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MANAGING THE INTRODUCTION OF **NEW AND HIGH-COST DRUGS** IN CHALLENGING TIMES: THE EXPERIENCE OF **HUNGARY** AND **POLAND**

By: Danica Kwong, Alessandra Ferrario, Jakub Adamski, András Inotai and Zoltán Kaló

Summary: Hungary and Poland are currently facing budgetary pressures to reduce health and pharmaceutical spending. However, they still must ensure that valuable innovative medicines are made available to patients. Risk-sharing schemes (RSSs) are a mechanism to achieve access, particularly for high-cost innovative medicines that payers might be reluctant to fund because of uncertainty around their cost-effectiveness in real life. RSSs can be designed to distribute financial risks, risks relating to health outcomes or a combination of both. Due to fiscal imperatives and complexities linked to the implementation of health outcome-based schemes, both countries have focused mainly on financial RSSs.

Keywords: *Pharmaceutical Cost Containment, Risk-Sharing Schemes, Innovative Medicines, Hungary, Poland*

Danica Kwong is a former Research Associate and **Alessandra Ferrario** is a Research Officer, LSE Health, London School of Economics and Political Science, UK.

Jakub Adamski is a Lawyer at Kancelaria Prawa Ryś i Współpracownicy, Warsaw, Poland.

András Inotai is a Senior Pharmacoeconomist at the Syreon Research Institute, Budapest, Hungary.

Zoltán Kaló is Professor of Health Economics at the Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University (ELTE), Budapest, Hungary. Email: danicakwong@gmail.com

Introduction

In the recent difficult economic climate, many governments are cutting health and pharmaceutical budgets as part of wide-ranging austerity measures. Expenditure on drugs is particularly viewed as a major driver of health spending[1] and thus an attractive target for spending cuts.

These pressures have compelled payers to implement a wide range of cost containment measures on pharmaceuticals. In Europe, a number of countries reported the immediate implementation of policies such as enforced price cuts, as well as changes in co-payment levels, VAT rates on medicines and distribution margins.[2]

On top of the difficult economic circumstances all of Europe is facing, Central Eastern European countries such as Hungary and Poland must simultaneously deal with additional challenges. These include manufacturers imposing the same pharmaceutical price levels as for higher-income European countries as a tactic to avoid low prices spilling over through international

reference pricing and parallel import practices,[3] in addition to pressures to reduce overall deficit.

An additional consideration is that the increasing proportion of the non-working population (including the unemployed, older people and disabled) in these countries also has implications for their social health insurance financing structures; shrinking payroll contributions could result in fewer available funds to spend on health.

> Both countries employ a swathe of payback measures

Against this backdrop of austerity, however, payers and health ministries maintain a responsibility to provide access to valuable innovative medicines[4] for patients in need, even if these medicines are costly. To address this need, payers are increasingly employing mechanisms that require pharmaceutical manufacturers to share the risk of reimbursing and making available these new medicines, particularly with regards to high-cost new oncology and immunomodulating medicines.

These mechanisms are aptly known as managed-entry schemes (or sometimes more narrowly defined as risk-sharing schemes, though not all of them include a risk-sharing component).

Reimbursement structures and processes

The Hungarian and Polish reimbursement systems share many similarities.

The financing of new innovative medicines rests respectively with the Hungarian National Health Insurance Fund (NHIF) and the Polish National Health Fund (NHF). The decisions on whether to publicly fund them are made by the Reimbursement Department at the NHIF and the Polish Ministry of Health.

Health technology assessments (HTAs) are mandated as a prerequisite to the reimbursement negotiation process of new medicines in both countries; these are conducted respectively by the National Institute for Quality and Organisational Development in Health Care and Medicines in Hungary and the Agency for Health Technology Assessment in Poland (AHTAPol). Of note, the published cost-effectiveness thresholds in both Hungary (2–3x Gross Domestic Product (GDP) per capita/Quality Adjusted Life Year (QALY)[5]) and Poland (3x GDP per capita/QALY or Life Year Gained[6]) are intended as soft reference points. Manufacturers may apply for reimbursement at any price that they feel to be justified; but in practice, applications should be submitted with a cost-effectiveness claim deemed 'acceptable' (acceptability being loosely based around the threshold) to enhance the likelihood of the medicine being accepted for positive reimbursement. In reality however, Hungary and Poland, like many other countries, tend to consider budget impact more strongly than cost-effectiveness in reimbursement decision-making.

Later we discuss risk-sharing schemes as a mechanism to achieve access, particularly in the case of high-cost innovative medicines that payers might be reluctant to fund because of perceived uncertainty around their cost-effectiveness.

Pharmaceutical cost containment strategies

Both countries have recently enacted drastic economic reform plans with significant implications for pharmaceutical expenditure. In 2011, the Hungarian government introduced a structural reform plan (*Széll Kálmán plan*) with the intention to meet obligations from the European Union relating to the country's excessive deficit. Within this plan, the stated aim is to reduce public pharmaceutical spending by over 35% during 2012–2014.[7]

In 2012, Poland introduced the latest Reimbursement Act to fully implement the European transparency directive as well as to alleviate budgetary pressures. To that effect, the Act introduced several mechanisms to decrease pharmaceutical expenditure – most notably: basing statutory prices on mandatory negotiations; setting price limits for generic drugs and drugs which have lost their marketing exclusivity (both at 75% of the original price); and introducing adjusted fixed wholesale and retail mark-ups. To date, the Act seems to be serving its purpose by providing savings to the Polish NHF, both by applying downward pressures on prices as well as reducing the level of reimbursement to the pharmacy sector paid by the NHF; however, it is noteworthy that NHF spending on high-cost hospital drugs did increase under the Act. The Act also made progress on increasing access to medicines, introducing measures such as mandatory bi-monthly reviews of the reimbursement lists which resulted in 13 updates to the list in 2012 and 2013 (compared to the 13 updates that occurred during the entire period of 2005–2011).

Both countries employ a wide swathe of payback measures to contain pharmaceutical spending which are either implemented in relation to individual products (e.g. clawback) or therapeutic groups (payback based on market share). A general pharmaceutical budget ceiling is also designated in both countries as an additional safety measure; when expenditure exceeds the ceiling, industry is required to pay back a certain proportion. In Hungary, the ceiling is designed so that when it is exceeded by 10% or more, industry must pay back 100% of the excess consumption. In Poland, pharmaceutical companies must cover 50% of the overspend if the ceiling (17% of NHF's total health budget[8]) is exceeded. The payback is shared across companies that have received a larger reimbursement amount in comparison to the previous year; the distribution among these companies is calculated on a 'per product' basis taking into account the ratio of each company's price to the product which sets the reimbursement limit in the group. Thus far, the effectiveness of other cost-containment measures in both Hungary and Poland has meant that the ceilings have never been reached.

It is salient to note that across both countries, engaging in a risk-sharing scheme exempts manufacturers from general paybacks.

Table 1: Financial risk-sharing schemes in Hungary and Poland

	Hungary	Poland
Price-volume schemes	Yes; generally applied for all new pharmacy drugs	Yes
Confidential discounts	Yes	Yes
Dose/volume capping	Yes	Yes

Utilisation of risk-sharing schemes in Hungary and Poland

Risk-sharing schemes (RSSs) are a relatively novel mechanism available to payers for financing innovative medicines that are high-cost. While RSSs have been implemented by a number of countries in recent years, there is not yet a consensus amongst policy-makers on their appropriateness or their utility relative to administrative burden. This is in part due to the diversity of RSS types and their varied implementation across countries; but above all, it is due to a lack of data suitable for evaluation. However, as an alternative to pure cost containment strategies (for example, mandatory price reductions), RSSs have potential advantages as a longer-term, more sustainable framework that distributes risk between the payer and the manufacturer to further their mutual goal of facilitating patient access to new medicines. RSSs can be designed to distribute financial risks, risks relating to the outcome or performance of the treatment not being as expected in real life, or a combination of both financial and performance uncertainty.

Financial schemes aim to minimise the risks to the payer in making a positive reimbursement decision and publicly financing the new medicine. Examples of commonly used financial RSSs in the two countries include:

- price-volume schemes: a volume of sales related to a target population is negotiated; the manufacturer will offer a rebate or discount on any sales exceeding the predetermined threshold
- confidential discounts: manufacturers agree on discounts independently with reimbursement authorities in each country without having to reduce the official list price of the drug
- dose/volume capping: manufacturers offer discounts or even full rebates after an agreed spending or volume threshold is reached; thresholds can be set on overall levels or per patient.

While information about the number or details of RSSs is held in commercial confidence in the two countries, some information is available.

> confidential discounts comprise the majority of schemes proposed in Poland

In Poland, the most commonly proposed RSSs in reimbursement applications in 2012 were confidential discounts (34.61%), various price-volume schemes (11.54%) or payback schemes (23.08%) and others (26.92%).[9] Confidential discounts comprise the majority of schemes, serving both as a way to diminish cost to the payer and as a counter-measure for manufacturers against external reference pricing. Such conditions are most commonly concluded for drugs purchased directly by hospitals or used in drug programmes; payers want a discount from the high cost of these products and manufacturers benefit from the ease of concealing the price in the purchases through tenders. The paybacks are settled directly between the companies and the NHF. Due to the specifics of inpatient hospital treatment (a relatively small number of patients and health service providers allowing for effective monitoring of the treatment and gathering of data), it is reasonable to predict that most future schemes will be concluded for inpatient medicines.

It is worth noting that the Minister of Health recognises the value of RSSs, and tries to incentivise pharmaceutical companies by allowing an exemption from general payback schemes if companies propose and engage in such schemes. At the same time, companies may be fined by the Minister of Health if the risk-sharing conditions are not met.

Within the Hungarian context, price volume schemes are mandatory for all innovative drugs reimbursed from the pharmacy budget of the NHIF. Different volume restrictions are applied for hospital products, so that risk is shared not only with pharmaceutical companies, but also with hospitals. Of note, volume restrictions have not always been successful in meeting patient needs; the volumes reimbursed are often insufficient, leading to unequal access across the country.

Further potential for RSSs in the future

To date, both countries have focused mainly on financial RSSs. Stakeholders cite lack of administrative capacity, infrastructure and political will as obstacles to attempting outcomes-based RSSs.

In comparison to financial schemes where the overarching objective is to manage budget impact with limited consideration of the real-life added value of introducing the drug, outcomes-based schemes aim to achieve true risk sharing between the two parties by linking current, or future, reimbursement to real-life effectiveness. Coverage with evidence development (CED) schemes recognise that efficacy data from clinical trials is often insufficient to accurately gauge

utilisation or cost-effectiveness in real-life clinical practice. In CED schemes, real-life data are collected during the initial reimbursement period, after which the reimbursement status may be adjusted based on the drug's performance and utilisation in real life.

> Price volume schemes are mandatory for all innovative pharmacy drugs

In an outcome guarantee (also commonly known as payment-by-results) scheme, the manufacturer would offer a rebate or a discount if the drug does not achieve a predetermined outcome level. As yet, few countries have fully embraced health outcomes-based risk sharing. This is certainly understandable within the current economic climate; payers are compelled to focus on containing budget impact and certainly would face difficulties in setting up and maintain resource-intensive data collection registries. In Hungary, a framework for such schemes was actually developed in 2010 but application of the framework has been stalled. Poland's capacity to monitor outcomes-based schemes is limited at the moment. In 2012, 3.85% of the 26 RSS proposed included a payment by result element.[9] There are some isolated registries maintained privately or by non governmental organisations (NGOs) for certain diseases, but there have not been efforts from public institutions to coordinate data-sharing. There is some push to set up electronic prescribing and registries, but bureaucratic delays are undermining timely implementation.

As RSSs are a relatively new mechanism, there is certainly room for creativity and innovation. In recognition of the political constraints on governments in the current economy, manufacturers could propose risk-sharing arrangements and offer to set up and fund monitoring registries for outcomes-based schemes. Such arrangements would especially appeal to health ministries if manufacturers were to set up registries that integrate into and strengthen existing data collection systems (rather than standalone drug-specific monitoring projects). Outcomes-based routes could prove advantageous to the manufacturer rather than yielding to discounts or other financial arrangements.

There is not yet a general consensus within the policy community on whether RSSs are a good method to achieve the mutual goals of payers and industry, nor has there been a systematic evaluation of their impact. In the case of Hungary and Poland, governments are facing budget constraints and patients are facing reduced access to medicines; thus new policy tools such as RSSs that potentially allow for rational spending, while ensuring patient access to new medicines, should be attempted implemented, evaluated and considered in a committed manner.

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