experiences of other countries.
Policy/ies targeted: Demand side measures to influence the prescribing and dispensing of generics first line
Stakeholder(s) involved: Physicians and health authorities
Region covered: Middle East and Europe
Study design: One year (12 months up to end September 2009 vs. 12 months up to end September 2010) pre and post policy analysis of the impact of the two generics policy in HAAD on utilisation patterns for PPIs, statins and ezetimibe in ambulatory care (2 highest expenditure classes in 2009). Changes in utilisation patterns measured by converting packages dispensed (IMS data) to Defined Daily Doses (DDDs - ATC/DDD 2010 version).
Time period: 12 months up to end September 2009 vs. 12 months up to end September 2010
Setting: Ambulatory care
Intervention(s): Policies to enhance the prescribing and dispensing of generics versus originators and patent protected products in a class.
Result(s): a) PPI utilisation increased by 10%. Single sourced esomeprazole and pantoprazole by increased by 33% and 27% respectively versus 10% reduction for multiple sourced omeprazole - increasing overall expenditure by 11%. b) Statin utilisation increased by 14%. Atorvastatin/ rosuvastatin utilisation increased by 14% (87.5% of total statins in 2010) with simvastatin increasing by 13% (7% total statins in 2010). Utilisation of ezetmibe also increased. Total expenditure on statins and ezetimibe increased by 11%. These changes in utilisation patterns and expenditure mirror those among Western European countries with currently limited intensity of demand measures, e.g. France, Ireland and Portugal.
Conclusions: Anticipated efficiency savings from the various initiatives surrounding generics in HAAD have not materialised. Future policies under consideration include those based on successful experiences among European countries to enhance prescribing efficiency, e.g. education, formularies, benchmarking and incentive schemes.
Lesson(s) learned and success factor(s): It is essential for health authorities to have a comprehensive strategy surrounding generics to enable maximum efficiency savings. Just addressing one component such as INN prescribing when multiple sources without the others limits efficiency gains in practice.
Keywords: generics, demand side reforms, Abu Dhabi
Funding Source(s): Funded through grants from HAAD

Developing quality indicators and appropriateness scenarios for prescribing: rationale, methods and examples

Stephen Campbell (University of Manchester, stephen.campbell@manchester.ac.uk)
Associated Authors: Brian Godman, Björn Wettermark

Problem Statement: Medical practitioners have an important role in patient safety through the judicious prescription, and careful monitoring, of patients' medicines. This relates both to appropriate quality and efficient prescribing and avoidance of unsafe and hazardous prescribing that puts patients at risk. Therefore, assessing the quality and safety of prescribing by general and hospital practitioners is an important facet of any health care system but this must be rooted in a conceptual framework of quality of care with a clear purpose for data collection at a systems, practice and individual practitioner level respectively.
Objective(s): To develop a conceptual basis for the appropriate, safe and efficient usage of prescribing and to develop and test quality indicators (Campbell et al 2002, Campbell and Lester 2010).
Policy/ies targeted: demand side measures to enhance prescribing efficiency, effectiveness and safety arcoss Europe
Stakeholder(s) involved: Primary care practitioners and policy makers
Region covered: UK but knowledge transfer to Europe generally
Study design: Combination of descriptive studies and consensus techniques and proposed observational retrospective study principally between 2001 and 2007, using defined daily doses (DDDs) and Euros/ 1000 inhabitants/ year. Demand side measures based on the 4Es " Education, Engineering, Economics and Enforcement.
Time period: Lessons learned from UK from 2000 onwards
Setting: UK primary care practices
Intervention(s): Consensus techniques, safety prescribing indicators
Result(s): A conceptual framework for developing and testing good quality and safe prescribing has been constructed based on access and effectiveness within a framework of structure-process-outcome has been developed (Campbell et al 2000). Consensus techniques (Delphi Technique and The RAND Appropriateness Method) have been used to develop indicators (Campbell et al 2002). A multiple approach has or is being been used. 1) This has resulted in the development of for example 34 prescribing safety indicators appropriate for assessing the safety of prescribing of individual GPs (Avery et al In Press). 2) The plan is to focus on the demand side attributes of the 4Es (Education, Engineering, Economics, Enforcement) to maximise the quality and efficiency of prescribing by developing and applying a scoring system using national prescribing and drug utilisation databases to see if it predicts utilisation and subsequent prescribing behaviour.3) An indicator testing protocol has been developed to test UK Quality and Outcomes Framework indicators (Campbell and Lester 2010) that can be used to test prescribing indicators.

Conclusions: Multiple strategies are required to ensure quality, efficient and safe prescribing at a systems, practice and individual practitioner level respectively.
Lesson(s) learned and success factor(s): These strategies can deploy quality indicators and appropriateness scenarios within demand side reforms to maximise prescribing utilisation. However, they must be both developed and tested using rigorous methodologies.
Keywords: prescribing, safety, consensus
Funding Source(s): N/A

Developing safety indicators for appropriate and inappropriate prescribing: methods and examples

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Problem Statement: General practitioners have a critically important role in patient safety through the judicious prescription, and careful monitoring, of patients' medicines. Nevertheless, many patients are put at risk, and some are harmed, as a result of hazardous prescribing in general practice. Therefore, assessing the safety prescribing by general practitioners is an important facet of any system for assessing fitness to practice as well as ensuring the rational use of medicines.
Objective(s): To develop a set of prescribing safety indicators for individual GPs in the UK in the following categories: A: Cardiovascular and respiratory disease, B:Central nervous system (including analgesics), C: Anti-infective agents, D: Women's health and urinary disorders, E: Musculoskeletal, F: Hazardous care prescriptions, interactions and allergy, and G:Laboratory test monitoring.
Policy/ies targeted: Safety of prescribing within general practice
Stakeholder(s) involved: General practitioners
Region covered: UK
Study design: A conceptual framework for good quality and safe prescribing was constructed and a RAND Appropriateness Method was used to develop safety indicators.
Time period: 2010
Setting: General medical practices and prescribing staff
Intervention(s): RAND Appropriateness Method
Result(s): 34 prescribing safety indicators appropriate for assessing the safety of prescribing of individual GPs were developed (Avery et al In Press). Violation of any of the 34 indicators indicates a potential patient safety problem. Cover hazardous prescribing across a range of therapeutic areas, hazardous drug-drug combinations, prescribing with a history of allergy and inadequate laboratory test monitoring
Conclusions: This study adhered to a validated systematic consensus method for developing appropriateness scenarios and a wide range of sources were used to identify potential prescribing safety indicators, which all had an accompanying evidence-based summary. Only indicators directly attributable to the prescribing of individual GPs were included. However, the indicators do not take in to account a doctor's volume of prescribing. The indicators could also be used for the purposes of audit, GP appraisal and in intervention studies.
Lesson(s) learned and success factor(s): If implemented, it will be important to determine whether the use of prescribing safety indicators and avoiding/correcting hazardous prescribing and inadequate actually improves prescribing performance/safety and patient outcomes.
Keywords: prescribing, safety, general practice
Funding Source(s): N/A

Report Cards on Prescribing Behavior: Assessing the Impacts of Public Disclosure on Antibiotic Prescribing Rate

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Theatersaal)

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Problem Statement: In Korea, the separation of prescribing from dispensing was introduced in 2000 and the provision of feedback on prescribing patterns to healthcare facilities started in 2001. These policies aimed to reduce overprescription of medicines, in particular, antibiotics. Yet, the antibiotic prescribing rate (APR) for acute upper respiratory tract infection (AURI) was still very high, at 70.08% in 2003. Antibiotic overuse contributes to high antibiotic resistance in the country.
Objective(s): to assess the impacts of the public disclosure of APR for AURI through report cards
Policy/ies targeted: Report cards were used in two ways. The first report cards revealed the list of primary clinics of which APR is under the 25th percentile in October 2005. Then, the APR for AURI of all healthcare facilities, in the form of report cards per facility, have been publicly disclosed on the website of the Health Insurance Review Agency (HIRA) since February 2006.
Stakeholder(s) involved: The implementors are the government officials of the Ministry of Health and Welfare and HIRA. The target group are healthcare facilities.
Region covered: WPRO. A national program in Korea.
Study design: An empirical study using interrupted time-series without comparison series.
Time period: From 2004 to 2009
Setting: Both outpatient and inpatient sectors, which are covered by the public, the National Health Insurance.
Intervention(s): To examine the effect of report cards on both APR level and its trends, the dummy variable for report cards and the interaction terms between the dummy variable and trends were included in the empirical model.
Result(s): After the second report cards were implemented, primary clinics, secondary hospitals, and tertiary hospitals reduced their APR for AURI by 9.7%, 12.9%, and 4.8% respectively. However, report cards did not impact trends in antibiotic use for AURI. Restricted to primary clinics, the response to public disclosure varied across specialties. Pediatricians are the most sensitive specialty group to public disclosure. We found the heterogeneous impact of report cards on antibiotic use for AURI among quartile groups based on the mean APR prior to report cards. While primary clinics at the fourth quartile reduced APR for AURI by 19%, the APR for AURI of primary clinics at the first quartile

increased by 8%. When the first public disclosure was introduced, this unintended consequence of report cards - an increase in antibiotic use of low antibiotic prescribers - was also found in the assessment of the first report cards.
Conclusions: Public disclosure of antibiotic prescribing rates through report cards can be a new intervention to effectively reduce antibiotic use for AURI. The heterogeneous impacts of public disclosure imply that more-tailored interventions are necessary to maximize the desired impacts of public disclosure.
Lesson(s) learned and success factor(s): There are two successful determinants of using APR report cards. First, the high level of media attention strengthened the impact of public disclosure. Second, an internet-friendly system enabled this policy to be implemented. An electronic claims data system allowed the generation of the outcome variable, APR for AURI, as 95% of National Health Insurance claims data are collected and analyzed at the Health Insurance Review Agency.
Keywords: report cards, public disclosure, antibiotic prescribing, antibiotic prescribing practices
Funding Source(s): None to declare

Potential methods to enhance prescribing efficiency, implications for sustaining healthcare systems

Oral presentation
(Fri, 30 Sept, 11:45-12:00, Theatersaal)

Brian Godman (Division of Clinical Pharmacology, Karolinska Institutet, Sweden; Prescribing Research Group, Liverpool University, UK, Brian.Godman@ki.se)
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Problem Statement: Considerable variation in generic utilisation. European countries must learn from each other to increase generic utilisation to sustain equitable and comprehensive healthcare.
Objective(s): Assess the influence of different demand side measures on subsequent generic utilisation in Europe, including the influence of different approaches to prescribing restrictions, to guide countries in the future.
Policy/ies targeted: Influence of different demand side reforms on subsequent utilisation of generics.
Stakeholder(s) involved: Physicians and payers
Region covered: Europe
Study design: Retrospective analysis of the influence of demand side reforms on the utilisation of different PPIs and statins in over 20 European countries/ regions. Only administrative databases used, with utilisation measured in number of DDDs (ATC/DDD 2010). Classes chosen as both contain generics, originators and patented products with limited therapeutic differences between them; however, considerable price differences once generics are available. Demand side reforms broken down by 4Es (Education, engineering, economics and enforcement) and validated. Main outcome measure: % change in utilisation of omeprazole (O) and esomeprazole (E), simvastatin (S) and atorvastatin (A) plus rosuvastatin (R) (A + R) in 2007 as % of total utilisation versus utilisation patterns seen before generic 'O' and 'S' reimbursed.
Time period: Analysis between 2001 and 2007. Years chosen as generics became available in Western EU countries during this time.
Setting: Ambulatory care
Intervention(s): Demand side measures collated under the 4Es.
Result(s): Considerable differences in utilisation patterns in 2007 across Europe, e.g. utilisation of 'S' varied between 5% to 85% and 'A+ R' from 1% to 75% of total statins depending on the extent/ intensity of 4 Es. A/R utilisation decreased by 66% in Austria in 2007 vs. 2003 following prescribing restrictions. Reduced influence of regulations in Norway with less stringent follow-up. Increased 'S' utilisation in ES, SE and UK with lower or similar utilisation of 'A/R' following extensive combination of 3 of the 4 Es (not enforcement) - similar patterns among PPIs. Utilisation of esomeprazole fell in Norway after prescribing restrictions but appreciably less than for 'A' as different circumstances. In France, Ireland and Turkey, 'A + R' utilisation increased after generic 'S' with limited demand side measures. Similar changes for PPIs enhancing expenditure compared with ES, SE or UK.
Conclusions: Multiple and intensive interventions change utilisation patterns and enhance subsequent prescribing enhance efficiency. Care needed though when planning prescribing restrictions and their potential impact.
Lesson(s) learned and success factor(s): The impact of different demand side measures are additive. Care though when considering the impact of prescribing restrictions as need to take cognisance of both their implementation and follow-up for maximum impact.
Keywords: generics, demand side reforms, prescribing efficiency
Funding Source(s): In part with funds from the Karolinska Institutet

Essential to review health policy initiatives when comparing utilisation patterns across countries?

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Theatersaal)

Marija Kalaba (Republic Institute for Health Insurance, Belgrade, Serbia, marija.kalaba@rzzo.rs)
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Problem Statement: Previous research has highlighted differences in the utilisation of statins across Europe (EuroMedStat) study. However, there have been limited explanations for the differences seen to guide future policy.
Objective(s): Assess statin utilisation across Europe between 2001 and 2007 alongside ongoing health policy and other interventions to provide explanations for differences seen to shape future research and publications
Policy/ies targeted: Demand side measures influencing subsequent utilisation patterns
Stakeholder(s) involved: Physicians, patients, payers and pharmaceutical companies

Region covered: Europe
Study design: Retrospective analysis of the influence of different demand side measures on subsequent utilisation of statins in over 20 European countries/ regions. Only administrative databases used, with utilisation computed in Defined Daily Doses (DDDs – ATC/ DDD version 2010). Demand side reforms broken down by 4Es (Education, engineering, economics and enforcement) and validated with the payers in each country. Main outcome measure is differences in DDD/ TID (Thousand inhabitants per day) from 2001 to 2007 alongside a description of the health policy initiatives.
Time period: The analysis principally took place between 2001 to 2007.
Setting: Ambulatory care
Intervention(s): Influence of demand side measures on statin utilisation
Result(s): There was increased utilisation of statins in all countries, varying between 2 and over 5 fold between 2001 and 2007. However overall utilisation rates (DDDs/ TID) in 2007 varied considerably – from 0.8 in Lithuania to 3.28 in Serbia, 12.3 in Estonia, 94 in England and 115 in Scotland. Reasons for low utilisation in Central and Eastern European countries included higher patient co-payments and prescribing restrictions, e.g. in Lithuania statins initially restricted to secondary prevention and only for 6 months. High utilisation of statins in UK helped by quality targets linked with considerable financial incentives combined with recent studies encouraging prescribing of higher strength statins. As a result, considerable shift in prescribing to 40mg and 80mg simvastatin vs. 10 and 20mgs, with a similar change for atorvastatin.
Conclusions: Substantial differences in utilisation patterns between countries make it mandatory in future cross national studies to always record potential reasons behind any differences seen. Otherwise, there may be tendencies for readers to dismiss the outliers.
Lesson(s) learned and success factor(s): It is essential to always record health policy initiatives driving utilisation in cross national studies else there may be a tendency to dismiss outliers – both high and low. We have shown very good reasons for the differences seen to guide future studies.
Keywords: statins, utilisation, demand side measures
Funding Source(s): In part with a grant from the Karolinska Institutet

High rate of self purchasing of oral antibiotics in Serbia: implications for future policies

Oral poster presentation
(Fri, 30 Sept, 12:15–12:30, Theatersaal)

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Problem Statement: High antibiotic consumption in Serbia, with expenditure on antibiotics also growing with increasing use of newer expensive antibiotics. In Serbia patients can also purchase antibiotics directly at community pharmacies, which is illegal but currently unchallenged. Consequently, there is a need to reduce self purchasing and overall antibiotic consumption to reduce resistance development and conserve resources.
Objective(s): (a) Assess the extent of self purchases in Serbia, (b) Compare overall antibiotic consumption (reimbursed and total) with consumption in other EU countries documented on ESAC database, (c) Suggest measures to reduce antibiotic consumption and expenditure (reimbursed and self purchasing) based on experiences in other countries.
Policy/ies targeted: High self purchasing of antibiotics in Serbia plus high prescribing rates versus other European countries.
Stakeholder(s) involved: All key stakeholder groups
Region covered: Europe
Study design: Retrospective drug utilisation analysis of oral antibiotic consumption in DDDs and DDDs/ TID including the Penicillins – J01CA, J01CE, J01CF, J01CG, Cephalosporins – J01DB, J01DC, J01DB, Macrolides J01FA, and Quinolones – J01MA, J01MB, in both database: reimbursed – issued on prescription (RZZO) and the total including self purchases (Medicines and Devices Agency, ALIMS) from 2005 to 2009. Total utilisation rates in 2007 compared with ESAC database for the same classes across Europe. Potential measures suggested based on the experiences of the co-authors.
Time period: 2005 to 2009
Setting: Ambulatory care
Intervention(s): Future interventions described
Result(s): a) Reimbursed utilization decreased in Serbia 2009 vs. 2005 by 5%, 15.94DDD/ TID in 2009 vs. 16.74 in 2005, with changes in utilization among 4 reimbursed classes ranging from +29.7% for macrolides to – 8% for penicillins; b) Total consumption (ALIMS data) appreciably higher than reimbursed – increasing overall DDDs/TID in 2005 to 38.21 (128% increase vs. reimbursed) and 34.35 in 2009 (115% increase); c) Lowest % change in total consumption 2009 vs. 2005 (DDD basis) was – 2.5% for the penicillins versus a 27% increase for the cephalosporins and quinolones; d) Overall in 2007, Serbia third highest utilization for cephalosporins (6.18 DDD/ TID vs. 0.05 in Denmark/ Netherlands), highest for penicillins (17.34 vs. 4.33 in Netherlands), second highest for macrolides (11.98 vs. 0.89 in Sweden) and third highest for quinolones (3.45 DDD/ TID vs. 0.44 in Denmark)
Conclusions: Extent of self purchasing antibiotics in Serbia is appreciably greater than other European countries including Spain, where self purchasing increased overall utilisation by over 30%. Overall antibiotic consumption in Serbia is high compared with other EU countries. Reduced antibiotic consumption must become a high priority among all national authorities in Serbia to reduce resistance development and conserve resources. Apart from compulsory implementation of existing law, additional measures could include monitoring of antibiotic prescribing against agreed guidance and educational campaigns among patients.
Lesson(s) learned and success factor(s): Community pharmacists not being challenged for breaking the law, coupled with limited demand side measures, enhances antibiotic consumption in Serbia vs. other EU countries.

Keywords: antibiotics, self purchasing, Serbia, total and administrative databases
Funding Source(s): Ministry of Science and Technology of the Republic of Serbia grant No 173014.

Generic drug policies, utilisation and prices. An international study

Poster

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Problem Statement: Worldwide use of generics remains low. Many countries have adopted policies to promote the use of generics. To evaluate the impact of these policies is extremely important.
Objective(s): To summarize and classify policies to promote generics. To evaluate their impact on generic volume. To explain the interplay of generic drug prices and utilization.
Policy/ies targeted: The categories used by Espín and Rovira (2007) 1. Regulations to promote rapid introduction of generics. 2. Encouraged or mandatory prescribing of generics, 3. Generic substitution by pharmacists, 4. Information and incentives for prescribers, pharmacists, and consumers, 5. Positive lists, reference price systems, and procurement by tendering.
Stakeholder(s) involved: Health authorities , Pharmaceutical industry, consumers and patients associations, medical doctors, pharmacists
Region covered: OECD countries
Study design: Policy evaluation by means of a model of the impact of generic promoting policies on generic volume. The analysis is a difference-in-differences model with fixed effects for year and country. The model also includes country-level, time-varying covariates as appropriate. We introduce prices into the model including measures of the different pricing strategies in the utilization equation.
Time period: 1995-2007
Setting: Primarily out-patient drug consumption in the framework of pharmaceutical benefits covered with public funds.
Intervention(s): The policies to promote generic drug utilization developed in OECD countries
Result(s): To identify those policies more effective in promoting generic drugs. To clarify the interplay between policies aiming at lower prices and policies to promote utilization.
Conclusions: At the moment we do not have any conclusions since the project is ongoing. We hope to have conclusions by the time the conference will be held next September.
Lesson(s) learned and success factor(s): As this is an ongoing project we still cannot answer this question. We hope to have results by the time the conference will be held next September.
Keywords: Generic drugs, generic drug policies, policy evaluation, difference in differences models
Funding Source(s): At the moment we have no specific funding sources. Prof. Feldman holds an endowed chair by Blue Cross. Prof. Lobo directs the Chair on Economics of Medicines funded by Fundación Abbott

Promoting rational drug use among rural women in Oyo State of Nigeria

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Problem Statement: The World Health Organization (WHO) Action Programme on Essential Drugs has succeeded in promoting pharmaceutical policies in developing countries. However, much still left undone to the rural women populace who are deprived of access to standard health care deliveries and left in the hand of charlatans and quacks for medical attention and needs
Objective(s): The study aimed at investigating the source of drugs been sold to the rural populace, the pattern of polypharmacy, and effect interventions in terms of regulatory, educational and managerial to better drugs used.
Policy/ies targeted: Drug distribution and regulation in Nigeria Rural Community
Stakeholder(s) involved: Drug regulators
Region covered: Four communities of Egbeda local government in Oyo State, Nigeria, West Africa
Study design: Simple survey were conducted to assess the knowledge on rational drugs used. In addition, qualitative approach was adopted in form of in-depth interviews and key-informants interview with Patent Medicine Sellers and untrained Health Care Providers in the communities. Training was organized for these Medicine Sellers to educate and improve skill to identified some simple disease and referred complicated cases. In addition, pictorial adverts on adverse drugs effects and handbills in Yoruba were distributed in the community
Time period: June 2010 – December 2010
Setting: Four rural communities setting of Arolu, Alagba, Aroko and Agoro in Egbeda Local Government OYO STATE
Intervention(s): Training for proper handling and distribution of drugs
Result(s): The result reviewed that same-class, augmentation, multiclass, adjunctive and total polypharmacy were being practiced in the various communities. The women in the communities were not adequately informed and involved in medicinal decisions. After, six consecutive training and regulatory agencies monitoring. The indiscriminate selling and buying of drugs in the four communities relatively improved. Nevertheless, the 40% of households women visited still have recently purchased drugs that were not needed. Conclusively, Government and NGOs need to pay more attention to rural community were over 70% of rural women abide to make them have access to health and Health Care Providers
Lesson(s) learned and success factor(s): Monitoring and evaluation need to be strengthed. Rural communities are neglected.
Keywords: Rational, rural community, Medicine seller, Health Care Providers, Adverse Drug Effects
Funding Source(s): Self

Essential Medicines in Private Pharmaceutical Market of Armenia

Poster

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Problem Statement: In many developing countries the necessary essential medicines are not always available, accessible, and affordable to those in need. The aim of the national pharmaceutical policy is to supply a country with efficient, safe and high quality drugs that would be equally accessible for each citizen.
Objective(s): Based on the internationally accepted concept by WHO that the essential drugs are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the community can afford, we aimed to observe the pharmaceutical market of Armenia with regard to availability of essential drugs, to price difference among generics with the same active ingredient and to some other representative parameters of supplied and produced drugs in Armenia.
Policy/ies targeted: generic promotion ,essential medicines
Region covered: WHO region, national level
Study design: Analysis
Time period: From February 2011 to May 2011
Setting: Private sector
Intervention(s): Information about essential medicines was elicited from price-lists of four largest vendor companies in December 2010.
Result(s): According to our analysis Armenian biggest wholesalers receive and distribute essential medicines from 42 overseas exporters. The local production of drugs is comprised 13.4%, all generics. The widest range of essential drugs by therapeutic group was group of anti-infective drugs for systematic use (28.2%). Generics were more (76.8%) than known brands (21.8%). All companies together delivered 168 (54.4%) drug names from 309 in the National List of Essential Medicines (NLEM). Hundred thirty two drug names (14.1%) in required dosages by NLEM were not found among 936 drugs suggested by companies. By assuming that the price difference between the most expensive generic and the cheapest generic should not vary significantly we received one extreme difference with "Aciclovir 200mg № 20 tablets package" was approximately $23.The mean price difference of other generics was approximately 1.500 AMD or $ 4.1 (SD-1816.6, Mean-1496.6, 95%CI [621-2372]).
Conclusions: Further analyses will help to deeper understand the pharmaceutical market of Armenia by comparing the export volumes and the prices of generic essential medicines with international reference prices, by studying a dynamics of essential drugs availability in follow-up. Promotion of generic medicines is well established in Armenia which assumes the improved affordability without consideration of quality and prices.
Lesson(s) learned and success factor(s): This study results could be a valuable source for policy considerations and the assessment of national drug supply. One can imply about widely accepted and widely used essential medicines in Armenian health care market.
Keywords: Essential drugs, private pharmaceutical market, generic drugs, developing country, wholesalers

Recent policies to enhance renin-angiotensin prescribing efficiency in Europe, implications for the future

Poster

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Problem Statement: Renin-angiotensin drugs (ACEIs and ARBs) well accepted for treating hypertension and CHF. Coughing can occur with ACEIs leading to development of ARBs. However, only 2 - 3% of patients discontinued ACEIs in clinical trials due to coughing resulting in prescribing restrictions for ARBs in Austria as higher costs than ACEIs, limiting utilisation in practice. Similarly in Lithuania. Other demand side measures in Spain (Catalonia) also limited ARB utilisation at higher costs. Need to compare influence of different interventions as payers must increase their prescribing efficiency.
Objective(s): Compare the influence of more aggressive ARB prescribing restrictions in Croatia vs. Austria, as well as other reforms (education, engineering and economics) in Portugal, Scotland and Sweden vs. Spain, to provide future guidance.
Policy/ies targeted: Different demand side measures
Stakeholder(s) involved: Payers, physicians, pharmaceutical companies
Region covered: Europe
Study design: Retrospective observational study documenting the influence of reforms on utilisation of ACEIs alone/ combination (C09AA01to16, C09BA01 to 15, C09BB02 to 12) and ARBs alone/ combination (C09CA01 to 08, C09DA01 to 07, C09DB01 to 04) from 2001 to 2007 using DDDs. Years chosen to mirror published studies. Only administrative databases used. Demand side measures collated under the 4Es (education, engineering, economics and enforcement). All data validated with providers to enhance robustness.
Time period: 2001 to 2007
Setting: Ambulatory care
Intervention(s): Different demand side measures (4Es) to limit ARB utilisation.
Result(s): a) Renin-angiotensin drug utilisation increased in all countries between 2001 and 2007 at between 70% to 160%, appreciably greater increase in Scotland possibly linked with quality targets mirroring the situation with statins, (b) prescribing restrictions in Croatia greater influence in limiting ARBs than in Austria, enhanced by educational and economic activities (potential for fining physicians who abuse the prescribing restrictions), (c) limited utilisation of ARBs in Scotland mirroring Austria and Croatia, helped by intense demand side activities (3 of 4 Es) especially prescribing targets, (d) moderation of ARB utilisation in recent years in Sweden mirroring Spain (Catalonia) with again 3 of 4 Es, (e) growing ARB utilisation in Portugal with limited intensity of demand side measures, resulting in rising expenditure (Euros/1000 inhabitants/ year) vs. stabilisation in other EU countries despite increased utilisation.

Conclusions: Multiple demand side reforms essential to limit ARB utilisation, mirroring findings in other studies. Nature and follow-up of prescribing restrictions also important to maximise their influence, again confirming other studies.
Lesson(s) learned and success factor(s): Intensive multiple demand side reforms necessary to change physician prescribing to combat industry pressures. This mirrors the findings from other cross national studies.
Keywords: renin-angiotensin drugs, prescribing efficiency, demand side measures
Funding Source(s): In part with grants from the Karolinska Institutet

Strand 3 -
Hospital pharma and interface management

Enhancing the utilisation of generic clopidogrel: a case history for future guidance?

Oral presentation
(Fri, 30 Sept, 11:30-11:45, Sitzungssaal)

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Problem Statement: There is an urgent need for European countries to maximise efficiency gains from generic availability. However, savings will be reduced by companies challenging market entry as well as encouraging the prescribing of the originator. Clopidogrel provides a good case history as the initial generics were a different salt with fewer indications.

Objective(s): Appraise the activities of regulatory and health authorities, as well as health insurance agencies, across Europe to licence, reimburse and enhance the utilisation of generic clopidogrel at low prices. Utilise the findings to provide future guidance.

Policy/ies targeted: Encouraging the prescribing of generics at low prices.

Stakeholder(s) involved: Physicians, pharmacists, patients, generic and originator manufacturers

Region covered: Europe

Study design: Feedback from payers and their advisers in over 20 European countries and regions, combined with desk research, to analyse and collate regional and country responses across Europe. The findings subsequently validated with the payers and their advisers in each country to enhance robustness of the findings.

Time period: 2006 to 2011

Setting: Ambulatory care

Intervention(s): Interventions to enhance generic prescribing such as compulsory generic substitution along with educational and other activities to address concerns with generic clopidogrel

Result(s): Considerable variation: a) Generic clopidogrel reimbursed for all indications in Croatia (Nov 2006), with reference pricing; (b) In Austria, authorities stated no efficacy or safety problems with different salts and indications; prescribing restrictions eased for generics (c) In Finland first generic reimbursed in Dec 2009; mandatory substitution; (d) Initial confusion in France – some authorities advocating prescribing originator whilst others INN. Now resolved with substitution target of 75%; (e) In Lithuania generic clopidogrel reimbursed in 2009 with compulsory INN prescribing; (f) Scotland, prescribing of generic OK with limited risks; (g) In Portugal, first generic approved in April 2009; however, some formulations challenged leading to withdrawals (h) In Sweden, mandatory substitution agreed prior to generics. In contrast: (i) Hospital clinicians still prescribing originator in Spain; activities to address this; (ii) Originator challenged generics in Norway and Slovenia. In Norway, generic removed from reimbursement in Oct 2010; however accepted again from March 2011. In Slovenia, generic available from June 2006 – June 2008. Subsequently, removed as patent problems but reimbursed from May 2010. Considerable variation also in reimbursed prices; in some countries already below 10% of originator pre-patent prices.

Conclusions: Considerable variation. Activities thwarted by physicians and/ or originator in some countries. Countries can learn from each other.

Lesson(s) learned and success factor(s): Countries can learn from each other as there were considerable differences in responses to generic clopidogrel as well as reimbursed prices.

Keywords: generics, reimbursed prices, substitution, demand side measures
Funding Source(s): Funded with the assistance of the TLV in Sweden.

Characteristics of medicines management in Austrian hospitals

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Sitzungssaal)

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Associated Authors: Nina Zimmermann, Sabine Vogler, Claudia Habl, Christine Leopold, all WHO Collaborating Centre at the Health Economics Department of Gesundheit Österreich GmbH / Austrian Health Institute, chief hospital pharmacists of several Austrian hospitals

Problem Statement: Medicines management in hospitals is an increasingly important area, both for patients as well as financially since the starting treatment in hospitals has effects on the out-patient care. In Austria, the out-patient and the in-patient medicines sectors are two distinct segments, with different organisation and funding, and the hospital sector has for a long time been disregarded in pharmaceutical policy analysis.

Objective(s): To survey medicines management in hospital in Austria and to identify specific characteristics

Policy/ies targeted: procurement, tendering, negotiations, funding mechanisms

Stakeholder(s) involved: hospitals and hospital owner organisations

Region covered: Austria (Europe)

Study design: Descriptive survey (desk-top research, interviews)

Time period: 2009/2010

Setting: In-patient sector plus interface, public and private sector

Result(s): Only 17% of hospitals in Austria have a hospital pharmacy, whereas medicines management in the hospitals without a pharmacy is guaranteed by the "pharmaceutical depot" which has to be supplied by a licensed pharmacy. A major part of medicines is purchased decentrally by the individual hospitals or hospital owner organisations. Procurement by tendering is rather rare, but is increasingly playing a role. Discounts and rebates are granted for some medicines, and cost-free medicines, which are legally allowed, are a practice for some indications. A need for interface management has been identified by all stakeholders, and the representation of Social Health insurance representatives in the Pharmaceutical and Therapeutics Committees, as provided for by law, can be considered as a good practice for interface management.

Conclusions: The medicines supply system in Austrian hospitals has some characteristics (e.g. focus on negotiations, free-cost products) which are found in only a few other countries. Hospital pharmacists play an important role not only for quality assurance but also in economic terms and, increasingly, at the interface. However, to tackle the intransparency in hospitals, in particular regarding the actual hospital prices, which is incentivized by the organisation of the Austrian health care system with two distinct funding systems, changes in the overall regulatory framework would be needed.
Lesson(s) learned and success factor(s): To fully understand the pharmaceutical system of a country, both the out-patient and in-patient sectors and their interaction need to be known. Building knowledge and initiating a dialogue between representatives of both sectors is a key prerequisite for implementing policy measures, and this survey contributed to build a bridge between regulatory authorities, payers and hospitals in Austria.
Keywords: hospital pharmacists, procurement, cost-free medicines, interface management, Pharmaceutical and Therapeutics Committees
Funding Source(s): Research done within the PHIS (Pharmaceutical Health Information System) project funded by the Executive Agency for Health and Consumers (EAHC) and the Austrian Federal Ministry of Health

Influence of hospital choices of competitive drugs on the pharmaceutical consumption in the community

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Oral presentation
(Fri, 30 Sept, 11:45-12:00, Sitzungssaal)

Problem Statement: Hospital doctors influence general practitioners' prescribing patterns. But, no study has focused on the impact of hospital choices of drugs on prescribing patterns in the community.
Objective(s): To investigate the influence of hospital drug use on the pharmaceutical consumption in the surrounding community.
Policy/ies targeted: Impact of hospital choices of drugs on the ambulatory care sector.
Stakeholder(s) involved: Hospital and community physicians and pharmacists, pharmaceutical firms, health insurers.
Region covered: Western Europe
Study design: Quasi-experimental
Time period: 2008
Setting: French university hospitals and their catchment areas.
Intervention(s): Purchased quantities in 2008 for 25 of the 29 university hospitals for 9 classes were extracted from the national survey about drugs in hospitals. Reimbursed quantities in 2008 from non-hospital doctors' prescriptions for patients living in the hospital's catchment area were extracted from the national health insurance database. Quantities for each brand were expressed in defined daily doses and converted per 1000 inhabitants-day. The classes were chosen because of their high level of competitiveness and were divided into 2 groups according to the weights of their hospital and ambulatory markets: "hospital" (setrons, LMWH and erythropoietins) and "ambulatory" classes (PPI, ACEI, angiotensin II receptors antagonists (ARA), statins, alpha-adrenoreceptor antagonists (AAA) and SSRI).
To account for simultaneous causality, a multivariate 2 stage least squares model with instrumental variables was used to explain variations in community consumption.
Result(s): Hospitals selected between 30 and 52% of the available drug entities for these 9 classes. Overall, an increase of 1 day of treatment in the hospital was associated with an increase of 21.8 days of treatment in the hospital's catchment area ($p<10-4$). More precisely, this effect was mainly due to the "ambulatory" classes, as, as expected the effect was close to zero for the "hospital" classes (but significant for LMWHs). The influence also varied according to classes: from 8.0 for AAA to 51.8 for ACEI. It was significant for 4 out of the 6 "ambulatory" classes (ACEI, ARA, statins and PPIs). The spillover effect was maximal for the cardiovascular drugs (ACEI, ARA and statins). Not taking into account simultaneous causality resulted in overestimating the overall effect (25 vs. 21.8).
Conclusions: Hospital consumption influences community use of drugs and vice-versa. A strong effect was found, especially for competitive classes used on the long term basis. This is in line with pharmaceutical firms' strategies to get their products selected by hospitals. It also raises the question of the relevance of the current pharmaceutical policy silos and argues in favour of a joint regulation for the hospital and ambulatory care sectors.
Keywords: Interface management, prescribing influences.
Funding Source(s): Direction de la recherche, des études, de l'évaluation et des statistiques (Ministéres chargés de la santé, des solidarités et des comptes publics), France. Centre hospitalier universitaire de Toulouse, France.

Do European rheumatoid arthritis patients have equal access to treatment with new medicines?

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Oral presentation
(Fri, 30 Sept, 12:00-12:15, Sitzungssaal)

Problem Statement: Health care systems aim to achieve optimal health and economic outcomes for society as a whole as well as for the individual patient. Effective but expensive medicines, such as biologicals, may lead to different measures taken by governments/regulators and prescribers to achieve this goal thereby resulting in differences in access to treatment.
Objective(s): Building on previous reports on access to treatment in rheumatoid arthritis (RA), the objective was to further explore the use of the biological tumour necrosis factor alpha (TNFalpha) inhibitors used in the treatment of RA as a proxy of access to treatment with new medicines over time and to add opinions from key leading rheumatologist to put the obtained results into perspective.
Policy/ies targeted: drug use policies, in/outpatient setting
Region covered: Norway, Portugal, Ireland and the Netherlands
Study design: Drug utilization study
Time period: 2003 - 2007
Setting: This study examines the international use of a relatively new class of medicines in the in- and outpatient public sector in Portugal (PT), Norway (NO), Ireland (IE) and the Netherlands (NL).
Result(s): Prevalence of RA varied between 0.46 (NL) â€“ 0.56 (NO) per 100 inhabitants. Utilisation of TNFalpha inhibitors varied widely from 0.32 (PT) to 1.89 (NO) DDDs/1000 inhabitants/day (2007). An association between health expenditures per capita and the degree of

utilization of TNFalpha inhibitors was found (R2 = 0.81). When the use of TNFalpha inhibitors became more established (increased clinical evidence, increased number of prescriptions, extension of indications), the association was stronger. Differences in health expenditure were nevertheless not the only determinant of usage. Causes of intercountry variation were manifold including differences in guidelines, reimbursement regulations and according to key rheumatologists: access to rheumatologists (PT), (non)adherence to guidelines (PT,NL), consultation of colleague before initiation (NO) and budgetary constraints.
Conclusions: The prospects of patients receiving TNFalpha inhibitor treatment depend on the country where they are living. In case uniformity of management and treatment would be considered to provide health benefits, the extent and the causes of variation should feature prominently on future public health agendas.
Lesson(s) learned and success factor(s): 1) Large variations in the utilisation of TNFalpha inhibitors between four European countries exist. 2) Utilisation of TNFalpha inhibitors can not be conclusively linked to one characteristic, with the exception of health care expenditure. 3) In case of evidence based treatment of RA, the causes of variation should feature prominently on future public health agendas
Keywords: TNFalpha inhibitors, rheumatoid arthritis, utilisation, biologicals, access, intercountry variation
Funding Source(s): none declared.

The market for hospital medicine in Denmark, an evaluation of centralised public tenders for pharmaceuticals

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Problem Statement: A major part of recent pharmaceutical expenditure growth is due to high growth rates in specialist areas for which treatment often takes place in a hospital setting. Yet the market for hospital medicines and their procurement are still poorly understood.
Objective(s): The objective of this contribution is to characterise the market for hospital medicines in Denmark in terms of its organisation and developments between 2005 and 2009.
Policy/ies targeted: In Denmark hospital medicines are publicly financed and procurement is centrally organised. 98% of all medicines â€“ patented as well as off-patent - administered at Danish public hospitals are purchased through a public procurement agency by means of public tenders.
Stakeholder(s) involved: The primary stakeholders affected by these procurement practices are the public funding bodies that finance hospital treatment and pharmaceutical companies but hospital doctors and patients may be indirectly affected.
Region covered: The study covers entire Denmark.
Study design: We describe the tendering procedures and the market for hospital medicines by means of key indicators to compare pharmaceutical markets. Using data on actual contract prices we decompose pharmaceutical expenditure growth into the contributions from newly introduced medicines, and price and volume growth.
Time period: The study period is 2005 - 2009.
Setting: The study is an observational study of the market for hospital medicines.
Intervention(s): We evaluate the long term impact of centralised pharmaceutical procurement of hospital medicines on market structure and the price development.
Result(s): The market for hospital medicine is more concentrated than the pharmaceutical retail sector and the share of generics and parallel imported products is significantly lower. Between 2005 and 2009 expenditures for hospital medicines more than doubled - accounting for almost 40% of the total Danish pharmaceutical market in 2009. Price increases however - although positive and higher than in the pharmaceutical retail sector - were only moderate. The majority of the expenditure growth was due to an increase in utilisation and the introduction of new medicines in the hospital sector.
Conclusions: Centralised pharmaceutical tendering may therefore have important implications for competition and industry structure in the long run.
Lesson(s) learned and success factor(s): Tendering alone, as applied in the Danish market for hospital medicines, is an insufficient tool to contain pharmaceutical expenditure growth especially for new patented medicines.
Keywords: Pharmaceuticals, Hospital, Procurement, Denmark, Tendering, Pricing
Funding Source(s): The study was financially supported by Amgros, the Danish public procurement agency for hospital medicine, which also provided the data.

WHO and Global Fund harmonized tool for Pharmaceutical Country Profiles

Poster

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Problem Statement: A huge amount of data on the pharmaceutical situation of developing countries is collected every year by donors and researchers alike, but little of this information is made available to the public. Because of this and of lack of coordination between partners, several duplications of effort occur posing a significant burden on national counterparts.
Objective(s): Both WHO and the Global Fund decided to create Pharmaceutical Profiles in order to collect data to improve their support to countries. In order to reduce duplication of effort, an harmonized questionnaire was developed and enriched with a manual and glossary to facilitate data collection. The questionnaire was then piloted in one country to refine mechanisms for collaboration and to test the user-friendliness of the questionnaire.
Policy/ies targeted: Data collection on the pharmaceutical sector of middle and low-income countries.
Stakeholder(s) involved: WHO, Global Fund, Ministry of Health, Principal Recipients of GF grants.
Region covered: Global
Study design: The harmonized tool, in the form of a macro-enable word file, was prefilled with data available at WHO and Global Fund before being sent out.
Time period: December 2010-January 2011
Setting: The harmonized tool was piloted in Republic of Congo, a francophone, lower-middle income country.

Intervention(s): In the pilot country, the WHO Medicines Adviser and the Global Fund focal point acted as coordinators and selected the key respondents for each section of the questionnaire.
Result(s): After a series of technical meetings between Global Fund and WHO, a common pharmaceutical profile was agreed upon by the two organizations. Prefilling of the questionnaire took about half day of work and the same amount of time was necessary at country level to check the quality of prefilled data. Data collection at country level took about 15 working days. This is considerably less than the amount of time necessary to collect data for the WHO pilot profiles (55 days). This improvement can be attributed to the collaboration between the two agencies at country level.
Conclusions: It is possible to reduce burden of data collection in countries through interagency collaboration and harmonization of initiatives. In the course of 2011, the harmonized tool is being rolled out to all WHO member states.
Keywords: Pharmaceutical Country Profiles, Global Fund.
Funding Source(s): Global Fund, World Health Organization.

Oral poster presentation
(Fri, 30 Sept, 12:15-12:30, Sitzungssaal)

Access to high cost medicines: a systematic review of the literature

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Problem Statement: Health care systems in western countries face increased rationing of drugs due to the increasing costs related to medicines. There is an ongoing debate regarding the availability and funding of newer expensive medicines, often termed as "high cost medicines".
Objective(s): Aim of this project is to provide a critical review of the literature pertaining to high cost drugs. The specific objectives were to identify the viewpoints and perceptions of different stakeholders regarding "access to high cost drugs", to identifying barriers which influence the access and usage of high cost drugs, and to review the quality of the literature.
Policy/ies targeted: Decision-makers health care providers, economists and physicians, can be informed regarding the issue in detail with a systematic review of the literature. The different influences and underlying rationales could be explained regarding the stakeholders' views and the barriers regarding access. This knowledge would help us to formulate policy questions which in turn could be beneficial to improve access for patients.
Stakeholder(s) involved: Politicians, decision-makers, physicians, patients, public
Region covered: global study about OECD Countries
Study design: Retrospective review of the literature: Different databases were searched for papers about high costs drugs. We found 374 papers and selected 39 for the final analysis and synthesis of the systematic review.
Time period: published evidence between 1999 to 2010
Setting: Developed and high income economies
Intervention(s): Synthesis of the litertaure which resulted in policy questions
Result(s): All stakeholders were concerned about the challenges regarding high cost drugs. The stakeholders opined that the process and criteria for reimbursement has to be transparent and it should be fair for all patient groups. The evidence identified several barriers preventing access to high cost drugs. These include the financial status of a society, but also the decision-making process. The patient-physicians communication and the behavior of physicians and patients are affected by high cost drugs. Issues like rescue at all costs, reinforced by the media, can bias the objectivity of the decision making process on several levels. However, objectivity of the process is important to claim equality. The decision to receive the treatment at any cost could be detrimental as the patients have to pay high out-of-pocket costs.
Conclusions: This review concludes that stakeholders agree that access could be promoted through transparency and involvement of all stakeholders, especially patients and public in the decision making process. Moral issues and the rule of rescue could have a big influence on the decisions regarding increasing inequalities, especially empowered by the media. Besides, media can be influenced by the pharmaceutical industry. Obtaining equality in access is another part of a legitimate process. Further work is required to explore different influences on objectivity. Surveys of physicians present a good opportunity to explore viewpoints and barriers to access on several levels.
Keywords: High cost drugs, Fourth hurdle, Healthcare rationing, Physicians' opinions, Patients' opinions, Access to drugs, Bioethics
Funding Source(s): Supported by a grant for Philip Wahlster from the German Academic Exchange Service.