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EDITORIALS

E1 Challenges and opportunities for pharmaceutical pricing and reimbursement policies
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Even though access to affordable medicines is a human right, it is not ensured worldwide. The Priority Medicines Report 2013 [1] identified pharmaceutical gaps that continue to remain: diseases of public health importance for which pharmaceutical treatments either do not exist or are inadequate (see also K4). Where adequate treatments were available, access might be limited due to high costs of the medicines that can neither be funded by individuals nor by the communities. Ensuring equitable access to safe and effective medicines is a complex task. To prevent individuals from incurring into financial hardship when accessing health care, including medicines and to reduce the barriers to medicines access, quality of care and increasing equity, the World Health Organization (WHO) has been promoting Universal Health Coverage (UHC). During the last years a number of countries worldwide have been working towards UHC.

Still, there is a disproportion in resource allocation for health care, including medicines, between countries at different levels of income. While expenditure is not necessarily a good indicator of better access, it is worth noting that in 2005/2006 (latest data available at international level) for example, 16% of the world’s population living in high-income countries accounted for over 78% of global expenditures on medicines [2].

Equitable access to new high-priced medicines: Increasingly, funding of medicines has also become a challenge in high-income countries. Ageing populations and increasing prevalence of non-communicable diseases play an important role in this in addition to two main, more recent factors which are responsible for continuing pressure on public budgets. First, the global financial crisis hit some of the more affluent countries such as European countries (see E2, one strand of the PPRI Conference being devoted to the crisis). Second, a number of new high-priced medicines, including medicines for which no treatment was previously available, have been marketed, and more are in the pipeline. While this is promising for patients, it has been met with concern by policy-makers and payers since these medicines tend to be sold at premium prices. Frequently, these are medicines in the areas of oncology and/or medicines for rare diseases (orphan medicines). For the latter, special policies were designed in order to incentivize the pharmaceutical industry to do research in this field of presuming low volumes [3]. However, several orphan medicines rather have high sales volumes, and in total, orphan diseases are not so rare [4]. The best-known example for a high-priced medicine, however, is for the treatment of hepatitis C: in 2014, sofosbuvir challenged the publicly funded health care systems of numerous countries the world over and triggered discussions about the appropriateness of existing policy options to deal with high-priced medicines.

Pharmaceutical pricing and beyond: In order to confront challenges of access to new, potentially high-priced medicines, there is a need for the effective use of existing policies and for new and innovative policies that are not solely limited to pricing. In March 2015, the WHO Regional Office for Europe published a report about access to new medicines [5] that offers a review of interventions that policy-makers might choose to manage the market entry of high-priced medicines in order to improve patient access to potentially innovative medicines and to reward and incentivize industry for research while ensuring financial sustainability (see also K2). The report made clear that in addition to activities alongside the market entry of medicines, policy-makers should consider undertaking measures before launch, such as horizon scanning and planning far in advance, and post-launch activities to strengthen the compliance to guidelines and formularies and to improve the medicine management at the interface of in-patient and out-patient sectors (see also Strand 3 of the PPRI Conference, E3).

Further, more collaborative approaches between the different actors have been suggested, including a closer cooperation between the regulatory authorities and public bodies for pricing and reimbursement. In order to reduce possible overlaps between the licensing and the pricing and reimbursement processes and ensure early access to promising new
medicines, the European Medicines Agency launched in March 2014 the pilot project of ‘adaptive pathways’ which foresees an early approval of a medicine for a restricted patient population based on small initial clinical studies. The first approval is followed by progressive adaptations of the marketing authorisation to expand access to the medicine to broader patient populations based on ‘real-life’ clinical data on utilization [6]. In addition to a stronger cooperation between authorities, increased dialogue with other stakeholders has been recommended, in particular discussions on what constitutes a fair reward for industry innovation while still preserving access for patients [5]. Patients and citizens must not be forgotten in the debate. It was recommended exploring ways of how to better involve them since their potential to strengthen the quality and legitimacy of the decision-making process has been acknowledged [1].

New challenges and opportunities: In the field of pricing, common policies are increasingly being questioned because they appear to be no longer able to deal with new challenges such as high-priced medicines. In the Council conclusions on ‘Innovation for the benefit of patients’ as of 6 December 2014 European policy-makers noted with concern that, due to the very high prices of some innovative medicines, patients do not always have access to innovative treatments [7]. Concerns have been voiced that medicine shortages that have increasingly been observed also in higher-income countries, are, among other factors, attributable to existing pricing policies [8]. External price referencing (i.e. international price comparison) is the commonly applied pricing policy in European countries [9] and, increasingly, in several countries over the world [10]. This policy tends to incentivize marketing authorization holders to first launch medicines in countries with higher price levels, and delay, and even refrain from, launching in low-price countries [11]. While this has been long known, EPR’s possibly limiting impact access has been recently observed particularly in countries that were hit hard by the crisis and related to new high-priced medicines – the two main recent challenges mentioned above. As a result, alternative pricing and funding models have been implemented or are under discussion. In recent years, managed-entry agreements were introduced in several countries. However, while they are instruments to manage uncertainty and to allow faster patient access to new medicines, with possibly limited data on their effectiveness, they tend to contribute to intransparency due to their confidential contents [12,13]. Although value-based pricing as an integrative pricing and reimbursement policy is only in place in few countries (e.g. Sweden), tools (e.g. health technology assessments) aiming to assess value are applied in several countries [14]. Discussions have started whether, and how, the economic situation of a country could be considered into pricing policies [15].

At the same time, new opportunities could be seized. The recent and future patient expiries of high-cost, frequently biotechnological, medicines is very likely to patient access to highly effective medicines at lower prices and to offer potential savings to public payers. However, it has not been fully explored yet how to make best use of biosimilar medicines, and even generics.

The 2015 Vienna PPRI Conference provides a forum to discuss these issues with leading experts including Suzanne Hill (WHO, K1) and Andy Gray (University of KwaZulu-Natal, K3) and different stakeholders. Strand 1 of the PPRI Conference is particularly dedicated to current and recurrent challenges in pharmaceutical pricing and reimbursement and possible opportunities, with key-notes of Veronika Wirtz (Boston University, K4) and Arnold Vulto (Erasmus University Hospital) as well as presentations about policies to deal with high-cost medicines (e.g., O1, O2, O5, O14) and experiences with generic policies (O6).

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E2 Policies beyond the crisis: lesson learned
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Some European and further countries have been hit by the global financial crisis since 2008, and some of them were hit hard. The crisis has had major impacts on the health systems, including the pharmaceutical sector since cost-containment measures with possible negative impacts were set. Responses to the global financial crisis: According to a survey with the PPRI (Pharmaceutical Pricing and Reimbursement Information) network (see also E4), a total of 445 measures (related to pharmaceutical pricing and reimbursement) were reported during the period of 2010-2014. This corresponds to, on average, nearly 13 measures per country, but with great variability between the countries (range: 2-44). The most frequently reported policy measures were price cuts, followed by changes in co-payment and in the reimbursement lists (formularies). The highest number of measures (130 measures) was reported for 2012 in which the crisis was at the peak in some countries. Overall, during the 4 years, Portugal was the country that reported the highest number of measures, followed by Belgium, France and Iceland. An analysis for merely 2010-2011 evidenced that price cuts and changes in co-payments were also the policy measures taken most frequently in that time period. But countries with the highest
number of measures were different at that time; this included Iceland, the Baltic States (Estonia, Latvia, Lithuania), Greece, Spain and Portugal [1]. Despite the limitations of that survey (in particular a possible reporting bias), the study suggested that during the global financial crisis a higher number of pharmaceutical policy measures were taken, several had a focus on cost-containment, and that these were frequently measures that could be undertaken short term. However, a crisis might also offer an opportunity to move forward with policy options that had not been feasible at other times. Despite this focus on cost-containment during the crisis, policies to achieve other objectives, such as encouraging a more effective and efficient use of medicines and promotion of generic policies could also be observed, in the Baltic states, for instance [2,4].

Cuts in public expenses risk negatively impacting health outcomes. First analyses available for Greece suggest that the crisis, and the policy responses to it, brought negative effects on the quality of health services, a lower utilization of health care and signs of worse health outcomes, such as increasing rates of mental health, suicides, and epidemics, and a deterioration of self-rated health [5,6]. There is less evidence on the impact of the crisis in the pharmaceutical sector. The effect on public pharmaceutical expenditure was observed, with modest and even negative growth rates in the ‘crisis countries’ during some years [7,8]. Vandoros and Stargardt [9] concluded for Greece that ‘there is a major drop in pharmaceutical expenditure. However, the drop has been slow and could only be achieved through increased efficiency if the quality of healthcare and public health should not be compromised. They also addressed the threat that companies could withdraw from the Greek market in the light of the low price levels for originator medicines to which several other European countries refer to in their price setting [10]. However, product withdrawals took place at a very small scale in Greece [9].

More research is needed to learn whether, or not, access to medicines has been negatively impacted by the crisis. A study on eight European countries (three economically stable, and five less economically stable countries) showed that although less economically stable countries implemented more pharmaceutical policy changes during the recession than economically stable countries, pharmaceutical sales volumes (quarterly sales of products in the 10 highest-selling therapeutic classes in each country between 2006 and 2011) increased in almost all countries, whereas sales values declined, especially in less stable countries [11]. The authors suggested that the decline in the value of sales with the increases in volume might indicate that pharmaceutical purchasing had become more efficient. However, an analysis focusing on only two countries (Finland and Portugal) and one group of medicines (antipsychotics) showed slight, probably unintended, decreases in overall use of antipsychotic medicines and increases in generic market shares of major antipsychotic products from January 2007 to December 2011 [12].

Policy approaches in ‘non-crisis’ countries: Strand 2 at the 2015 Vienna PPRI Conference explores which pharmaceutical policies, particularly in the area of pharmaceutical pricing and/or reimbursement, countries chose to respond to the financial crisis. A key note by Panos Kanavos (London School of Economics) addresses the situation in Greece. Susan Spillane (National Centre for Pharmacoeconomics, Ireland, O10) looks at the impact of generic substitution and the reference price system that were recently introduced in Ireland, on pharmaceutical expenditure and generic penetration. Susanne Mayer (Medical University of Vienna, O12) analyses whether, or not, socioeconomic inequalities in medicine use exist in Central Eastern Europe, and how pharmaceutical policies can reduce them.

However, the PPRI Conference will not only focus on the countries hit by the financial crisis. It is also of interest which policy options were implemented and/or are being discussed in ‘non-crisis’ countries, and which have been the impacts of such policies. Countries in Europe and beyond are investigated. A key note by Zaheer-Ud-Din Babar (University of Auckland, KS) will inform about pharmaceutical policies in Australia and New Zealand. With regard to low- and middle-income countries, Yared Santa-Ana-Tellez (Utrecht University, O11) analyses price changes of antibiotics and perceived suboptimal or inadequate policy changes related to Over-the-Counter medicines in Mexico and Brazil. Peter Schneider (Austrian Public Health Institute, O4) analyses the impact of discounts on the medicine price levels. In a country poster session numerous pharmaceutical systems from Europe and the world over will be presented.

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burden for the budget for which they are responsible. This may particularly be an issue for high-cost medicines [1].

The urgent need to improve this type of interface management has been identified in the European Commission’s co-funded project ‘Pharmaceutical Health Information System’ (PHIS) running from 2008 until 2011 [2]. It has been followed up in the 2nd Pharmaceutical Pricing and Reimbursement Information (PPRI) Conference held in Vienna on 29 and 30 September 2011, with a special strand devoted to it. At a fringe meeting alongside the PPRI Conference, several Conference delegates expressed their interest in continuing work to improve medicine management at the interface of the out-patient and in-patient sectors. As a follow-up activity the seminar ‘Integration of Pharmaceuticals Management’ was organised in Stockholm in September 2012 to raise awareness about the issue and to share good practice examples [3].

However, there are few best practice examples to improve interface management that is also known under different terms, such as seamless care, integrated care, transmural care and continuity of care [4]. The different terms are highlighting the novelty and limited evidence base in this field. Measures set at a micro-level of individual hospitals consist of cooperation with out-patient carers, including interventions at admission and particularly hospital discharge [5]. At the system level where the organisation and funding of the pharmaceutical system could be addressed, measures would imply legal and organisational changes such as joint reimbursement lists for both out-patient and in-patient sectors and joint Drugs and Therapeutics Committees with representatives from both sectors. However, only a few European countries have such policies in place [2,6]. In the Stockholm healthcare region in Sweden, a list of essential medicines recommendations (called the ‘Wise List’) valid for the out-patient and in-patient sectors is annually decided by a Joint Drugs and Therapeutics Committee (OTC) [7]. In Scotland, joint lists of recommended medicines for primary and hospital care have been present for over 20 years, with an involvement of both primary and secondary care physicians in the DTCs and in developing joint guidance and guidelines [8]. At the 2015 PPRI Conference Ken Paterson (University of Glasgow, UK) gives a key note in strand 3 and presents the experience in Scotland with joint formulary committees.

Treatment packages of medicines and medical devices: Medical devices are playing an increasing role in medical treatment, in particular pathways for evaluation and funding of personalized medicine were composed of a medicine for treatment and a medical device for diagnostics purposes, substantial differences have been identified between European countries that have reimbursement systems for combined diagnostics and therapeutics (e.g. Germany, the UK and France), whereas for other countries (e.g. the Netherlands, Finland and Norway) no clear pathways for evaluation and funding of personalized medicine were identified [9]. An example can be found, for instance, in the treatment of breast cancer, with trastuzumab and gastrectomy [10].

Collaborative approaches: Recent developments have, once again, highlighted the need for further cooperation between countries and stakeholders. Over the last years, the cooperation between competent authorities of European countries has been strengthened, thanks to EU initiatives such as the High Level Pharmaceutical Forum (2006-2008) [11] and the Platform on Access to Medicines (2010-2013) [12] and voluntary initiatives, such as the PPRI project [13], see also E4). A major challenge for Member States cooperation was fosfobuvir for the treatment of hepatitis C, with its high price challenging the financial sustainability of publicly funded health care systems. In his key note at the 2015 PPRI conference (strand 3), Florent Dromzée (French Ministry of Health) draws lessons from the envisaged cooperation between EU Member States in the ‘fosfoovir case’. In this context, supportive approaches through scientific evidence and cooperation between authorities and payers are highly valuable, and should go beyond the issue of pricing and reimbursement alone, but also consider pre-launch and post-launch activities (see [1], K2, P8). At the PPRI conference, Anna Nachtnebel (Ludwig Boltzmann Institute for HTA, Austria, O15) demonstrates the value of collaborative models for increasing efficiency of early assessment of medicines, at the example of oncology medicines, and Wim Goetsch (National Health Care Institute, the Netherlands, O13) highlights the need for strengthening cooperation between HTA agencies, taking sofosbuvir as an example. The 2015 PPRI conference coincides with the 30-year anniversary of the Nairobi Conference on the Rational Use of Drugs (see also K3). The Essential Medicines List (EML) is an important tool to prioritise medicines reimbursement, as part of Universal Health Coverage programs in countries; however, the criteria for inclusion into EML have been an issue of discussion given the recent inclusion of highly effective and high-priced medicines in EML (O14).

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References
COMMENTARY

E4

The Pharmaceutical Pricing and Reimbursement Information (PPRI) network – a decade of exchange of information and policy research?
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Policy-makers throughout Europe and beyond have been working to develop and implement, and further adjust, the most appropriate mix of policy measures in pharmaceutical pricing and reimbursement to ensure equitable access to medicines despite limited budgets. The experience with policies in other countries is highly valuable information for them.

In order to support policy-makers, the Pharmaceutical Pricing and Reimbursement Information (PPRI) network of competent authorities was established in 2005, with the aim to offer a platform for competent authorities of pharmaceutical pricing and reimbursement to exchange information and data and to establish a sustainable reporting system for country information.

Within the decade of PPRI’s existence, more than 60 country reports (information about medicines policies for the out-patient sector, hospital pharmacy reports, and integrated country profiles about the out-patient and the in-patient sectors) of 28 different countries and more than 60 country posters were produced. Comparative analyses were undertaken, e.g. in the PPRI report [1], the PHIS Hospital Pharma report [2] or in scientific articles [3-5]. A glossary [6] and indicators were developed and are regularly updated. These deliverables have been shared in the open domain (http://whocc.goeg.at/Publications/).

In addition to these reports and tools, the instrument of PPRI network queries has proven its importance. A PPRI network query allows PPRI network members to ask for specific and quick information about a policy and situation in the other countries represented in the PPRI network [7]. In total, 319 PPRI queries have been launched until June 2015. The PPRI network is predominantly Europe-based. It has been growing over the years and currently comprises competent authorities for pharmaceutical pricing and reimbursement from 45 countries (thereof all 28 European Union Member States, another twelve European countries, and five non-European countries) as well as European and international institutions (European Commission, OECD, WHO, World Bank). Face-to-face meetings of the PPRI network are organised twice a year. The PPRI network is characterized by trust and mutual respect.

The last decade has brought both new challenges (e.g. financial constraints due to the crisis, new premium-priced medicines) and opportunities (e.g. new policy tools such as managed-entry agreements, patent expiries of biotechnological medicines) for policy-makers. Participation in the PPRI network has supported them to deal with these developments and discuss possible solutions and collaborative approaches. In the light of on-going challenges, the PPRI network is well placed and prepared to continue playing its role as discussion and information exchange platform for the years to come.

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KEYNOTE SPEAKER PRESENTATIONS

K1

Affordable innovation: future directions in pharmaceutical policy
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In 2009, Jayadev and Stiglitz [1] proposed ‘two ideas’ to increase innovation and reduce pharmaceutical costs and prices. These were the use of value-based pricing and promoting public funding of clinical trials. Since then, NICE has tried and not yet succeeded to introduce value-based pricing, Persson and Jonsson [2] suggest that international reference pricing should cease, Gilead has made billions on the basis of exorbitant pricing of new products for hepatitis C, and prices for new products for cancer are causing concern even in the US [3]. At the same time, there has been considerable work on how to promote research and development to meet health needs in developing countries [4], the reported cost of drug development seems to continue to increase [5], the structure of the multinational industry has changed significantly [6], there are major area of market failure such as antibiotics, and investment in public-private partnerships to promote innovation continues to grow. Given this complex landscape, this abstract briefly reviews the current ideas and strategies to promote innovation in pharmaceutical development. It provides a review of some of the issues about pricing and affordability of new medicines, and some options for ensuring that innovation is affordable. These options are likely to require some significant changes in our current approaches to negotiating pharmaceutical prices with suppliers, increased global and regional collaboration as well as increased transparency about clinical effects that are relevant to patients, costs of research and development and explicit consideration of willingness to pay by different countries.

The problem of declining innovation in the pharmaceutical industry has been well described [6]. Trouiller et al. summarised the problem in 2002 [7], showing how few molecules had been approved by the FDA that were of relevance to neglected tropical diseases. The Priority Medicines for Europe and the World Report in 2004 [8] was one response, to identify priority products for potential development by European pharma. The regulatory framework for orphan drugs in both the USA and Europe was another mechanism [9] and similarly, the push for paediatric medicines tried to use incentives (patent protection) as well as sanctions to encourage needed product development.

In 2012, the report [4] by the Consultative Expert Working Group on Research and Development identified a group of proposals that they
considered most likely to promote innovation in research for products relevant to low and middle income countries. These were: a ‘Global Framework’ on research and development, open approaches to research and development innovation, pooled funds, direct grants to companies, milestone prizes and end prizes and patent pools. They made recommendations on how much they thought countries should contribute to financing research and development activities, and also suggested that the WHO should take a coordinating role, including a global health research and development observatory.

Another example of promoting innovation may be the increasing number of public-private partnerships. There are the well-established entities, such as UNITAID and DNDi who have a portfolio of products for malaria and neglected tropical disease respectively. New products from both are on the market. Another venture, the Innovative Medicines Initiative is the biggest public-private partnership to date, and is also hoping to promote the development of innovative medicines.

But what about the price of the new products?: Prices of new medicines are a global problem. In the USA, prices of new cancer medicines have risen in real terms by 10% per year since 2005 [10], such that the entry price of recent new molecules – for example, ipilimumab for melanoma – is now estimated to be USD120,000/patient/course of treatment – approximately twice the average annual income. Some perceive the patent laws in the US legislation as partly contributing to the high prices, but mostly they appear to be due to ‘what the market will pay’. So the medicines for hepatitis C, sofosbuvir and the combination with ledipasvir, marketed by Gilead, have public prices of USD1,000 per pill in high income countries. We have estimated that, at this price, the cost of treating even a small proportion of the total Hep C infected patient population is unaffordable for most high income countries. Even medicines for orphan disease, where arguably higher prices might be justified on the basis of small market volumes are setting new price records, despite public funding of a significant proportion of the development costs in some cases for example, ivacifactor for cystic fibrosis [11].

In most high income countries, a number of policies are used to manage prices of medicines and expenditure. The choice of policy has to be set in the context of the balance between health and industrial imperatives, but usually includes some, or all, of: price-setting techniques (reference pricing, profit ceilings, cost-plus pricing and value-based pricing), control of supply chain prices and mark-ups from ex-manufacturer to dispensing, managing purchasing (through lists, tenders, price volume agreements and pooling procurement) and price signals, through co-payments, or premiums to promote generic completion and prescribing.

In low and middle income countries, although medicine prices are often reported to be high, there is less control of the supply chain and use of price setting techniques. As a result, especially in countries without comprehensive coverage or insurance, out of pocket payments can be catastrophic for individuals. While direct evidence of the effect of pricing policies in LMICs has been limited [12], it would seem reasonable to assume that controlling prices and mark-ups would have the same effect on price as it does in high income countries. How to take control of a market is a much more difficult question.

Newer approaches to managing prices are also developing. A number of high income countries are using policies such as ‘risk sharing’, ‘managed entry’ (‘pay for performance’ and ‘coverage with evidence development’) [13,14]. The impact on access and prices these types of schemes will have is not clear, but there are certainly questions to consider: for example, if measurement of patient outcomes is required for payment, does that require a separate registry for each disease? And if so, how are the data managed and analysed? Who decides what will be measured? Who protects patient privacy and how?

Similarly, the use of confidential rebates and discounts appears to be increasing [2] such that the public prices listed are almost meaningless. If prices are negotiated behind closed doors, what principles are used to ensure an appropriate or fair price and how should it be done? Cost-effectiveness thresholds are one approach but can have a distorting effect and affordability are not explicitly considered. But the public anger over what is perceived as corporate greed [15] is likely to push for at least one change, which is much more transparency about the basis for pricing. GSK has provided one recent example of transparent cost-plus pricing, for their new malaria vaccine. Luzatto et al. [9] suggest the same principle should apply to prices for medicines for orphan diseases. Differential pricing has been tried by Gilead for its products for hepatitis C, but without consideration of budget impact, which has been proposed as an alternative [16] or countries’ willingness to pay. So to be able to afford innovation, we need to change our approach and bring all of these strategies together: we need to consider international price negotiation, with fair profit margins and transparent understanding of all production costs, as well as quality use of medicines. Stiglitz may be right about value-based pricing as a solution – but the challenge is how to get there.

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K2
Managing new premium-priced medicines in Europe
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An issue of growing concern for health policy-makers in Europe is the continuing rise in spending on pharmaceuticals. In OECD countries pharmaceutical expenditure rose by 3.5% per year between 2000 and 2009, and averaged 18-19% of total health expenditure [1]. Similar averages are seen across Europe, with pharmaceutical spending representing the largest component of ambulatory care [2]. Spending in some countries has dropped since 2009 on account of specific policy decisions taken due to the financial crisis, but in others this growth has remained constant [1,3]. Contributing to this is the continual introduction of new premium-priced medicines, particularly for biologicals given the appreciable number in
development and their envisaged high prices [3-6]. And while the introduction of new therapies and current rapid pace of therapeutic innovation, particularly for noncommunicable diseases, is extremely positive from a patient perspective, managing their entry and longer term affordability especially under health insurance schemes and vis-à-vis existing lower-cost therapies poses a series of challenges to policy-makers regarding therapeutic complexity and higher costs [7].

To mitigate such pressures and to balance the demand for new medicines and the financial impact of their introduction, further development of systems and processes to optimize the entry of new medicines is necessary across Europe; this applies to countries with well-developed medicine policies and regulation traditions and those with less mature systems. And while many European countries have not traditionally required active priority-setting for access to medicines, appraising new medicines using pharmacoeconomics is increasingly seen as critical to improve efficient spending while maintaining an appropriate balance between access and cost-effectiveness. Indeed, policy-makers are in need of wider guidance on how to optimise the entry of new medicines to ensure the financial sustainability of their health care systems while encouraging the development of new treatments to address areas of unmet clinical need.

Although not an exhaustive list, areas in which the challenges around the sustainable management of new medicines are especially acute include:

- new medicines for patients with cancer where the price of new drugs has doubled over the past 10 years, up to US$10,000 per month, and often with little relationship between reimbursed costs and associated health benefits [5,8].
- new therapeutics for hepatitis C where patients are potentially being denied new effective direct-acting antivirals due to extremely high prices [9,10].
- orphan drugs where there is considerable unmet need for small patient populations, and where annual acquisition costs can be as high as US$500,000 per patient per year [11,12].

These represent examples of new premium-priced medicines which carry considerable implications for countries’ health budgets due to being either high volume (for treating many patients) or high cost (because of the cost of a single course of treatment).

The importance of this issue, and the need for guidance across European countries, is underscored by the results of a 2014 query undertaken by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Network (i.e. a network of competent authorities hosted by Gesundheit Österreich GmbH (GÖG), a WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies based in Vienna, Austria, see E4). The survey of 42 countries, most of which are in Europe, revealed that countries are struggling with the overall issue of defining what constitutes a high-cost or premium-priced medicine [7], annex 1]. Additionally, countries’ understandings of a threshold for what constitutes an innovative advance over existing (lower-cost) therapies were shown to differ, with respondents noting that their countries did not have specific policies for the pricing and reimbursement of premium-priced medicines versus other medicines (although several are working on inpatient policies in particular).

Building on the PPRI query, and with the aim to help facilitate debate on policies around the introduction of new high-cost or premium-priced medicines, the European Medicines Agency (EMA) has published a series of papers to help policy-makers consider the important factors to be taken into account when facing the introduction of new medicines. These considerations include economic aspects, patient needs, and balanced approaches for access.

Figure 1(abstract K2) Activities to manage the entry of new medicines Source: [7] (adapted from [10,13,14] Journal of Pharmaceutical Policy and Practice 2015, Volume 8 Suppl 1 http://www.joppp.org/supplements/8/S1 Page 7 of 30
It is clear that decision-makers across Europe will increasingly be faced with difficult choices in respect of new pharmaceuticals, and that achieving a sustainable balance between ensuring access and affordability around genuine therapeutic advances and treatment outcomes will be paramount.


References

K3 Pharmacetical pricing and reimbursement policies: perspectives for the future
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Setting the scene: For many years, the global approach to pharmaceutical pricing and reimbursement policies has been informed, first and foremost, by the key differences between those systems which relied on public sector procurement and supply, and those which were based on reimbursement. The first approach was considered to be the most appropriate for developing countries. Funding for healthcare services was based on disbursement from the fiscus, often exceeded by funds obtained from donors or development partners, and supplemented by considerable out-of-pocket payments in the form of user fees. In such systems, where medicines were provided by the state, they were often procured by a central medical store, and then distributed to public sector clinics and hospitals. Pricing interventions were limited to the application of limited competitive bidding, for a list of medicines determined centrally and severely limited. In some, but not all cases, this national essential medicines list was informed by the WHO Model List of Essential Medicines, updated approximately every 2 years since 1977. While procurement of generic medicines was the norm, a sophisticated generic medicines in Europe, the World Health Organization Regional Office for Europe (WHO Europe), working with a number of partners, undertook a review of the specific policies and principles for managing their entry (including financing) across the different phases of the medicine product cycle (note that for the purposes of the WHO report, a broad definition of a new premium-priced medicine as one whose acquisition cost is greater than EUR 10,000 per patient per year for the public payer, and is replacing an existing medicine (also covered by the public payer), was adopted). Figure 1 locates potential policy actions throughout the medicines continuum; that is, from pre- to peri- to post-launch activities. This serves to indicate where the value of individual patient health outcomes from medicines treatment may be considered. Pre-launch activities provide policy-makers with a forward-looking perspective on new medicines in development. They can systematically anticipate and prioritise therapeutic innovation with the highest potential for impact on potential clinical and treatment outcomes, and health system impact (cost and benefit to patients and budget implications). Peri-launch activities address, among other things, issues of access and affordability and are generally around pricing and reimbursement policies, with the aim of ensuring that prices reflect clinical and therapeutic value for the patient. The use of health technology assessment (HTA) is also crucial here. Post-launch activities are those undertaken to address the appropriate and sustainable use of medicines, and oriented around an evidence-based assessment of their risk-benefit profile over time.

The WHO Europe report makes a series of suggestions on potential policy choices/directions, for policy-makers in Europe to consider, and these are oriented around the three phases indicated in Figure 1. Key steps in these processes should include methods to distinguish and reward meaningful clinical innovation, as well as evaluation mechanisms to assess the benefits in practice of the introduction of the medicines and impacts on health system budgets. Overall, amongst its recommendations for certain policy directions, the report concludes that:

- Prioritization processes should incorporate principles of collaboration and transparency, as a lack of collaborative and transparent policy-making and prioritization runs the risk of unfair and arbitrary treatment decisions and inefficient systems.
- Cooperation between stakeholders needs to involve better balancing of the value of innovation with equitable, affordable patient access. For while industry needs to be rewarded for its research and development efforts and the risk companies assume in pursuing innovation, it is also important to ensure that countries do not have to limit access because they cannot afford new medicines that represent a true therapeutic advance.
- In view of the considerable costs involved in these areas, collaboration among regional or subregional health systems could benefit from including a particular focus on chronic care, specialty medicines and rare diseases, such that networks of information exchange for new priority medicines in Europe including pricing trends, treatment protocols and guidelines, common principles for the registries for patient characterization and effectiveness and similar can offer a way forward [7].
substitution policy was often not in place. Generic prescribing was preferred, but rarely practised. Rational use of medicines was expected to follow, almost automatically, but rarely pursued with much vigour [1]. For many of these countries, stimulating a local manufacturing industry has either been irrelevant or of subsidiary interest. Locally relevant innovation has been reliant on external funding, largely delinked from local pharmaceutical policies.

The second approach, applied most vigorously in those countries with national or social health insurance systems, was appropriate to systems in which the financing of health care was separated from the provision of services. In relation to medicines in particular, a wider range of policy options were entertained, including a variety of measures to promote generic medicines use, the use of co-payments and other risk-sharing options, external reference pricing, distribution chain price controls and health technology assessment. In many such countries, health policy has had to co-exist, if not seamlessly dovetail with industrial policies aimed at protecting local manufacturing. Innovation has been almost exclusively driven, at least after initial public support, on the protection and exploitation of intellectual property. However, the applicability of many of these pharmaceutical policies to low- and middle-income countries has been questioned [2].

The challenge for the future is to identify a range of pharmaceutical prioritisation and reimbursement policies that are not only appropriate and supportive of countries’ attempts to introduce and entrench universal health coverage. They will also need to stimulate necessary and appropriate innovation, while ensuring a responsible and stable pharmaceutical industry, in alignment with national and regional industrial policies. This is a tough call, which calls for a delicate balancing of many disparate interests, in a way which is also patient-centred and cognisant of the human rights at stake. South Africa – an exemplar: South Africa has been engaged in the implementation of a National Drug Policy since 1996, with highly publicised challenges mounted by the pharmaceutical industry to the initial interventions [3]. Those early interventions included the introduction of mandatory offer of generic substitution, a ban on all samples of medicines, a non-discriminatory single exit price (factor gate price) for medicines and a ban on volume discounts, a maximum annual percentage increase in the single exit price, and a maximum dispensing fee for pharmacists and other dispensing practitioners. The policy has aimed to achieve ‘transparency’ in the pricing of medicines, but has failed to achieve this in relation to the logistics fee paid to wholesalers and distributors by manufacturers, and included in the single exit price. Although nationally-representative data are elusive, it appears that the generic share by volume (of prescriptions) is now in the mid-50 % range, and rising very slowly. However, there are concerns that systematic attempts have been made to circumvent the ban on volume discounts, and to create incentives for large buyers in the form of data fees, co-marketing fees and other forms of off-invoice bonuses. International benchmarking (reference pricing) has been repeatedly signalled, but as yet not implemented. The submission of pharmacoeconomic data to justify launch prices has been introduced, but remains voluntary. New, expensive, and often biological, products are placing an increasing burden on the medical schemes that serve the insured population.

Criticality, the pricing and reimbursement policies listed above apply only to the private sector, which caters for barely 17% of the population (excluding those who pay out of pocket) [4]. The public sector still relies on local competitive tenders, predominantly with a single supplier per product delivered to public sector health facilities either via central provincial stores or directly. These products are identified by means of a national Essential Medicines List, based on comprehensive standard treatment guidelines. The public sector-dependent population is not able to access medicines via the private pharmaceutical infrastructure of community pharmacies and private hospitals, but has to rely on overstretched and poorly resourced public sector facilities. The Minister of Health issued a Green Paper on National Health Insurance in 2011 [5]. A final policy document has not yet been issued, but an indication has been given of the implementation process will take up to 14 years. Among the challenges facing South Africa’s attempt to introduce universal health coverage will be the need to move from a public sector selection, procurement and supply system to one based on reimbursement and a typical insurance-style purchaser-provider split.

At the same time, South Africa is home to the largest pharmaceutical manufacturing capacity on the African continent. Local preference procurement policies underpin the local industrial policy. Efforts to create an active pharmaceutical ingredient manufacturing capacity are underway. South Africa is also trying to reform its intellectual property system to be more critical and appropriate [6].

Perspective for the future: If recent product launches and the prices demanded are to be taken as a signal, and combined with the trend towards individualised medicine, then health systems in all countries are facing an insuperable demand for additional resources. There is much interest in expanding the process of health technology assessment to low- and middle-income countries. In part this may be achieved through greater transparency, data sharing and the publication of models that can be repopulated with locally-determined cost data. However, what will be critical is the application of this suite of methods to the selection and appropriate pricing of the bulk of reimbursed medicines, as well as to new and expensive medicines.

Much more attention will need to be paid to the responsible use of medicines, and to systems which allow for a reliable estimate of the value of medicines under typical use. Whether that will enable widespread use of performance-based pricing remains to be seen. What is critical is that performance-based pricing must not provide a fig leaf behind which unacceptable launch prices can be hidden. Reimbursement policies and processes will also need to measured against their effects on responsible use, and adjusted where their effects are shown to be perverse and not in the interests of patients. Lastly, as was signalled strongly at the outset of this conference, consideration will need to be paid to the effect of pricing and reimbursement policies on necessary and appropriate innovation. Standing still is not an option, and complacency is entirely unwarranted.

References
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K4 Priority medicines for Europe and the World: setting a public-health-based medicines development agenda
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Background: This presentation will summarize key results of the 2013 report Priority Medicines for Europe and the World [1] which is an update to the original 2004 report and takes into account changes in global health and pharmaceutical innovation since 2004.

Methods: Using a global public health perspective for Europe and the world and based on the principle of equity and efficiency the report identifies gaps in the development and research of pharmaceutical technologies which are needed to meet the priority health care needs of the population but which have not yet been developed. Four criteria were used to determine the gaps: the burden of disease in Europe, its trend, common risk factors amenable to pharmaceutical intervention and the principle of “social solidarity”. The gaps are divided into three groups depending whether treatment exist, how effective it is and whether the delivery mechanisms or formulation are appropriate of the target population.
Results: (1) Antibacterial resistance and pandemic flu are two areas where treatments exist but may become ineffective soon.

(2) Treatment options are available for cardiovascular diseases, HIV, cancer, depression, diabetes, pneumonia, diarrhoea, neonatal malaria, tuberculosis, neglected tropical diseases and postpartum haemorrhage but the pharmaceutical delivery mechanisms or formulations are not appropriate for the target populations.

(3) For stroke, osteoarthritis, Alzheimer’s disease and other dementias, chronic obstructive pulmonary disease, hearing loss and low back pain, treatment does not exist or is not sufficiently effective.

Discussion: To provide incentives for development to fill these pharmaceutical technology gaps innovations are needed in the areas of market regulation as well as pricing and reimbursement policies. To respond to new knowledge that is being produced about the pharmaceutical technologies multiple market authorization and reimbursement decisions over time may be required instead of a single decision at one point in time. For example, there seem to be large room for improvement of how to use electronic medical records. To further develop value-based pricing and adaptive licensing new methods for evidence generation, benefit risk assessment and regulatory dialogue need to be developed.

Reference

K5
Pharmaceutical policies in Australia and New Zealand
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This presentation will cover the pharmacy systems in Australia and New Zealand, the funding and reimbursement of medicines, the medicines supply system as well as an overview of medicine pricing policies in both countries.

New Zealand has a very effective monopsony purchaser, the Pharmaceutical Management Agency of New Zealand (PHARMAC). PHARMAC negotiates the prices of inpatient, outpatient medicines, vaccines and medical devices, and manages a capped national budget for outpatient and cancer pharmaceuticals. PHARMAC uses a variety of mechanisms to obtain lower prices, including competitive tendering, sole supply contracts, reference pricing, bundling deals, risk sharing agreements and promoting use of generics. As a result, New Zealanders have universal and nationally consistent pharmaceutical coverage, with lower patient pharmaceutical co-payments than many comparable countries.

In Australia, the Pharmaceutical Benefits Scheme (PBS) is the programme that provides subsidised prescription medicines to all Australians. In Australia several pricing reforms have been done, including a recent one in 2014. Australia also uses reference pricing for generic medicines and for groups of medicines with similar safety and health outcomes that can be used interchangeably. Overall, these policies have been effective in decreasing medicines prices and pharmaceutical expenditure. However, the critics argue that the Australia has higher prices of generic medicines when compared with New Zealand and the United Kingdom.

Australia and New Zealand both have excellent national medicines policies, which ensure the equitable access to cost-effective and safe medicines. In both countries, pharmacoeconomic analysis is compulsory to select medicines for reimbursement. New Zealand is able to achieve savings because of a combination of program budgeting and price negotiations; however, New Zealand has also been criticised because fewer medicines are available in New Zealand as compared with Australia. However, there is a dearth of research on whether or not the lack of access to some innovative medicines in New Zealand, or switching patients to different brands of medicines, adversely affects patient outcomes.

The topical issues for both countries in medicines policies include trade negotiations with the USA, access and funding of cancer medicines and the ageing population in both countries.

K6
Scottish collaboration to integrate medicine therapy between out-patient and in-patient sectors
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Moves to harmonise good prescribing practice in Scotland (population 5.2 million) began two decades ago with the development of prescribing formularies in each of primary and secondary care in major geographically-based health boards. These formularies were then combined to produce ‘joint formularies’, the aim being to promote best and most efficient prescribing of evidence-based medicines in both the community and hospital settings.

Fifteen years ago, the challenges of new, and often expensive, medicines were addressed by creating a national health technology assessment organisation (Scottish Medicines Consortium (SMC)) to undertake rapid assessment of the clinical effectiveness and cost-effectiveness of new medicines. The SMC involves clinicians (doctors and pharmacists) from both primary and secondary care and from all across Scotland, ensuring short precise communication to and from the prescribing ‘front line’. Clinical guideline development (by the Scottish Intercollegiate Guidelines Network (SIGN)) was already an active process, again involving clinicians from both sectors in all guidelines.

Ten years ago, with these systems in place and to avoid ‘mixed messages’ to the prescribing community, considerable efforts were made to develop ‘rules of engagement’ to ensure consistency across all prescribing advice. Only new medicines accepted for use by the SMC may be included in local formularies, and SIGN clinical guidelines will also only recommend use of SMC-approved medicines. This approach aims to maximize the consistency of prescribing advice and practice across the country.

Monitoring of adherence to advice has been undertaken locally and generally with a ‘light touch’, but ongoing developments are seeing the introduction of more detailed monitoring using centrally-held computerized prescribing data, particularly in primary care in the first instance.

The collaborative process has been evolutionary and took over 10 years to get from first steps to the present fully-integrated system. The process has been characterized by full involvement of clinicians throughout, with clinician leadership and ownership of the individual components such as formularies, the SMC and the SIGN. Other stakeholders, including the public, patient advocacy groups and the pharmaceutical industry are involved in parts of the process as appropriate.

Although established to encourage high-quality prescribing, the processes have also proved very useful in promoting cost-effective prescribing and in helping to achieve the best use of limited resources in both primary and secondary care. The expenditure required to develop and maintain the processes has been modest compared with the gains achieved and thus may represent a useful model for other small/medium-sized healthcare systems.

ORAL PRESENTATIONS

01 Financial based agreements and performance based agreements: the Belgian experience
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Background: In times of financial hardship, making innovative treatments affordable for society, accessible for patients and profitable for pharmaceutical companies is a challenge. Reimbursement is often threatened by uncertainties about the financial impact or evidence for a treatment. A contractual agreement between the payer and pharmaceutical company can link reimbursement to financial thresholds (financial-based agreements) or performance of a drug (performance-based agreements).


The aim of this study was to investigate the experience with contractual agreements in Belgium.

Methods: Qualitative research was performed to obtain insights into the perspectives of different stakeholders. Semi-structured interviews were conducted between September and December 2014. Interviewees were recruited through purposive sampling. Interviews were audio-recorded, verbatim transcribed and analyzed using the grounded theory approach.

Results: Sixteen interviews were conducted, involving three representatives of the National Institute of Health and Disability Insurance (NIHDI), three representatives of sickness funds, seven representatives of a pharmaceutical company or pharmaceutical industry association, and three health care providers. All parties indicated that contractual agreements allow real-life data generation for treatments that would not be accessible for patients otherwise. The majority of agreements applied in Belgium establish financial compensations that a pharmaceutical company needs to accomplish in order to get a treatment reimbursed, with limited role for performance based aspects. Financial compensations remain confidential while the list price stays artificially high. The Belgian list prices influence other European prices due to the external reference pricing system. Industry representatives feel like financial based agreements are the only way to keep up the list price of the treatment. Representatives of the NIHDI notify the financial security that these agreements provide, while more data generation is allowed. In the light of financial based agreements, all stakeholders question the inherent meaning of the list price with regard to the value of the drug and the influence on external reference pricing. All parties emphasize that more attention for the added value of the treatment and a shift to more performance based agreements is required, although several hurdles still need to be conquered. Given current evolutions towards earlier market access, such as adaptive pathways and medical need programs, development of performance based schemes is a must.

Conclusions: The European external reference price system drives the application of financial based agreements but at the same time, the value of the list price becomes meaningless. All stakeholders show eagerness for development and application of performance based agreements.

Consent to publish: All participants of the study provided written consent to use the data for research purposes.
Several European countries implemented external price referencing (EPR) as a pricing policy for medicines, and as such they use price data from other countries as a benchmark to determine their medicine prices. In current EPR practice undiscounted official list prices are taken as a reference. There is some debate as to which extent discounts have an impact on medicine prices. The aim of the study was to investigate whether and how much medicine prices would change if discounts were considered.

Methodology: Ex-factory prices of 30 medicines (15 medicines from the outpatient sector and 15 medicines from the in-patient sector) that accounted for high expenditure for public payers in Austria were surveyed for 16 European countries (Belgium, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Portugal, Sweden, Slovakia, Spain and the UK). In addition to these official list prices, the statutorily discounted ex-factory medicines in Germany were collected and compared.

Results: Overall, for the 30 selected medicines, Germany was the country that had most frequently the highest prices (in 40% of the 30 medicines), followed by Sweden (23%) and Denmark (13%). If discounted medicines instead of list prices were considered for Germany, Sweden was most frequently the highest-priced country (37% of the medicines), followed by Denmark (17%). Together with Austria and the UK, Germany ranked third (10%). In a comparison of list prices only, Swedish prices were in the fourth quartile in 85% and German prices in 80% of the medicines. Considering discounted prices for Germany, their prices ranked in the fourth quartile in only 30% of all medicines, compared with 89% for Sweden and 47% for Austria and Denmark respectively. Among the analysed medicines the impact on the price level was strongest for medicines with the comparably highest prices.

Conclusions: In several European countries pharmaceutical manufacturers grant confidential rebates to public payers [1], leading to lower actual prices compared with list prices. Since EPR is usually based on official list prices, countries risk over-paying. This case study in which statutory, published discounts for a sole country were considered suggests a high impact on medicine prices. Taking discounts into account, medicine price levels in Germany were comparably lower. A consideration of discounts in further countries is likely to show further reductions in medicine price levels. Disclosure of discounts might help improve pricing policies in European countries.

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Reference

A cost/benefit analysis of self-care initiatives in the European Union: who gains, who loses?
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European health systems have increasingly come under pressure to implement cost-containment measures while simultaneously maintaining or even enhancing high-quality health care. In the field of medication of minor ailments, a promising approach to achieve this is initiatives promoting patient involvement (i.e. self-care). Therefore, the aim of the study was to analyse potential costs and benefits related to self-care oriented health systems in the European Union.

A cost/benefit analysis (CBA) was conducted covering modified access to prescription medicines, extended range of authorized prescribers and internet/telephone information portals. Costs and benefits were calculated for selected initiatives: minor ailment schemes (MAS), non-medical prescribing (NMP) and NHS Choices in England. The CBA covered four perspectives: patient, provider (physician, pharmacist), system and society. A standard costing approach was used to facilitate transferability of results.

In all studied initiatives, patients benefit from time savings due to avoided physician visits, compensating for occasionally higher out-of-pocket payments for medicines. Physicians are confronted with a negative benefit due to loss of income, which corresponds to a positive effect at the system level. If the initiatives’ costs do not provide for additional remuneration for pharmacists, increased time for consultations will lead to a negative benefit for pharmacists.

In order to gain a positive societal net benefit, participation rates (in terms of patients with minor ailments refraining from a GP consultation due to the initiative) of 27.5% for MAS and 4.4% for NHS Choices are required. For NMP costs at providers’ (i.e. pharmacists’) levels are too high for a positive societal net benefit.

Self-care initiatives based on modified access schemes and information portals may lead to a societal benefit, whereas the mere extension of prescribing authority does not do so. As actual cost components of the initiatives (e.g. provider remuneration) and pharmaceutical reimbursement policies (e.g. prescriptions fees) are likely to affect savings and costs, these have to be considered when implementing a policy.
health technology assessment (HTA) by offering a more holistic perspective to value assessment and acting as an alternative priority setting tool.

Objectives: In this abstract we develop a methodological framework and argue that MCDA needs to subscribe to robust methodological processes related to the selection of objectives, criteria and attributes in order to be meaningful in the context of health care decision-making and fulfil its role in value-based assessment (VBA) and as a resource allocation tool.

Policies targeted: A methodological framework to inform the value assessment of new medical technologies which can help determine coverage decisions and, possibly, pricing mechanisms.

Stakeholders: Primary and secondary input from a multiplicity of institutional, academic, and other stakeholders (clinicians, methodologists, health economists) under the auspices of the Advance-HTA project consortium.

Region covered: A generic framework that can be applied across all WHO regions and levels.

Methods: Study design: Methodological framework development.

Time period: April 2014 – April 2015.

Setting: Generic framework of value assessment that can be applied to inpatient and outpatient settings in any country.

Interventions: Methodological framework development.

Results: We propose a methodological process comprising five distinct phases (problem structuring, model building, model assessment, model appraisal and development of action plans), outline the stages involved in each phase and discuss their relevance in the HTA process. Additionally, criteria and attributes need to satisfy a set of desired properties, otherwise the process of preference elicitation can produce spurious results. The resulting MCDA output, which can take the form of a single universal value index, can be informed by stakeholder participation and therefore can be robust and reflective of stakeholder preferences.

Conclusions: Assuming the methodological process we propose is adhered to, the application of MCDA presents two very distinct advantages to decision-makers in the context of HTA and VBA: first, it acts as an instrument for eliciting preferences for a wider set of criteria leading to a more complete assessment of value; and, second, the process of preference elicitation is informed by direct stakeholder participation. Both features contribute to greater rationality and increased transparency in decision-making.

Setting: to inform coverage decisions for cancer medicines used in inpatient settings.

Interventions: application of a pre-existing methodological framework and experimental case study through a decision conference.

Results: Of objectives considered included therapeutic, safety, innovation and socioeconomic criteria. Three alternative treatments were ranked based on their overall value, using value scores reflecting their performance across all the criteria while considering their relative importance, as informed through stakeholders’ preferences. Simulation of payer’s resource allocation decisions on the coverage of the options were made on value for money grounds through the use of a “cost-per-unit of value” metric.

Conclusions: MCDA possesses the prerequisites of a value-based assessment methodological framework. The multiplicity of criteria that can be incorporated to assess value, the weights that can be applied to the criteria and the stakeholders’ involvement across every stage, all of which are fully transparent, provide a unique combination of broadness, resilience and inclusiveness making it an ideal decision-making tool.

O9 Approval, reimbursement and pricing of high-cost cancer medicines in Australia

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Background: Australian government expenditures on chemotherapy medicines are increasing faster than any other area of health care with an average annual growth rate of 63% from 2009/10 to 2013/14. Funding decisions on new, high-cost cancer medicines are challenging because of insufficient evidence on benefits and risks of new cancer medicines and high prices requested by pharmaceutical companies. We reviewed the current approval, reimbursement and pricing strategies for cancer medicines and the development of new regulatory and funding pathways in Australia.

Methods: A review of government documents from websites of the Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Scheme in Australia, the Food and Drug Administration (FDA) in the USA, the European Medicines Agency (EMA) and National Institute for Health and Care Excellence (NICE) in Europe.

Results: Of all cancer medicines approved by at least one of three regulatory agencies, the FDA, the TGA and the EMA, between 2010 and 2013, Australia authorised the fewest number of indications for cancer medicines (n=54, 59%) compared to the UK (n=72, 78%) and the US (n=68, 74%). Australia approved a higher number of indications for funding (n=21, 39%) than NICE in the UK (n=14, 19%). Delays in approval and funding are multifactorial and partly explained by time required for price negotiations. In May 2015, there were special pricing arrangements in place for 23 new cancer medicines including all tyrosine kinase inhibitors and monoclonal antibodies. Since 2010, four cancer medicines were approved for funding via a managed entry scheme requiring submission of more conclusive evidence of cost-effectiveness.

Conclusions: Australia has implemented rigorous methodologies for assessing the value-pricing of new medicines while developing new managed entry pathways. The confidential nature of the agreements between the Australian government and pharmaceutical companies limits the evaluation of the outcomes with regards to pricing of cancer medicines compared with other countries.

O10 Introduction of generic substitution and reference pricing in Ireland: early effects on state pharmaceutical expenditure and generic penetration, and associated success factors

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76 (Suppl 1):18

Problem statement: There is increased recognition that economic evaluation has limitations because it does not capture a number of important dimensions of value. This may lead to a lack of comprehensiveness and a lack of transparency.

Objectives: Past research has indicated that Multiple Criteria Decision Analysis (MCDA) could be used as an alternative methodology for assessing new medical technologies in the context of Health Technology Assessment (HTA). The objective of this study is to apply in practice an MCDA framework for the value assessment of a set of therapeutic options in metastatic colorectal cancer through a simulation exercise based on MCDA principles.

Policies targeted: A process to inform the value assessment of new medical technologies which, in turn, can help determine coverage decisions and possibly pricing mechanisms.

Stakeholders: All stages of the framework were informed by extensive stakeholder engagement through their participation at a decision conference workshop. Stakeholders (13 in total) included health care professionals (e.g. clinical experts), methodology experts (e.g. health economists), patients, patient advocates, and others (patients and carers), while adopting the perspective of a decision-making HTA body.

Region covered: The context of the study relates to England and Wales at a national level (EURO region), but it can be applicable across all WHO regions and levels.

Methods: Study design: experimental case study.

Background: In response to the financial crisis and under the EU/IMF Programme of Financial Support, Ireland committed to make savings on pharmaceutical expenditure, including through a system of generic substitution (GS) and reference pricing (RP) [1]. This intervention involved GS based on fifth level ATC code (active substance), which was followed by RP 3-5 months later. The aim of this analysis was to determine estimates of savings to the healthcare payer resulting from the introduction of GS and RP and to examine utilisation patterns pre and post intervention.

Methods: This study was a retrospective analysis of patient-level national pharmacy claims data from January 2013-October 2014 inclusive. These data were sourced from the publicly-funded Irish community pharmacy drug reimbursement schemes. For each product deemed interchangeable for GS, average prices over the prior 6 months were calculated (‘pre-price’). Pre-prices were then assigned to claims records for the product over the 6 months following RP. Actual ingredient cost expenditure and expected expenditure based on pre-prices were compared and total savings were calculated. Trends in generic versus proprietary product uptake were also monitored.

Results: Forty-one product types representing 15 active substances (fifth level ATC) underwent GS and RP between August 2013 and May 2014, resulting in a minimum of 6 months follow-up. For the scheme serving the majority of public patients, GS/RP accounted for an overall combined relative decrease in ingredient cost expenditure of 53% in the 6 months following implementation, amounting to combined 6-month savings of over EUR 35 million (total ingredient cost expenditure on these drugs following GS/RP: EUR 31m). Greatest savings were observed for the drug atorvastatin, which incurred a 71% expenditure drop, while lowest relative savings were observed for the drug ramipril, which incurred a 24% expenditure drop. Generic usage rates for the drugs concerned increased on average by 44% with GS/RP introduction.

Conclusions: The introduction of GS and RP led to substantial savings which corresponded to pre-policy health service official estimates. Compliance with policies is high with generic drug usage targets now exceeded. Success factors included enactment of supportive legislation in 2013, acceptability of active-substance based GS and the phased nature of the policy introduction. On-going work will identify non-compliance with the policies and will aim to elucidate factors affecting the same. The long-term impact of the policies has yet to be determined.

Reference

O11

Price changes of antibiotics and perceived substitutes in the context of OTC policy changes in Mexico and Brazil

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Problem statement: The over-the-counter (OTC) sales restriction of antibiotics in Mexico and Brazil might have created incentives to maintain the sales revenue by increasing antibiotics prices and attract the consumption of substitutes by decreasing their price.

Objectives: To explore price changes of antibiotics and their substitutes in Mexico and Brazil.

Methods: Study design: Quasi-experimental. Time period: January 2008-March 2013. Setting: IMS Health retail quarterly trade prices from the private sectors in Mexico and Brazil. Groups studied were: antibiotics, cough-and-cold medicines, non-steroidal anti-inflammatory drugs (NSAIDs), and analogues. The latter two groups were combined in the analysis of median price per defined daily dose (DDD). All prices were adjusted for inflation rate and converted to US Dollars.

Interventions: Interrupted time series analysis to measure price changes (level and slope) after the OTC sales regulation of antibiotics and seasonal price changes. Stationarity and autocorrelation corrected using ARIMA models.

Results: After the regulation in Mexico the median price of antibiotics increased by $0.06 per DDD (p<0.001, level increase) with a slope decrease of $0.21 per quarter (p<0.001), NSAIDs-analgesics prices decreased by $0.11 (p=0.04) with a slope increase of $0.02 (p=0.002) per quarter, and prices of cough-and-cold medicines increased by $0.36 (p=0.006). In Brazil prices of antibiotics did not change after the regulation, NSAIDs-analgesics median price increase by $0.04 (p<0.001) with a slope decrease of $0.01 (p=0.001) per quarter, and cough-and-cold medicines price slope increased by $0.02 (p=0.001) per quarter. For both countries we observed seasonal variation in prices with highest prices during warm seasons where use is relatively low (spring and summer). The difference in price of antibiotics between winter and summer was $1.5 (p<0.001) in Mexico and $0.31 (p=0.02) in Brazil, and for cough-and-cold medicines this difference was $3.07 (p<0.001) in Mexico and $0.58 (p<0.001) in Brazil. The difference in price of NSAIDs-analgesics between winter and autumn in Mexico was $0.17 (p<0.001) and in Brazil was $0.09 (p<0.001).

Conclusions: After the regulation in Mexico prices of antibiotics increased while prices of NSAIDs-analgesics decreased. In Brazil NSAIDs-analgesics prices increased. However these changes were outweighed by the seasonal variation in prices.

Lessons learned and success factors: Possible effects on prices need to be considered when designing and implementing pharmaceutical policies, to anticipate or prevent unintended outcomes.

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Socioeconomic determinants of medicines use in Central Eastern Europe: the role of pharmaceutical policy in reducing inequalities

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Background: Even though access to essential medicines is a human right, inequalities in access resulting in differences in medicine use between socioeconomic groups are known from several countries worldwide. However, the socioeconomic determinants of medicine use in Central and Eastern European countries (CEECs) have not yet been explored. For a sample of eight countries (Bulgaria, Czech Republic, Hungary, Latvia, Poland, Romania, Slovenia, and Slovakia), this study thus aims to analyse whether socioeconomic status influences medicine use and investigates to what extent observed inequalities can be explained by current (lack of) pharmaceutical policies and how policies can help reduce existing inequalities.

Methods: Quantitative analyses on socioeconomic determinants of medicine use (based on cross-sectional data from the first wave of the European Health Interview Survey) and qualitative analyses of the national pharmaceutical policy framework (based on information produced in the Pharmaceutical Pricing and Reimbursement Information project) for the time period 2000-2009 were conducted.

Results: Women and people with chronic diseases and lower self-assessed health were found to have a higher likelihood to take medicines. In the field of non-prescribed medicines that were usually not
reimbursed by the public payers, people with higher education and/or higher income were attributed a higher chance of consuming these medicines in seven of the surveyed countries. Regarding prescribed medicines, such a socioeconomic gradient in medicine use was only observed in three countries (Latvia, Poland, and Romania). The analysis of pharmaceutical policies identified private expenditure, overall investment in health systems, rational use of medicines and clear procedures for inclusion of medicines into reimbursement as major factors that co-determine this socioeconomic gradient in medicine use in Central and Eastern Europe. Latvia, Poland and Romania had a comparably high share of patients’ contributions, and Latvia and Romania were furthermore strongly hit by the global financial crisis and reacted through cost-containment measures.

Conclusions: A socioeconomic gradient in medicine consumption was found in the CEECs, particularly regarding non-prescribed medicines and, as a trend, it tended to favour the more affluent population. Public pharmaceutical policies usually addressed prescribed, reimbursed medicines, and in several countries, the appearance of sofosbuvir appeared to have positively contributed to improving access to these medicines for people with a lower socioeconomic status. Pharmaceutical policies aiming at reducing inequalities in medicine use require not only a consideration of the role of co-payments and other private expenditure but also adequate investment in medicines and transparent and clear processes regarding the inclusion of medicines into reimbursement.

013
Why we should have more collaboration on HTA in Europe: the example of sofosbuvir
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Problem statement: Sofosbuvir is the first of a series of new and promising agents that can be used to treat chronic hepatitis C in adults. But even after price negotiations, the impact of sofosbuvir on health care budgets is too high to treat all affected patients in Europe.

Objectives: To demonstrate, using sofosbuvir as an example, that separate pharmaceutical assessments (HTAs) may support the timely and consistent exchange of information and therefore joint HTAs may have additional value for timely and consistent decision-making around Europe. This may reduce obstacles to initiate voluntary joint price negotiations.

Methodology: Study design: Review.
Time period: 1 August – 1 November 2014.
Setting: The study addresses the out-patient sector and examines the public sector.
Intervention: We sent a questionnaire in August/September 2014 and reviewed full HTA reports from September- November 2014.

Results: The results of the questionnaire showed that, 7 months after sofosbuvir received market authorisation, in 11 countries the assessment of the effectiveness sofosbuvir had not yet started, in nine it was ongoing and in seven it was completed. Of the 11 countries that had not started an assessment, five Eastern European countries reported that the MAH had not yet submitted an application for reimbursement of sofosbuvir. The analysis also showed that in the seven reports from different European HTA organisations several relative effectiveness assessment elements were in common.

Conclusions: At present, the MAH seems to set the pace of HTA assessments in Europe which reduced the possibilities for payers to participate in voluntary joint price negotiations. Furthermore, HTA organisations in Europe agree on key methodological aspects of their relative effective assessments, which supports the conclusion that joint relative effective assessment is feasible.

Lessons learned and success factors: We assert that joint assessments may assist European countries in an earlier and more synchronized start in their discussion with the MAH on reimbursement and pricing of these new drugs. Crucial success factors for joint assessments are timeliness and topic selection.
Results: In order to identify potential ways of collaboration a workshop with 12 agencies from nine countries all involved in assessing new oncologic drugs was held in 2010. Following this workshop, the LBI-HTA started to send out "calls for collaboration" to identify partners interested in jointly conducting reports. Up until now, 11 calls have been sent out resulting in 15 collaborations with a total of six institutes. Collaboration initially led to some delays in report production, but since the same agencies repeatedly indicated interest in collaboration, familiarity with processes and development of trust was eventually achieved ultimately leading to efficiency gains. Besides the active production of joint reports, rapid relative effectiveness assessments produced in international collaboration within the European HTA Network EUnetHTA can serve as basis for local reports [3]. So far, four assessments on pharmaceuticals have been published by EUnetHTA of which one addressed an oncologic drug. This assessment was enriched with local and context-specific information and therefore allowed a fast and less resource-intensive production of a report.

Conclusions: Increasing financial pressure on health care systems and limited research resources necessitate exploring ways of sharing and reusing research findings. Local initiatives driven by individual agencies but also European-wide developments offer the opportunity to produce assessments more efficiently and to reduce redundancies.

References

POSTER PRESENTATIONS

P1
Unintended consequences of co-payment regulations in Belgium: the case of atorvastatin
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Problem statement: In Belgium, the average annual growth rate of per capita health spending decreased from 2.3% between 2000 and 2006 to 1.6% between 2007 and 2013 [1]. Nonetheless, Belgium’s Gross Domestic Product (GDP) grew at markedly lower rates (2.1% and 0.8%, respectively), implying that pressures on sustaining affordable and equitable health care increase.

Objectives: We assessed the impact of co-payment regulations on prices and sales figures for atorvastatin in Belgium before and after the patent expiry in 2013. Policies targeted: Reference pricing system; Copayment regulations. Region covered: EURO: Belgium (national).

Methods: We related sales figures to coinciding price evolutions, and broke the costs down by their bearer. On the one hand we analysed a data extraction from IMS Health for Belgium for the period 2007-2013. The IMS Health database contains sales figures of a representative sample of community pharmacies including the number of packages sold (per CNK number) per month. On the other hand, we studied the corresponding unit price tables of the Belgian centre for Pharmacmico-therapeutic Information (BCFI, an independent source).

Results: In March 2013, the public price for Lipitor® 98*80 mg was EUR 123.51, and the price for Atorvastatin Mylan® (same package size) was EUR 62.52. The co-payment amount borne by patients was the same for these products (EUR 14.5 for each), but the costs borne by the government through the National Institute for Health and Disability Insurance (NIHDI) were markedly different (i.e. EUR 109.1 for Lipitor and EUR 48.02 for the generic Atorvastatin). For the 19,777 reimbursed packages of brand atorvastatin in 2013, the latter (reimbursed) costs amounted to EUR 2,157,671, which is about 1 million EURO more than would have been covered to cover the same sales volume of the equivalent generic. Both packages were considered low-cost medicines resulting in the same ‘minimalised’ patient’s contribution, thereby eliminating any incentive for the physician or patient to choose a generic medicine.

Conclusions: In this case, the reference pricing system was a vain attempt to curb public drug expenditures. Looking ahead at the patent expiry of resvasatin in 2016, the effectiveness of existing regulations to curb growing pharmaceutical expenditures requires urgent reconsideration, based on the lessons learnt from case studies such as ours. A potentially feasible option would be to abolish the maximum co-payment level per package in the Belgian reimbursement system for therapeutically interchangeable drugs.

Reference

P2
Impact of Generic Price Linkage System and Reference Price System on prices of pharmaceuticals – comparison of Austria and Finland
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Background: To contain costs of medicines, many countries have introduced policies targeting lower prices of generics[1]. Measures taken in Austria include Generic Price Linkage and in Finland Generic Substitution and Reference Pricing, where competition plays a crucial role.

Objectives: The aim of this study is to assess the Generic Price Linkage system and the system that includes Generic Substitution and Reference Pricing by comparing prices of generics and originators and the number of generics entering the market in Austria and in Finland.

Methods targeted: Generic Price Linkage, Generic Substitution, Reference Pricing.


Region covered: EURO, Austria and Finland.

Methods: Study design: Policy evaluation. Time series design was used to estimate changes in price levels. Time period: 2009–2013.

Setting: Pharmaceuticals used in outpatient care and prescribed either in the public or private sector. Ten active ingredients with high sales in Finland and reimbursable in both countries were included in the analysis. Interventions: Prices of original products whose patent protection expired during 2010–2012 and generics comparable with them were analysed 6 months before and 12 months after generic entry. Price levels were measured in wholesale prices proportioned to the number of Defined Daily Doses in the package (EUR/DDD).

Results: One year after generic entry, prices of the originators had fallen, on average, by 46% in Austria and by 21% in Finland. Prices of the generics were 66% lower in Austria and 59% lower in Finland than prices of the originators before generic entry. The mean number of generics per active ingredient was 6.3 in Austria and 5.1 in Finland.

Conclusions and lessons learned: Even if uptake of generics is lower in Austria (26% in volume) than in Finland (36%), the Austrian pricing
system appears to be more efficient to lower prices. Price competition in Finland is probably reduced by a concentrated generic market. It has been stated that free competition lowers generic prices more efficiently than linking the price of a generic to the price of the originator [2]. That is not necessarily the case. Success of a policy measure also largely depends on how the details of the measure are constructed.

References

P3
Availability and prices of essential medicines for chronic diseases in older people in the Asia Pacific Region
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Background: Little is known about the prices and availability of medicines for chronic diseases used by older people in the Asia Pacific Region. The objective of this study was to assess the availability and prices of essential medicines for chronic diseases in 11 countries, namely China, Fiji, India, Indonesia, Lao, Malaysia, Mongolia, the Philippines, Sri Lanka, Thailand and Vietnam. The study was carried out at an international level.

Methods: A secondary analysis of medicine prices and availability data from the Health Action International’s database on medicine prices, availability and affordability was undertaken in March - May 2015. Data on the availability and price of 15 medicines used for chronic diseases prevalent in the older population were obtained from facility-based surveys conducted in 11 countries between 2001 and 2013. Prices were converted into the base year of 2014. Patient prices were adjusted for inflation and purchasing power parity and procurement prices for inflation and official exchange rates. Data were analysed for lowest priced generic (LPG) and innovator brand (IB) products in both the public and private sectors.

Results: The availability of medicines for chronic diseases was suboptimal across countries in the Region. The median availability of any medicine (IB or LPG) in the public sector was 35.5% compared with 56.7% in the private sector. Thailand and Indonesia had the highest levels of availability in the public sector (80% and 60.1% respectively) while in the private sector it was India and Fiji (90% and 83.4% respectively). Countries in the Region paid 1.4 times the international reference price (IRP) to procure LPGs and 9.1 times the price for IBs. India and Fiji achieved low procurement prices (0.4 and 0.6 times IRP for LPGs) while the Philippines had the highest procurement prices for both IBs and LPGs. In general, patient prices were lower in the public sector than in the private sector (21.5 times IRP vs. 32.2 times for IBs and 6.6 times vs. 11.5 times for LPGs). In the public sector, Malaysia and India provided medicines free of charge while the Philippines charged the highest price.

Conclusions: The availability and prices of medicines for chronic conditions were highly variable across the Asia Pacific Region. Medicines were more available in the private sector, but at an excessive price. Implementation of policies to improve the availability and reduce the prices of essential medicines for chronic diseases is needed.

Background: This analysis addresses the impact of policy change when over-the-counter medicines (OTCs) were excluded from the reimbursement list by law since July 1, 2012 in the Czech Republic. Selected OTCs remained reimbursed with the approval of insurance funds, usually under certain conditions of reimbursement (for specific indications or patient groups).

Objectives: This analysis aims at determining how many OTCs were reimbursed before the exclusion and how many of them and under what conditions of reimbursement remained to be reimbursed. The second objective of the analysis is to estimate the financial effect of exclusion on the payers and patients. The third objective is to describe what type of OTCs are reimbursed and under what conditions of reimbursement, as well as to compare annual costs of reimbursed OTCs versus annual costs of prescription-only medicines (POM).

Methods: SDC’s list of reimbursed medicines valid as of 1 June 2012 was compared with the list of reimbursed medicines valid as of 1 July 2012 to identify OTCs excluded from reimbursement. The financial impact of delisting OTCs was calculated based on consumption data and reimbursement price from the payers. The current reimbursement list (May 2015) was searched to identify the current spectrum of reimbursed OTCs.

Results: There were 238 reimbursed OTCs in June 2012 and 14 OTCs remained reimbursed in July 2012, based on registration number. The reimbursement is limited by conditions of reimbursement for most reimbursed OTCs. The delisted OTCs saved payers approximately 21.6 mil EUR (1 EUR = 27.624 CZK) in the first year after the delisting. The average price of not excluded OTCs has grown to 12.54% and the average price of excluded OTCs has grown to 10.70% since January 2012. The poster will show the analysis of consumption of OTCs in detail.

Conclusions: Almost 95% of previously reimbursed OTC medicines were excluded from the reimbursement system in 2012. OTC medicines that remain in the reimbursement system are reimbursed, for example, for patients with cystic fibrosis, diagnosed Sjögren’s syndrome (dry eyes), chronic pancreatitis. The payers saved 21.6 mil EUR due to the delisting. The delisting did not have a major impact on the price of excluded OTCs.

Background: Over 10 years after the establishment of the National Health Insurance Scheme (NHIS) in Ghana, the use of a median pricing methodology for pharmaceuticals remains a topic of debate due to its positive and negative outcomes. Residual effects of this pricing methodology include proliferation of low-quality medicines, irrational medicine use, insurance fraud and other undesirable outcomes. Of particular interest is the ripple effect of this median pricing policy on the entire pharmaceutical system. Ghana’s pharmaceutical system has limited local production capacity and is heavily dependent on importation. Medicine prices continue to rise and the medicine reimbursement value constitutes an increasingly larger proportion of overall claims values. With finite resources allocated to the NHIS, this presents a sustainability challenge to be addressed promptly.

Methodology: During a 2015 study of the pricing policy and the system, data were collected using the Management Sciences for Health (MSH) qualitative assessment tool for medicine benefit management programs. The tool was implemented during interviews with pharmaceutical system stakeholders in the Greater Accra, Cape Coast and Kumasi regions of Ghana. Stakeholders from tertiary hospitals, polyclinics, private and public pharmacies, importers/wholesalers, Ministry of Health, professional organizations etc. were interviewed to gather anecdotal evidence about the impact of pricing policy. Quantitative medicine claims data for the period July-December 2014 were also collected to analyze patterns of medicine utilization and reimbursement values. Market dynamics, foreign
exchange and medicine prices were considered in the comparison of reimbursement prices with the market value.

**Results:** Influential factors including importation fees, foreign exchange, demand and supply chain challenges are not considered in the median pricing methodology. The NHS pricing methodology is widely viewed as outdated, inefficient and a contributor to delayed reimbursements, subsequent financial crisis and a steady decline in the availability of medicines within the system. Anecdotal and quantitative evidence indicates the critical need for a revised pricing policy to include the key pricing factors in the near future.

**Conclusions:** As countries strive towards Universal Health Coverage (UHC), it is critical to consider medicines in all conversations, design and planning of programs due to their clinical and financial impact. Lessons learned from Ghana include the importance of evidence-based pharmaceutical pricing and reimbursement policies, detailed deliberation about medicine benefits during initial UHC designs and policy discussions and system strengthening in support of universal health coverage plans.

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**P6**

Retrospective financial analysis of medicines reimbursement services in community pharmacy

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**Background:** A problem for middle-income countries is unequal access to medicines. In Republic of Moldova (RM), reimbursed medicines did not decrease the burden of expenditures for medicines. In this context, the aim of this study was: evaluation of the importance of evidence-based pharmaceutical pricing and reimbursement policies, detailed deliberation about medicine benefits during initial UHC designs and policy discussions and system strengthening in support of universal health coverage plans.

**Methods:** As methods of study we used a survey, direct observation, break-even analysis[1] and literature review. The research was started in April 2014 and ended in May 2015. The study addressed revision of mark-up applied by wholesale and retail companies for reimbursed medicines in the retail pharmaceutical sector from 15% to 22% (using regressive mark-ups); and to introduce continuing education courses for pharmacists in the field of adherence and compliance to treatment for patients with non-communicable diseases, for medicines from the reimbursement list.

**Results:** The cognitive implication for reimbursed drugs was ‘almost never’ or ‘permanently’, with a relative frequency of 0.25 (Figure 1), and the most common time spent by pharmacists for dispensing was 10 minutes, with a relative frequency of 0.18 (Figure 2). These results confirm that the pharmacist loses most of their time for technical processing of the prescriptions, a fact demonstrated through direct observation of the process. The median of profitability for reimbursed drugs was -5.21%, for unreimbursed drugs +2.16% (Figure 3). The break-even point for reimbursed drugs is 22% of mark-up. The results show that it is not convenient for pharmacies to dispense medicines with reimbursed prescription because of a lack of benefit for them.

**Conclusions:** It is recommended to review the added mark-ups for reimbursed medicines in the retail pharmaceutical sector from 15% to 22% (using regressive mark-ups); and to introduce continuing education courses for pharmacists in the field of adherence and compliance to treatment for patients with non-communicable diseases, for medicines from the reimbursement list.

**References**

Figure 2 (abstract P6) Relative frequency of dispensing time

Figure 3 (abstract P6) Financial analysis of pharmaceutical retail enterprises in RM, 2014
Objectives: To develop a method of setting a Drug Price Reference Index (DPRI) in the Philippines to ensure good value for money in the procurement and reimbursement of essential medicines.

Methods: A database of prevailing drug procurement prices was created from actual purchase orders submitted in 2013 by government procuring entities in the Philippines. The database includes information on the unit cost, volumes of procurement, source/supplier/manufacturer, brand, mode of procurement and location of the hospital for each formulation and strength of all drugs in the National Formulary. Multivariate regression analyses were performed for commonly sourced essential drugs exploring possible determinants of drug costs, which include quantities procured and hospital bed capacity. Further cost comparisons were made for other potential determinants such as mode of procurement, supplier/manufacturer and distance of distribution.

Results: Price data were analyzed for 20 drug products with the highest share of procurement in terms of volume and value. Extreme wide variations in unit costs were consistently observed for all drugs analyzed. The price difference, i.e., high/low ratio, were found to be up to 60 times when comparing the highest with the lowest priced drugs. The variations in prices were not associated with volumes procured, distance of distribution and hospital bed capacity. Suppliers were also observed to charge different prices for the same brands to different public hospitals, indicating information asymmetry on reasonable prices of drugs.

Conclusion: Based on the observed wide variations in drug procurement prices in the Philippines, setting the DPRI at the median value for most drugs was found to be an appropriate method to set ceiling prices for public sector procurement. For monopolized pharmaceutical products, other methods may be more appropriate such as value-based pricing, price negotiations and external reference pricing to relevant countries.

P8 Policy options to deal with high-cost medicines – survey with European policymakers
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Background: The affordability and financing of new, frequently high-cost, medicines pose challenges to governments world-wide. In Europe, the conclusion from the new premium-priced medicines is of special concern and requires adapted policy options. The aim of the study was to survey whether and which pricing and reimbursement policy options European countries have implemented for new premium-priced medicines.

Methods: A cross-country survey was carried out through the instrument of a Pharmaceutical Pricing and Reimbursement Information (PPII) query with policy-makers responsible for pharmaceutical pricing and reimbursement in 42 countries, thereof all 28 European Union (EU) Member States and nine further European countries. Responses were received from 26 European countries and Canada between February and March 2014.

Results: Most respondents reported that they had no specific definition for high-cost and/or premium-priced medicines in their country, although they were clearly aware of the issue. Most countries responded that they did not yet have specific policies for the pricing and reimbursement of premium-priced medicines versus other medicines. Several countries reported about the use of managed-entry agreements, such as risk-sharing schemes and discount/rebate arrangements. In addition, the relevance of Health Technology Assessments (HTA) and pharmacoeconomic evaluations for these medicines was highlighted by some countries. The lack of in-patient policies in particular in high-cost and premium-priced medicines are often used in the hospital setting. Some European countries implemented specific funding models: While medicines used in the in-patient sector are usually funded out of the hospital budget (DRG funding), specific high-cost and/or premium-priced medicines are financed on an individual product basis (e.g., Belgium, Finland). Another option is funding of such medicines out of special funds (the Cancer Drugs Funds in England). Horizon scanning was reported from a few countries (Canada, Italy, the UK).

Conclusions: Although European governments were concerned with the cost issue due to new medicines, specific pricing and reimbursement policies have yet to be thought through in a systematic manner. Prioritization processes will increasingly be required for the introduction of new medicines. They should incorporate the principles of collaboration and transparency: Cooperation between countries in Europe and stakeholder dialogues could be further strengthened. This needs to involve better balancing of the value of innovation with equitable, affordable patient access.

P9 A forecasting model for drug utilization and expenditure integrating a Cellular Automata model with the Budget Impact Analysis approach.

Preliminary results
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Background: The considerable pressure on healthcare systems, exerted by increasing expenditures for new drugs, urges specific initiatives, including the development of new models, to optimize the managed entry of new medicines and guarantee their sustainability.

Objectives: To develop a forecasting model for drug utilization and expenditure of emerging medicines identified, prioritized and critically assessed by the Italian Horizon Scanning Project (IHSP), integrating a cellular automata (CA) model describing the diffusion process on the market with the budget impact analysis (BIA), performed before the market entry of a new drug.

Methods: Selection and critical evaluation of high-impact emerging medicines. Development of CA and BIA models for emerging drugs, using medical prescription data from the administrative ARNO-CINECA databases. Results: The first-in-class emerging anti-diabetic dapagliflozin was selected and critically evaluated by the IHSP about 12 months before the European Marketing Authorization (MA). Other competitors already on the market were identified. A CA model describing the diffusion process of more than 200 Italian specialties of oral antidiabetic drugs (ATC A10B), sold between 2000 and 2014 has been developed and validated. A protocol for the identification of the real-world target population in the ARNO-CINECA database was set up on the grounds of the expected indication for dapagliflozin. The estimation of the budget impact of dapagliflozin is ongoing based on the estimation of market shares, through the application of the CA model, the analysis of the identified target population and the analysis of the potential variations in related healthcare costs for the treatment of type 2 diabetes, after the introduction of dapagliflozin.

Conclusions: The proposed forecasting model (C-ToBIA model) predicts the impact of emerging drugs on the National Health System (NHS), under the sufficient conditions for estimability. The originality of the C-ToBIA model is basically related to the assessment of emerging drugs 12 months before the MA date, and the estimation of the diffusion process and the potential financial impact before market entry. The C-ToBIA model will help to timely estimate the possible utilization pattern of new medicines and their potential impact on the NHS before their market entry.

P10 Availability and affordability of medicines for children
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Background: Better access to essential medicines for children is an important pre-condition for improving their health and reducing mortality. However, the results of surveys implemented in some countries show that treatment of children is not always affordable due to a high cost of medicines. The objective of this work was to assess the situation with availability, prices and affordability of essential medicines for children in Armenia.

Methods: Data collection and analysis was conducted using an adaptation of the standardized methodology developed by the World Health Organization and Health Action International (Better Medicines for Children project). Data on availability of 37 paediatric medicines were collected from 33 private medicine outlets from all regions of Armenia (In 2013). Full patient prices of available medicines were recorded. Affordability was expressed as the number of days needed by a person who earns the minimum wage that was set by the legislation, to purchase a course of treatment described in clinical guidelines approved by the Ministry of Health.

Results: Only 13 of 37 (35.1%) paediatric medicines were available at medicine outlets. Originator brands were available for three of 13 medicines, generics, for all 13 pharmaceuticals. The mean availability of originator brands (OBs), highest priced generics (HPGs) and lowest priced generics (LPGs) were 20.5%, 52.9% and 43.0%, correspondingly. Only three of 13 LPGs were found at more than 80% of medicine outlets. Considerable difference was observed between prices of HPG and LPGs - on average prices of OBs were 7.4 times the price of LPGs. Affordability was measured for those six of 13 available medicines which were identified in paediatric clinical guidelines. As original brands for these six medicines were not available, affordability was calculating for lowest and highest priced generics. Cost of a course of pneumonia treatment ranged from 1.7 days' wages for amoxicillin suspension (lowest priced generic) to 4.8 days' wages for ceftriaxone injection (highest priced generic). For treating bacterial infection those on the minimum wage would have to pay for benzylpenicillin injection from 1.9 (lowest priced generic) to 6.3 days' wages (highest priced generic). Purchasing a salbutamol inhaler to treat asthma required 0.7 days' wages when using the lowest priced generic and 1.9 days' wages when using the highest priced generic.

Conclusions: The availability of paediatric medicines was low. Treatment can be unaffordable for those children who are not covered by the reimbursement system. Urgent interventions should be identified and implemented, including price control measures.

Results: The first example is a poly-pill compared with the separate tablets of the same substances. Probably there will be no studies that demonstrate the superiority of the poly-pill. Thanks to the RA, the cost of therapy with the poly-pill proposed by the applicant cannot be higher than the cost of therapy with the same substances in separate tablets. The second example is an add-on therapy. If there is no RCT proving the superiority, the price can be proportionally calculated as a share of the total cost of the treatment, which will be equal to the cost of the treatment with the exception of add-on therapy.

Conclusions: The new RA offers the tool to set the maximum price, for the drugs without proven superiority, by comparison with the cost of the cheapest comparator or a comparator with the best ratio. This price should be the starting point in negotiations from the payer's perspective. Thanks to this price, presented in the Recommendation of the President of the AHTATS, the Ministry of Health in Poland has a better negotiating position.

P11

Determining the prices of the medicines in the absence of superiority over alternative medical technology

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Problem statement: When there are no RCTs which prove that a new technology is better than the current drug or non-drug medical technologies currently financed by the public payer, the MAH is obliged to use the price equal to the cheapest reimbursed alternative.

Objectives: Presentation of a method offered by the new Reimbursement Act (RA), which allows one to determine the prices of medicines in the absence of superiority over alternative medical technology. This price is calculated by the AHTATS and must be placed in the Recommendation of the President of the AHTATS.

Methods: The primary goal of the new RA is to implement the principle of economical production. This should be kept in mind, while interpreting its content, because the act allows one to approach to each drug individually. At the beginning one needs to find a comparator currently financed with the lowest outcomes/cost ratio. The next step is to search for RCTs proving the superiority of the proposed drug over the designated comparator. In cases, where there are no such RCTs in the MAH’s submission, the official sales price of the drug, must be calculated in such a way that the cost of using it would not be higher than using the designated comparator. This has significant consequences because the Ministry of Health is obliged to use the calculated price in its final reimbursement decision.

Results: The example of the poly-pill compared with the separate tablets of the same substances. Probably there will be no studies that demonstrate the superiority of the poly-pill. Thanks to the RA, the cost of therapy with the poly-pill proposed by the applicant cannot be higher than the cost of therapy with the same substances in separate tablets. The second example is an add-on therapy. If there is no RCT proving the superiority, the price can be proportionally calculated as a share of the total cost of the treatment, which will be equal to the cost of the treatment with the exception of add-on therapy.

Conclusions: The new RA offers the tool to set the maximum price, for the drugs without proven superiority, by comparison with the cost of the cheapest comparator or a comparator with the best ratio. This price should be the starting point in negotiations from the payer's perspective. Thanks to this price, presented in the Recommendation of the President of the AHTATS, the Ministry of Health in Poland has a better negotiating position.

P12

Development of pharmaceutical prices in the Republic of Macedonia in comparison to selected countries outside the national reference baskets

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Background: Budgetary constraints - with annual growth rates that peaked at 20% - fuelled by the upcoming economic crisis demanded a change in the pricing model for pharmaceuticals in the Republic of Macedonia. Several neighbouring countries were faced with similar challenges, so the Republic of Macedonia carefully looked into their policies and thus introduced external reference pricing in 2011, which led to a reduction of prices. The specific was that both the Ministry of Health for the “unique price” (i.e. the maximum price) and the Health Insurance Fund as a basis for reimbursement performed price comparisons. The country basket for the Ministry of Health includes Bulgaria, Croatia, France, Germany, Greece, the Netherlands, Poland, Russia, Serbia, Slovenia, Turkey and the UK whereas the HIF references Bulgaria, Croatia, Serbia and Slovenia. Objectives: To show the trend of price reductions achieved for selected pharmaceuticals in the Republic of Macedonia as compared with the non-basket countries Hungary, Czech Republic and Austria. Policies targeted: Analysis of the effects of external price referencing in different countries. Stakeholders: Pricing and reimbursement authorities of the analysed countries. Region covered: International comparison focussing on Central and Eastern Europe countries.

Methods: Ex-post cross-country evaluation of pricing trends between 2009 and 2014 for selected out-patient medicines that are reimbursed by the Macedonian HIF using the national Macedonian price database and the European Integrated Price Database EURIPID.

Results: The prices of the selected medicines were reduced in all analysed countries but the extents of the decreases were different. It was also notable that some of the initially selected medicines (based on the Macedonian reimbursement list) were not marketed or reimbursed in the countries of comparison.

Conclusions: The analysis showed that a more regular exchange of information and pricing policies could generate higher savings for national pricing and reimbursement authorities as the price development of similar products was quite diverse.

P13

30 years of media coverage on high drug prices in the US – a never-ending story or a time for change?

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Background: US drug prices are among the highest worldwide as US policy makers have historically been reluctant to embrace price regulations, instead relying on market forces to set prices. However, the introduction of a number of breakthrough, highly effective and high-cost specialty medicines over the past years has stoked the fire of the long-running drug price debate in the USA. The prices of those specialty medicines – more than $100,000 per treatment course – have resulted in widespread outcry among patients, providers, insurers, and members of the Congress and the Senate. We aimed at analyzing whether the recent debate on drug prices reflects a sign of change in the drug pricing debate in US print media.

Methods: We used LexisNexis Academia – a database of legal, news and business sources – to determine how frequently the New York Times and Wall Street Journal featured articles including the term ‘drug pricing’ from January 1985 through June 2015. For the purpose of analyzing the media releases, we included each article in either one of the four categories: increase of drug prices, innovation, stakeholder’s response and proposed solutions and described the change of debate in each category.

Results: The media search on ‘drug pricing’ over the last 30 years showed that facts around high-cost medicines in the USA are changing: Drug prices of on- and off-patent medicine increase rapidly but from launch prices that are orders of magnitude higher than in the past [1]. Some new products are breakthrough therapies rather than marginal improvements over existing treatments with an indication for millions of patients with steep prices. Consequently more and more stakeholders (like doctors, public and private payers as well as Senators) are taking action and questioning whether the USA should contain free pricing for prescription medicines [2].

Conclusions: The frequency and content of media reports on drug prices in the New York Times and Wall Street Journal in the past 30 years may indicate a time for legal and policy change.

References

P14

Cost-Containment of Non-Formulary Medicines Accessibility: Malaysian Experience

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Background: As in Malaysia we are operating the public healthcare system through a fully subsidised moddou to the increasing trends of pharmaceutical expenditures as the Malaysian population grows, the total financial allocation for the MOH has also expanded from RM 15 million in 2010 to RM 16 million in 2012.

Methods: This study was designed to assess and review current practice and policy in the Malaysia pharmaceutical procurement procedures of non-formulary medicines. This was a quantitative study and was conducted in a cross-sectional study design. A purposive sampling method was applied in the study sample selection. The targeted samples to be involved in the selection were the public healthcare institutions in Malaysia. The study was conducted in the 13 major public hospitals in Malaysia. The data and information on the pharmaceutical procurement of non-formulary medicine management, financial allocation and expenditures on pharmaceuticals purchased in the selected facilities for the three consecutive years of 2011, 2012 and 2013 were collected and analysed statistically. The study has been conducted over a year. The study was carried out from February 2014 until February 2015. The study has been carried out in the major public hospitals in Malaysia focusing both on the out-patient and in-patient sectors.

Results: The need for the patient healthcare demands are under the purview of the government as we are conducting a subsidised healthcare system. Thus, the availability of medicines in the public institutions is restricted to their formulary. However, in certain circumstances, patient conditions might lead to the need for non-formulary medicines. Thus, this will indirectly lead to the burden of expenditures. In this study, p values of 0.046 and 0.007 were obtained for the correlation of the non-formulary medicine cost and the hospital financial allocation. The significant correlation shown has proven that these variables are as important components in assessing the pharmacy service competency.

Conclusions: From the study, the definite expenditures of the non-formulary medicines procured were identified. The monetary incurred, facilities involved and quantity of non-formulary medicines procured will be helpful in terms of forecasting pharmaceutical allocation. The outcome obtained aimed to fulfil the research gap in medicine policy towards the financial sustainability of the pharmaceutical services in Malaysian public healthcare institutions.

P15

Value of generic medicines: an health economics study

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Background: Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines. The debate on generic medicines has been centered on affordability and cost-savings so far. Positive health impact of generic medicines has, however, been scarcely discussed. The aim of the study is to examine the value of generic medicines in a more comprehensive way, particularly including the patient-related value. This involves generic medicines’ health impact in terms of not only medication adherence and compliance, but also in terms of health outcomes measured by primary endpoints or by more comprehensive health benefit measures as well as public health aspects.

Methodology: The analysis is based primarily on a structured literature review in relevant literature databases with focus on medical and economic journals / references (e.g. Pubmed or Econlit). Additionally, an internet research is conducted to identify scientific reports and papers from influential stakeholders and institutions. For the research of literature regarding the clinical benefit, the focus is on relevant guidelines and recommendations which are usually based on an evidence-based literature review and thus reliably representing the current state of evidence. This structured review is conducted for three selected drug classes: antihypertensives, adjuvant endocrine therapy for breast cancer, and an-tildepressants.

Results: The study is still ongoing and will be finished by the end of summer 2015. To this date, the following results can be shared: For the antihypertensives and adjuvant endocrine therapies to treat breast cancer, there is comprehensive evidence on the clinical benefit showing that patients benefit from drug treatment. Utilization of hypertension drugs and endocrine therapies in the last decades increased in the majority of the European countries. At the same time, hypertension-related mortality has decreased significantly in the EU countries (in Germany, for example, by about 50 % between 1998 and 2010). Breast cancer-related mortality decreased in European countries, in many of which by about a quarter up to a third. One of the designated causes for the observed mortality decline in both indications is better medicinal treatment options, though other factors such as guideline implementation also contributed. In a next step we will analyze the role of patient access to generic medicines as being the precondition for achieving both cost savings and health benefits.

Conclusions: The conclusions are still pending. The study is ongoing but will be finished by end of summer 2015.

Acknowledgements: The study was funded by the European Generic Medicines Association (EGA)
**P16**

**Prices of oncology medicines in European countries, Australia and New Zealand**

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**Background:** Medicines are of major relevance for the treatment of cancer. They appear to be among high-cost medicines; however, their prices are not generally known. In this context, the study aims to survey the prices of oncology medicines in European countries, Australia and New Zealand and explore differences across the countries.

**Methods:** Ex-factory prices per unit as for June 2013 of 31 oncology medicines in 16 European countries, Australia and New Zealand were surveyed and compared. Medicine price data for the 16 European countries were provided by the Pharma Price Information (PPI) service, and Australian and New Zealand medicine price data were retrieved from the respective Pharmaceutical Schedules. Official undiscounted list prices were taken into consideration. Price data refer mainly but not exclusively to the hospital sector and to medicines funded by the State.

**Results:** Data availability was higher in the European countries compared with Australia and particularly New Zealand. Oncology medicines are highly priced. None of the medicines surveyed had a unit price below EUR 10 in the 18 surveyed countries. Five medicines had an average unit ex-factory price between EUR 250 and EUR 1,000, and seven medicines had an average unit price above EUR 1,000.

The difference between the price of a medicine in the highest-priced country and the one in the lowest priced country varied between 28% and 233% except for one medicine with generics on the market (388%). A few medicines had lower outliers (particularly Greek and UK prices) and upper outliers (particularly prices in Switzerland, Germany and Sweden). Overall, Greek prices ranked at a low level, whereas Sweden, Switzerland and Germany showed price data in comparably high ranges.

No pattern was identified as to whether prices in Australia and New Zealand were high or low compared with European countries.

**Conclusions:** While no relevant price differences of Australia and New Zealand in comparison with European countries were found, funding of oncology medicines appeared to be more restrictive in these two countries, and access to be granted at a later stage. However, these official list prices do not include discounts and similar arrangements that are in place for several of the surveyed medicines in a number of countries.

**Acknowledgements:** The authors thank the colleagues of the Austrian Public Health Institute for providing medicine price data on European countries from their Pharma Price Information (PPI) service.

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**P17**

**Reimbursement policy optimization for Angiotensin-converting enzyme (ACE) inhibitors in Bulgaria: Controlling expenditure without undermining access to treatment**

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**Background:** A reimbursement policy for angiotensin-converting enzyme (ACE) inhibitors based only on controlling expenditure and not adequate for the patient access to treatment could not return expected results for long-term improvement of patients’ health. The study addresses the need for optimization of the reimbursement policy of the National Health Insurance Fund in Bulgaria (NHIF) which is based on payment of a certain percentage of the reference price within an INN group of drugs, i.e. 25%, 50%, 75% or 100% and covers the Bulgarian reimbursement market of ACE inhibitors, related to pharmaceutical expenditure and doctors and patients behaviour.

**Methods:** The study design is related to policy evaluation and impact assessment of alternative/what-if policy decisions related to reimbursement policy optimization. The methodology employed is mathematical modelling and simulation of the ACE inhibitor drugs market with the aid of computer modelling and simulation software. Designing and testing a reimbursement policy based on lower rates of patient co-payment, while at the same time providing means for controlling pharmaceutical expenditure, is the focus of this study. The simulation experiments use INN/ACE inhibitor prescription data by the NHIF and market data by IMS Health. These data are analysed and then used in a system dynamics model accounting for the doctors prescribing behavior, patient flows and NHIF expenditure, after which a number of policy experimentations are conducted related to alternative policy scenarios. The what-if scenarios are performed using an interactive learning environment or the so-called “management-flight simulator” which enables experimentation through instant changes in independent variables and their effect on the dependent variables within the modelled dynamic system in a historical and forecasted time frame between 2010 and 2020.

**Results:** The results show that lowering the level of patient co-payment by raising the level of reimbursement, coupled with incentives to improve access to therapy and compliance, would increase NHIF pharmaceutical expenditure on one hand, but on the other would increase the number of treated patients and at the same time would provide future savings from hospitalization of potential non-compliant and non-treated patients with chronic cardiac disease and cardiac incidents. Designing optimal reimbursement policy related to ACE inhibitors is a highly sophisticated process that needs to account for the dynamic interrelationships among all key independent and dependent factors within a systemic perspective, i.e. reimbursement levels, patient co-payment, access to treatment, compliance to therapy, doctors prescribing behaviour, pharmaceutical expenditure and government incentives to improve healthcare results.

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**P18**

**Optimising prescribing in primary care: an evaluation of financial and clinical parameters**

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**Journal of Pharmaceutical Policy and Practice 2015, 8(Suppl 1):**P18

**Problem statement:** The research carried out aimed to encourage evidence-based cost-effective pharmaceutical prescribing, reduce medicine related adverse reactions, improve patient quality of life and reduce pharmaceutical wastage. Prescribing data was evaluated and interventions were subsequently developed in an attempt to improve pharmaceutical prescribing by General Practitioners (GPs) across an enrolled population.

**Objectives:** (1) To evaluate the effectiveness of interventions being developed to optimise prescribing by GPs, (2) To recognise factors affecting prescribing patterns of medicines targeted by the programme, and (3) To identify other medicines information sources which influence GP prescribing.

**Policy targeted(s):** Pharmaceutical prescribing of medicines, in particular medicines available funded through the Pharmaceutical Management Agency (PHARMAC) was evaluated to observe trends in prescribing. These funded medicines are generally generics which are highly accessible to populations in which they are necessary.

**Stakeholder:** ProCare Health NZ is a Primary Health Organisation which was responsible for data collection and recruiting GPs within its District Health Board.

**Region covered:** New Zealand WPRO, Region number 13.

**Method:** Retrospective delay analysis of pharmaceutical data was conducted using Excel to identify potential reductions in expenditure and volume of targeted pharmaceuticals and pharmaceuticals overall. A pilot prospective, cross-sectional study investigating the perceptions held by...
GPs regarding the influence of Optimising Prescribing interventions on their prescribing practices was also carried out. Research was carried out over a two year period (July 2009 to March 2011). An overview of methodology and interventions used is shown in Figure 1.

**Results:** Some medicines showed changes in prescribing volume and pharmaceutical expenditure in response to the initiation of the interventions. For example, the prescribing volume of calcium carbonate in ProCare Network Manukau and East Health dropped sharply after the initiation of Optimising Prescribing interventions, which consists of medicines information bulletins and cell focus groups. However, the prescribing volume of calcium carbonate in ProCare Network Auckland declined before the intervention was initiated, implying that there are other sources of influence.
involved. From the pilot survey, Best Practice Advocacy Centre (BPAC) was cited by GPs as the most influential source of medicines information in their prescribing practice.

**Conclusion:** There is evidence, following the changes in pharmaceutical expenditure and prescribing volumes, in some investigated medicines. These show Optimising Prescribing interventions to be effective in influencing GP prescribing practices.

**Acknowledgements and funding sources:** The research associates would like to extend sincere gratitude and appreciation to everyone who has contributed towards this research. Dr Zaheer-Ud-Din Babar (BPharm, MPharm (Clin Pharm) PhD). Senior lecturer at the School of Pharmacy (University of Auckland) for his guidance and assistance throughout the duration of this research. Keith Crump (MPharm, PG Dip Pop Health, RegPharmNZ) for enabling the research associates to undertake this research as part of his wider work with ProCare Health Limited. Additionally, the continual support and assistance from ProCare Health is of great significance to this research and the associates sincerely wish to extend their gratitude to all persons involved in ProCare Health Limited. Dr Karen Hvizdos (BPharm PhD Clinical Prescribing Advisor; ProCare Health Limited) for supporting the directionality, overall outlook and focus of this research. John Streeter (Data Analyst) ProCare Health Limited for providing pharmaceutical data and for aiding with research results and methodology. Associate Professor Papaarangi Reid, (DipComH Otago, BSc, MRCB, DipObst, FAFPHM), Tumuaki and Head of Department of Māori Health at the Faculty of Medical and Health Sciences, University of Auckland, New Zealand for providing approval to carry out this research and study its implications on the Māori population. Dale-Lynne Sherman Godinet, ProCare Māori Manager at ProCare Health Limited for her assistance with the ethics approval process. The research associates would also like to extend our gratitude to Counties Manukau District Health Board and Auckland District Health Board for taking part in this research. Finally, the associates would like to extend their sincere gratitude to all the General Practitioners who took part in the pilot questionnaire and for their feedback and responses.

Acceptability: expert survey has shown that there is a very long patient journey for administration of biologics for advanced forms of JIA in patients with proved disability. There is a restriction of access to biologics on a regional level.

**References**


Background: Policy-makers aim to achieve the partially conflicting objectives of equitable access to medicines, cost containment and sustainable funding as well as reward for innovation. To do so, a range of policy options is available that has been extended in recent years to meet new challenges.

Objectives: To identify existing pharmaceutical reimbursement policy options in European countries.

Methods: A literature review was carried out using thesaurus and free terms in several databases and grey literature. Setting: Out-patient and in-patient sectors including possible measures at the interface of out-patient and in-patient sectors and stakeholders involved: State (as regulator), third party payers and patients (funders); pharmaceutical industry. Inclusion criteria: Studies or documents published between 1993 and February 2013 in all European Union (EU) languages performed in all 28 EU Member States and European Economic Area.

Results: In total 244 publications were selected, 61% of the selected studies were published between 2007 and 2011. Most literature referred to a sole country, particularly to large countries such as the UK and Germany. Descriptive work constituted a major body of literature; an impact assessment of policy measures was undertaken in 29% of the publications.

The five reimbursement policies most frequently mentioned were: co-payments (mentioned in 51% of the selected publications); reimbursement rates (45%); reference price systems (43%); positive lists (43%) and the reimbursement process (40%). More than every second publication addressed either HTA or pharmaco-economics. Generic substitution, reimbursement reviews, tendering and INN prescribing were identified in 35%–22% of the included publications. Nine per cent of the publications referred to managed-entry agreements, and 7% mentioned value-based pricing. Reimbursement policies addressed in low frequency were auction-based reimbursement and reimbursement on the basis of generic drugs. The five reimbursement policies most frequently mentioned were: co-payments (mentioned in 51% of the selected publications); reimbursement rates (45%); reference price systems (43%); positive lists (43%) and the reimbursement process (40%).

Conclusions: Standard elements of reimbursement systems in European countries were identified in several publications, whereas newer policy options were covered less frequently in literature. Discussions about tools on how to best assess the value of (new) medicines are recurring in literature. Discussions about tools on how to best assess the value of (new) medicines are recurring in literature.

The literature reflects, with some publication delay, the approaches of policy-makers with regard to pharmaceutical reimbursement measures. In the 1990s and early years of the new millennium, descriptive studies about national reimbursement systems were predominant, supplemented, at a later stage, by descriptions and analyses of generic policies. In the new millennium, discussions about value assessments and the importance of HTA and pharmaco-economics, frequently understood as a contrast to the pricing policy of external price referencing, were found. Policy options for new, high-priced medicines were particularly addressed in literature of recent years.

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P22
Insurance-based risk-sharing agreements
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Stretched healthcare budgets have been tending up patient access negotiations between healthcare payers and manufacturers. Data and the associated evidence available at registration are often deemed insufficient to accurately estimate the real-life clinical outcomes and budget impact. Payers want to reduce budget uncertainty and manufacturers need to evolve in a competing healthcare environment. Risk-sharing agreements (RSAs) are on the rising trend. Conceptually, RSAs have the remarkable advantage of reducing payer exposure to the financial risks associated with the introduction of a new healthcare intervention. However, engaging in a RSA should be cautiously thought through and planned as those contracts entail important financial implications, notably for the manufacturer. Monitoring costs are elevated and might jeopardize the implementation [1].

Nowadays, most of the current RSAs tend to shift the uncertainty around an expected outcome from the healthcare payer to the manufacturers. Payers want to reduce budget uncertainty and manufacturers need to evolve in a competing healthcare environment. Risk-sharing agreements (RSAs) are on the rising trend. Conceptually, RSAs have the remarkable advantage of reducing payer exposure to the financial risks associated with the introduction of a new healthcare intervention. However, engaging in a RSA should be cautiously thought through and planned as those contracts entail important financial implications, notably for the manufacturer. Monitoring costs are elevated and might jeopardize the implementation [1].

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Warranting budget predictability through new pharmacy remuneration models

This work is a description of a model implemented in Poland. Results show that policies implemented in European countries, wholesale remuneration is negotiated between the pharmacy sector and payers at least for reimbursable medicines, whereas in Cyprus and Malta pharmacy remuneration models have been put in place in five countries (Croatia, Ireland, the Netherlands, Slovenia and the UK).

Pharmacy remuneration that is both price-based and performance-based exists in seven countries (Belgium, Denmark, Finland, France, Germany, Norway and Switzerland).

Conclusions: Results show that policies implemented in European countries to compensate pharmaceutical distribution actors are similar. Frequently, remuneration is dependent on the price; this might incentivize the supply and/or dispensing of higher-priced medicines. In the community pharmacy sector, new pharmacy remuneration models have been put in place which are disconnected to the medicine price and support a wider role of pharmacists as health care provider. Changes in wholesale and pharmacy remuneration in recent years were done for cost-containment reasons in response to the crisis as well as for designing new remuneration models that are better aligned to the current challenges of supply management and dispensing of medicines.

P23
Pharmaceutical distribution remuneration in Europe
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Background: Medicine prices are considerably influenced by the maximum remuneration allowed to wholesalers and pharmacists. Remuneration of pharmaceutical distribution has to strike a balance between appropriate compensation for supply chain management and further services, while ensuring sustainability of public funding.

Objectives: The study aims to survey and compare remuneration policies for wholesale and community pharmacies for 30 European countries (all 28 EU Member States, Norway and Switzerland).

Methods: We performed a primary data collection with public authorities, wholesale and pharmacy associations as well as Internet and literature research. The analysis focuses on the reimbursement segment (i.e. full or partial cost coverage of public payers) of the out-patient sector, using data for the first quarter of 2015.

Results: The data show that in Cyprus, Denmark, Finland, the Netherlands, Norway, Sweden and the UK wholesale remuneration is negotiated between manufacturers and wholesalers. In the remaining countries, a maximum allowed wholesale remuneration is regulated on a legal basis, at least for reimbursable medicines. In these countries, wholesale remuneration generally depends on the price of the medicine. Regressive schemes have become more common than linear margins/mark-ups. In 28 of the 30 countries surveyed, pharmacy remuneration is regulated or agreed upon between the pharmacy sector and payers at least for reimbursable medicines, whereas in Cyprus and Malta pharmacy remuneration is not an issue as pharmacies are state-owned and directly belong to public sector. In 16 of these 28 countries, remuneration depends solely on the price of the dispensed medicine, and is usually a regressive scheme. A purely performance-based fee-for-service remuneration is in place in five countries (Croatia, Ireland, the Netherlands, Slovenia and the UK).

P24
Reimbursement categories as a way of allocating measures and monitoring expenditures on medicines
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Background: Control of expenditure on reimbursement of medicines distributed to patients through pharmacies poses many problems despite it providing easy access to the drugs. Other reimbursement categories, chemotherapy drugs and drug programs, allow health authorities to allocate measures and monitor expenditures under the whole budget for drugs.

Objectives: The aim of this publication is to describe two reimbursement categories in Poland, chemotherapy drugs and drug programs, and to assess strengths and weaknesses of them from the payer’s and patients’ perspective.

Policies targeted: The abstract presents evaluation of reimbursement categories which interface between out-patient and in-patient sectors, and influence of these reimbursement categories on public payer, health care providers (HCP), and patients.

Methods: This work is a description of a model implemented in Poland and an evaluation of current (up to 28 May 2015) policy in terms of rationalizing and controlling expenditures and access to health care services. The study examines the public sector and is related to the outpatient as well as in-patient sectors because of the mixed nature of these solutions.
Results: The essence of the solution implemented in Poland is agreements between the payer (National Health Fund (NHF)) and individual providers, but what is important is that neither the NHF nor HCP are obligated to enter into agreement. Medicines in drug programs or chemotherapy drugs are distributed by hospitals or on an out-patient basis. Their consumption is reported in detail to the NHF. Drug programs ensure that the quality, criteria are the same, the monitoring of therapy effects is simplified and the NHF can control it if it pays for the successful treatment. In general, the NHF is knowledgeable about the availability of services and maximum expenditures. On the other hand, adherence to the limit and freedom in concluding contracts may restrict the availability of services (queues, migration of patients in search of treatment) and burden patients with additional costs. Due to fixed exclusion criteria in drug programs there is a possibility that cessation of therapy may harm patients more than unsuccessful treatment.

Conclusions: Distribution of therapies to the patients within assessed categories limits access – only through contracted HCP (hospital and ambulatory care). In the case of patients, it rationalizes the use of medicines. Careful analysis of health needs and use of incentives for health care providers may allow a proper allocation of resources and ensuring patients an equal access to services.

P25
The effective and innovative cost saving of software in managing unregistered drugs
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Background: The Annual Report of Enforcement Pharmacy raiding of unregistered drugs has shown an increasing trend since 2010 until 2012 and there is a possibility that the seized value will keep on increasing year by year. For instance, in 2006 the Ministry of Health (MOH) has come out with the Malaysian National Medicines Policy (MNMPP): one of the strategies in the policy is the management of counterfeit drugs and one of the solutions is to monitor the retailers and wholesalers through inspection. The main objective of this study is to develop software for managing unregistered drugs through an awareness programme and inspection activities.

Methods: This is a cross-sectional retrospective study. The data were obtained from the Enforcement Pharmacy Unit, Selangor and the inspection form was created by the Pharmacy Services Division, Malaysia. The premises were divided according to districts and there are 12 districts in Selangor. All of the files were in Microsoft Excel and were divided by month from January until December 2013. Then, data were extracted from Microsoft Excel which included the district of the premises, type of the premises, type of offences, and the survey of the awareness of registered drugs.

Results: In total, only 474 (32.9%) general retailers are aware about registered drugs and 967 (67.1%) general retailers are not aware about registered drugs. About 12 districts were involved in the survey, and only one district (Hulu Selangor District Council) achieved more than 50% awareness about registered drugs. Finally, based on chi-square (0.226), the relationship between awareness and offences is not significant.

Conclusions: The general retailers are aware of the unregistered health products or even if they are not aware; those retailers would still commit the offences. This might due to the high profit that usually is the aim of the every business in the industry. This result will be used as a pioneering study and as a reference for future study. In addition, the data retrieved from the inspection form will also be used for the development of awareness and inspection software including all the details of geographical location of the premises. Monitoring of the premises by an enforcement officer costs a lot of money because there is no specific database that can be used as a reference and it is very tedious gathering all of the information about the general retailers’ premises.

P26
A framework for assessing the impact of pharmaceutical reimbursement policies on incentives to innovate
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Problem statement: The effect of pharmaceutical reimbursement policies on innovation is of interest to policymakers aiming to ensure access to effective medicines and contain costs while supporting development of effective new treatments for unmet health needs. Yet the ways in which reimbursement policies affect incentives to innovate are not well understood.

Objectives: To assist policymakers in evaluating the impact of current and prospective new policies, we developed a framework for analyzing the impact of pharmaceutical reimbursement policies on incentives to innovate.

Methods: The authors reviewed the research literature to identify hypothetical channels through which policies stand to influence the incentive to invest in development of innovative pharmaceutical products, and then developed a conceptual model illustrating direct and indirect channels of influence.

Results: We developed an analytical framework with which to explore the link between reimbursement and investment in research and development (R&D) yielding incremental, substantial, and radical innovations, as well as in novel products that do not offer new therapeutic advantages over existing treatments.

This framework posits that there are three ways that reimbursement policies and practices can affect an innovator’s expected return on investment (EROI) directly. The first is by establishing a particular payment level, which in turn affects average sales price in line with the share of the prospective market represented by the payer. The second is by setting a volume of sales at that payment level, as may occur in the case of competitive bidding, for example. The third is by influencing seller costs associated with development, manufacture, or sale. Reimbursement policies also stand to influence EROI indirectly by establishing different incentives for key actors. These incentives, in turn, affect effective price, volume and, in some cases, seller costs.

Conclusions: While researchers have investigated the links between EROI, ROI, and R&D in the pharmaceutical industry, there is no empirical evidence to directly connect ROI with innovation. Establishing such a connection would entail looking at technical questions such as the ability of potential innovators to achieve targeted research outcomes.

Lessons learned and success factors: Validation of our conceptual model and analytical framework will require further research. Furthermore, application of the framework is limited by the availability of data by which to assess the impact on key outcomes. Nevertheless, the framework can be helpful to policymakers faced with making timely decisions about adoption of new policies in the face of incomplete evidence.

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P27
Medicines optimisation in Northern Ireland - scope and results of a challenging project
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In Northern Ireland (NI), a Medicines Optimisation (MO) project has been successfully implemented by the Northern Health and Social Care Trust (NHSCT) over the last few years and continues to be developed. Historically, the approach taken to reduce medicine expenditure has been to focus almost exclusively on costs and cost-cutting initiatives. This methodology has had only limited success, as it fails to address the more fundamental aspects of the quality and safety of medicine use. Hence, in NI a new strategy was adopted, based on the premise that quality and safety drive health gain and economy. Thus, the model STEPSelect was developed (Safe Therapeutic Economic Pharmaceutical Selection) to ensure that medicine selection is fundamentally based on clinically related content such as efficiency, safety, documented effects on clinical end points and ease of administration. STEPSelect is a web-based tool developed by Digitalis Mm Ltd, enabling clinicians and other health care providers and managers to comprehensively select and procure medicines and medical devices.

The rationale for STEPSelect is that successful introduction of new medicines does not merely depend on clinical features of medicines only. Other factors, which are decisive for early adoption of new medicines are the knowledge base clinicians have of new medicines relative to existing ones and ownership and fellow peer review, when deciding about prescribing new medicines. STEPSelect is based on System of Objectified Judgment Analysis (SOJA) technology. SOJA is a selection method to facilitate rational drug selection and create a new quality in prescribing based on objectified consensus among clinicians. The STEPSelect method looks in the first instance at clinical features of health technologies. At a later stage of the evaluation, product quality and fitness for purpose are assessed (the so-called risk assessment stage) as well as the budget impact of a health technology and appropriate procurement steps and routines. Evaluations are carried out by Expert Groups, which are composed on the basis of a multidisciplinary nature consisting of clinicians, pharmacists, nurses and other staff as appropriate. In NI the STEPSelect technology has been applied to procurement of medicines in many different therapeutic groups such as statins, erythropoietin stimulating agents (ESA’s) and the use of biologicals in rheumatoid arthritis. Results with the method have invariably been positive in terms of support by clinicians and quality and cost reductions of prescribing, often in the region of 20-25% per therapeutic group.

**P28**

Biosimilar medicines: creating sustainable competition in an era of a new patent cliff in biological medicines

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For many years European governments have sought to ensure a high degree of competition in off-patent pharmaceutical markets in order to generate price competition - and consequently benefits such as improved patient access or savings for payers after patent expiry. The pharmaceutical industry believes that access to valuable new treatments and post-exclusivity competition are essential for the sustainability of healthcare systems. Biological medicines have become increasingly important over the last years. Twenty-seven per cent of pharmaceutical sales in Europe come from biological medicines. This market grew by 5.5% vs. a total market growth of 1.9% in value sales between 2012 and 2013. Many of Europe’s top selling biologic molecules are facing patent expiry by 2020 [1]. Most biological medicines come at a high cost and governments have difficulty in coping with these costs in their constrained pharmaceutical budgets, especially in current times of austerity. To date, biosimilars account for less than 0.5% of the $221 billion market of biological medicines worldwide. Biosimilars can bring huge savings for payers, and will increase the access to medicines for patients who could not otherwise afford treatment [2]. Governments must realize that biosimilar medicines are different to generic medicines and as such a unique approach is needed. By applying the generic pricing model to biosimilar medicines, governments risk marking the biosimilar market unsustainable and patients and payers will no longer benefit.

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**P29**

Exploring the Impact of health-care cost sharing mechanisms in health service users for all the 27 member countries of the EU

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**Objectives:** The main objective of this study was to investigate the cost-sharing mechanisms in pharmaceutical expenditure in EU-27 and to further explore the impact of policies on the broader NHS. The study was based on data from February to March 2015.

**Methods:** The following were the main research questions addressed: What are the main differences among the individual case studies, which were implemented in the countries concerned? Are the results included in this study expected to have a positive or negative impact on health care users? Are these results expected to ensure equal proportional allocation of the cost-sharing mechanisms among health care users? Regarding the methodology of the study, an extensive analysis of the targeted policies and practices was carried out based on the data obtained from the databases of the OECD, PubMed and Google Scholar.

**Results:** The results showed that, in the European South cost-sharing was introduced and implemented as an austerity measure in the context of
an imposed fiscal discipline, with Germany being the auditor of the European Central Bank. On the other hand, in the European North cost-sharing has traditionally been an integral part of their NHS. This cost-sharing policy has lead to significant impacts on health care systems, such as the control of excess demand and health services as well as the control of moral hazard. Cost-sharing policy has affected users as well. For instance, compensation issues in the case of biosimilars have not yet been resolved and the rate of visits in non-governmental organizations and other social clinics has increased tremendously (up to 23%).

Conclusions: Overall, the implementation of a strong cost-sharing mechanism can facilitate a sustainable and efficient NHS system based on the principle of equal rights. So far, all changes within NHS systems were proved necessary for ensuring viability and sustainable development. This policy appears to be a step in the right direction for improving the scope and the quality of the services offered by the NHS.