

A triumvirate of difficulties: Technology Assessments, Health Economics & Reimbursement Policies in C&EE

The Central and Eastern European countries are evolving at various leapfrogging jumps on different areas and sectors. Leapfrogging allows quick advancements, to the expense of rough accuracy, and, more importantly, the risk of leaving things overlooked behind.

We observe this very same type of behaviors in all sectors –both public and private- as well as for all of the links of the supply chain. This is not news, and fosters innovation, entrepreneurial spirit, and, the bottom-line, growth above the IMF conservative forecasting.

But leapfrogging –and sometimes jumping into implementing other countries’ processes, best practices, or legislation, have its problems – and very acute ones. Particularly, within the pharmaceutical sector, most of the large multinational manufacturers, as well as the international wholesalers, are contributing to jumpstart the market through the introduction of commercial effective push and pull techniques in the market place, as well as educating the customers into unforeseen value propositions, with mutual benefits for the physicians (accurate patient diagnosis and targeted treatment) as well as for the companies.

Nevertheless, it is not just the private sector the one that is trying to leapfrog. One common observation throughout the central & eastern European region, is that Health Economics and Outcome Research is being ‘imposed’ more as a means to deter an increase on pharmaceutical expenditures, than as a real focus to obtain a positive effective (or even cost-effective) improvement on the health care expenditures in the medium and long term.

Why is this happening? Why countries like Hungary (the major exponent), Bulgaria or Romania, with healthcare expenditure in GDP/capita that are about half of the developed



countries, are issuing legislation as if there is no tomorrow? Is this an effect of the crises, or an excuse because of the crises? What are the issues that these governments are trying to solve with the extreme approach that they are taking? Which type of control are they really exerting?

We need to come back several years, to understand that some countries, whereas maintaining antediluvian reimbursement drug lists for basic care, had taken on inappropriate, high-value full reimbursement lists for innovation – particularly on oncology, highly spreadable and “social” diseases. This dual policy, with very anisotropic budgeting – stagnated in one side, and sky rocketing on the other – generated a perverse result of snowballing of pharmaceutical expenditure, yet not fully rationalized.

The question still remains – how have the different governments arrived to the conclusion that there are cost cuttings to be passed, and which are the initiatives taken and why? What are the pharma-economists, or the university professors advising the governments? Why the strong deviation from what could be considered ‘long term’ sustainable strategy – and... what is for them ‘sustainable’ expenditure strategy? Maybe this is the basic question – what are the characteristics that these governments are

looking for in an ‘appropriate’ reimbursement policy?

The characteristics of an appropriate reimbursement policy are –in theory- easy to define: it should be reliable, support macroeconomic benefits, strict, consistent, transparent and fair, credible, unrestricted and focus on the long term, but, most importantly, it should be sustainable. In addition, it should be applied equally to pharmaceutical products and medical devices. But, who should assess and quantify all these characteristics? And how should they be defined as objective setting on an SMART manner?

Whereas the definition above might look very much strategic and flying 10,000 feet above ground, there are well-defined analytical performance indicators for each one of the characteristics in the definition, and there are even governmental western European quantifiable standards for each one of them. And here starts the problem. There are *different* quantifiable standards for different western European countries; all of them regulated *ad nauseum* by its legislative bodies, the NCE, the FAE, the IQWIG and the alike. Unfortunately, according to the latest open discussions¹ there seems not to be a unique solution in such complexly built-up systems in these countries – and even neighboring countries chose to develop different standards and methods: For example, in Scotland, a single technology assessment suffices. In its neighboring country, NICE requires a double submission process.

Why all these (un)necessary differences? Is there any hope, for less sophisticated countries, to adhere to a given already developed methodology and process to facilitate and

¹ Paris, European Conference for Health Care Systems Development under the French Presidency of the European Commission Sponsorship

advance leapfrogging without all the caveats already observed in other countries?

Unfortunately, Health Economics and Outcome Research, as well as Pharmaco-Economics have been the latest arrivals on a highly regulated and constrained market of pharmaceuticals – switching on / off the status of one small switch can have millions impact –not just financially, but also fiscally, socially and with ripple economical effects on other countries. Hence, the chosen reimbursement systems are so ingrained with national economic policy, debt levels and the highly specific healthcare structure in the country, that they cannot be used as a ‘turnkey’ approach for other countries.

But, if a given country (like would be the case in Eastern Europe, let’s imagine Uzbekistan or Kryzigstan) would decide to build almost from scratch a sustainable reimbursement policy system, what would be the characteristics of this policy? This is not an odd question; Turkey posed itself this question about 6 years ago, Russia is working on it currently, and Morocco has started research on it. But these countries have an additional benefit on their side: There is (or there was, in the case of Turkey) no healthcare structure for universal coverage, relying on out-of-pocket payments and private physician’s management. And this is not a benefit that countries like Hungary, Romania or Bulgaria have. The latter countries have an already complex healthcare structure with extended population coverage and very deep pockets. Therefore, it is not like ‘starting from scratch’, and the legislators and governments find themselves building on foundations of already doubtful effectiveness.

The quest of achieving a reimbursement policy that fulfills the needs of the population, the patients and the government has already been posed in enough countries to know which the first questions that it raises are: What would

happen if nothing gets reimbursed? What if all innovative technologies are reimbursed? what is an innovative technology? Or even more evident questions that everybody gives for granted, but when posed, never get a unique answer: Who are the payors? What is exactly HEOR? Is it a single (manufacturers) or double (government + manufacturer) technology assessment (TA) to be considered? Who would assure transparency on the decision of the TA factor thresholds?

In most of the cases, all of these above questions are answered by the appointed governmental health economists, or the commissions serving at this effect. Here we can find, inverted, the first ‘conflict of interests’ that are also found in any management book, when the ‘shareholder / manager’ conflict is described.

Whereas the manager (the pharmaeconomist), by education and trade is a risk-averse individual, and a financial manager, looking at positive RoI and the very long term, the government counts on running the healthcare system on continuous historical deficit, and sometimes looks for short term political or social benefits – or even side tuck-in or collateral effects, for example, on fostering growth of the GDP’s M1 through interventionism (national production, at higher local costs, compared to trading or importing captive revenues)

The Hungarian nightmare

A good example of this conflict is reflected on the convoluted –yet short term effective legislative changes integrated in Hungary in the last 24 months, and driven through a handful of national economists. The aim was to reduce the budget expenditure in pharmaceuticals by 2008 (exp. 1,86B €) to the same levels of 2004 (1,33B €). They succeeded, and even beat their own expectations, reaching a 1,26B €, i.e. about 0,5B

€ budget cost-cutting. But, why, and at which long term cost?

The Hungarian case is an almost by-the-book example of what happens when countries convert from state-controlled economies to liberal ones, and they only go half-way, for social reasons. When Hungary liberalized the economy, the government took a very conservative positioning on maintaining a good share of the social benefits enjoyed by the population –and passed legislation to preserve them, including (by other country’ stand ards) wealthy pension plans, as well as unemployment and disability benefits. The other interesting fact in Hungary was also the maintenance of the adherence to governmental structures in the country. A vast majority of the population –also much higher than by any other C&EE country standards, and only beat by the Belgians, belong to governmental legislative bodies, at all levels – regional or local councils- giving a very heavy twist of socially-based content administrative bottom-up legislation.

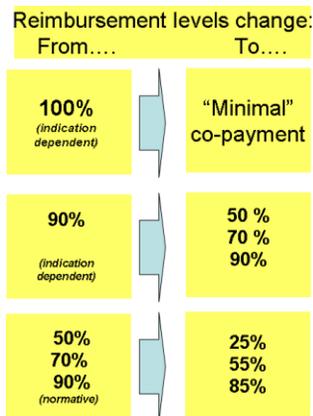
The consecutive Hungarian governments have found a difficult task on managing the budget of a country in continuous deficit due to its own social-focus interests. The heavy burden of fiscal debt (particularly pensions), in a country with already higher number of pension population than workers, and administratively handcuffed to deconstruct the source of the problem, has forced the government to turn into ‘quick wins’ at the expense of long term potential instability, tackling budgetary restrictions but focusing on squeezing value, in general, from the private sector, and in particular in the pharmaceutical expenditure.

In order to do so, the legislators took all the battery of cost-containment or budgetary control restrictions available in more developed countries, and passed them, one by one, in a staged, almost laboratory - controlled manner.

The Hungarian legislators took, for example, among others, the British Guided Prescription practices, the French Guided choice of pharmacist, the Spanish claw back clause, the German reference price cuts, and mastered all of them, taking them to new levels. They even created new potential deterrents for market growth and additional ‘free cash’ to the National Health Insurance, in the form of an additional tax of 20,000 €/year per capita of medical representative to be paid by the pharmaceutical companies.

Did all of these measures work in the short term? And, more importantly, what is the impact of these measurements in the long term for Hungary – and for the countries in the European Union? With hindsight, and market data available, we can now confirm that not all the cost-cutting measures worked. Actually, some of them had a perverse effect. Only a handful of them were effective in the short term, and only fewer of them can be considered as sustainable for a long term healthcare sustainable prospects. Let’s analyze some of them to understand the caveats of this approach.

By far, the most effective impact for this budget expenditure reduction (a one-off effect of >200 M € in ‘07, i.e., accounting for more than 40% of the decrease) was the reimbursement rate cut approved by the government, for all types of reimbursed drugs. This is a quick win from the legislators, putting the burden of debt into the patient’s pockets, and hoping –and expecting- that the higher co-payment will create a pull from the patient or the physician to use cheaper drugs.



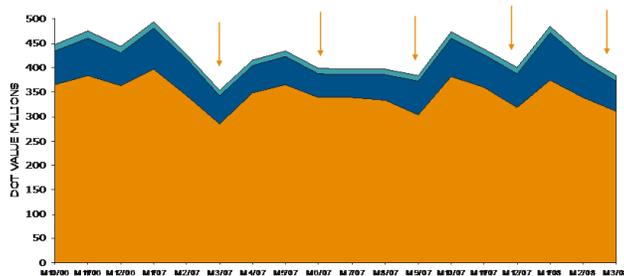
Unfortunately, this success story is not without risk - in some chronic illnesses, prior studies reveal that higher co-payments or burden of cost put in the patients, trigger lower compliance rates, with all the concomitant health issues and subsequent cost burden in the long term that it might imply for the healthcare system. This is one of the problems with quick cost-cutting vs longer term holistic health technology long term impact calculations, particularly in high-volume ‘silent killers’ (no symptoms) diseases, like cardiovascular and metabolic ones.

The second contributor to the pharmaceutical budget cut (132M €, sustained year-on-year) was the claw-back imposed to all the stakeholders (note equally distributed) in the supply chain, as a ‘shared risk of overspending’. This is not news to the sector – other countries, like Spain, have also claw-back regulations on absolute levels of sales –at bearable levels (2 – 3%). In Hungary, the claw-back hits the sector heavily: 12% of absolute sales’ claw back to manufacturers, 2,5% of margin to wholesalers, and pay-backs on margins also to the largest pharmacies.

Whereas in most of the countries, managers are rewarded to increase top (and bottom) line, in Hungary, the KPIs are to take a different dimension. Furthermore, considered that the manufacturers have an impact on the market, but they are not the final decision makers on the prescriptions. This one would have been still a ‘controlled’ situation, but, unfortunately, it was coupled with an ill-fated change on the pricing legislation, which has proven to be the most strategically dangerous change initiated by a government from a pharmaceutical sector point of view.

The new legislation for reference pricing passed in 2007 caused much more than just a headache to all GMs and Financial Directors in the pharma sector – irrespective of their branded or generic affiliation. The NHI defined a new modus operandi for the reference pricing: Quarterly – decided reference pricing, using on-line bidding systems. This system proved to be also quickly effective: During the year, the co-saving to the government was 100 M €, about 30 M € of them coming from direct co-payment savings. On average, about 1000 products in reimbursement lists decreased their price by >20%, with some categories (like C01), decreasing in up to 70% their prior year listing price. The figures tell already by themselves a horror story – but when the impact of this measure is considered in a more comprehensive manner, the implications of the impact reach stunning, ill-fated conclusions.

The first objective observations from this legislative change was observed on the supply chain (see figure below): both wholesalers,

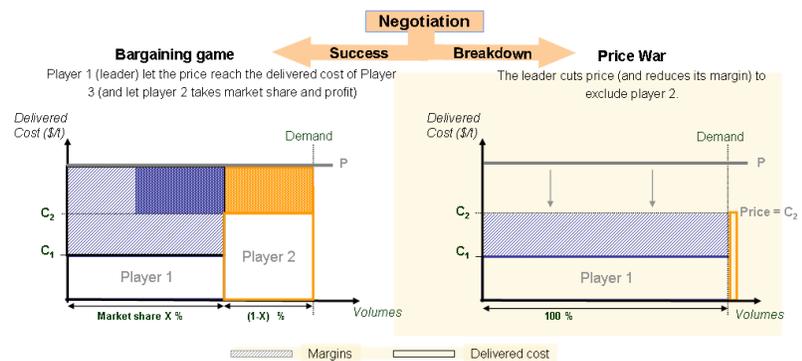


distributors and pharmacies applied a shelf depleting (and unfortunately market de-stocking) policy, to benefit, on their cash flow, from immediate purchases at the most reduced, new quarterly reference price reached in the on-line bidding.

Furthermore, and in subsequent quarters, due to the cutthroat pricing dynamics observed by some players, that would leave products out of reimbursement lists, pharmacies would decide to re-stock with a different supply of brands (or

generic suppliers). This, together with the generic substitution empowerment (and benefits) given by the government as an additional cost-cutting initiative, increased the power of the pharmacist's own budgetary decision to the detriment of the physician's prescription intent.

The reference pricing system would have been less effective, if all the players' in the market would have understood the concept of 'strategic value added' in competitive markets – everybody plays, yet everybody wins (see figure).



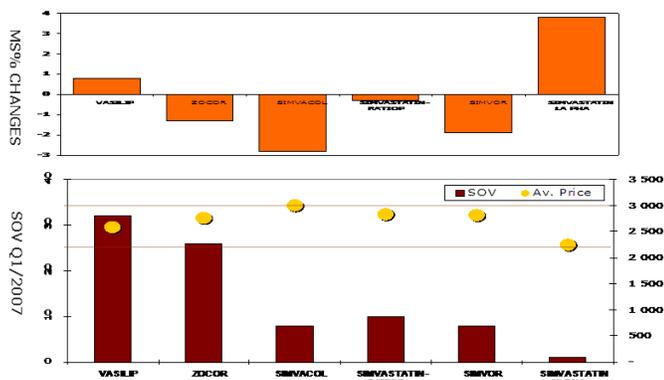
This is a little bit more complex approach to managing competitive situations, based on the "prisoners' dilemma", played in subsequent rounds, and carefully monitoring and responding to the competitor's changes in price.

This competitive strategy game, played in most business schools, and also on the offices of the board of directors of a good number of companies, helps understanding which is the own best strategy on market share sizing and pricing, that the company should take, according to its own product's costs, to accommodate competitors' entrance and maximize (within the framework of the pricing legislation) for all contenders the benefit in a cost effective manner.

These simulations and decisions, are, of course, taken within the framework of legality, avoiding

massive knock-down effect on the value of the therapy class, and, even if there was some initial resistance to play the game, by the two latter players, evidence of massive value loss, and the quick loss of market share, forced all the players into the lose-lose game.

A further market analyses evidenced the futility of (initially) all other efforts – the system had won. Investment on commercial detailing, on marketing mix plans, on long term sustainability was meaningless, as seen in the adjacent graph, in which the changes of market share are definitely correlated to pricing, and winning a percentage of a share point is forced to a very strong investment. And, against all conventional knowledge and experience, the completely irrelevant impact of the SoV, as can be seen in the illustration of the first quarter market dynamics after the spiraling down of pricing and the e-prescription kick off.



Nevertheless, the situation was short-circuited – the doctors realized of the legal difficulties to enforce punishing measures for prescribing out of the system, and of the easiness of ‘opting out’ of the system because of the patient specific situations’.

The damage, nevertheless, had already been done – prices had plummeted to levels

unforeseen in the market, generic penetration success criteria legislator’s rates had been achieved, and the system had won. But, what is the impact in the long term? In the case of innovation, the impact had been already observed in the market. Hungary, being itself contributor to maximal reference pricing in the cross-European complex system of pharmaceutical pricing, was impacting much larger markets, that hopefully, revisited prices only once per year. Austria, for example, has a bucket of 8 countries (among them, Hungary) that average their reference pricing. And Austria is at the same time reference price for other larger markets – so, the snowball effect is just a question of time and critical size.

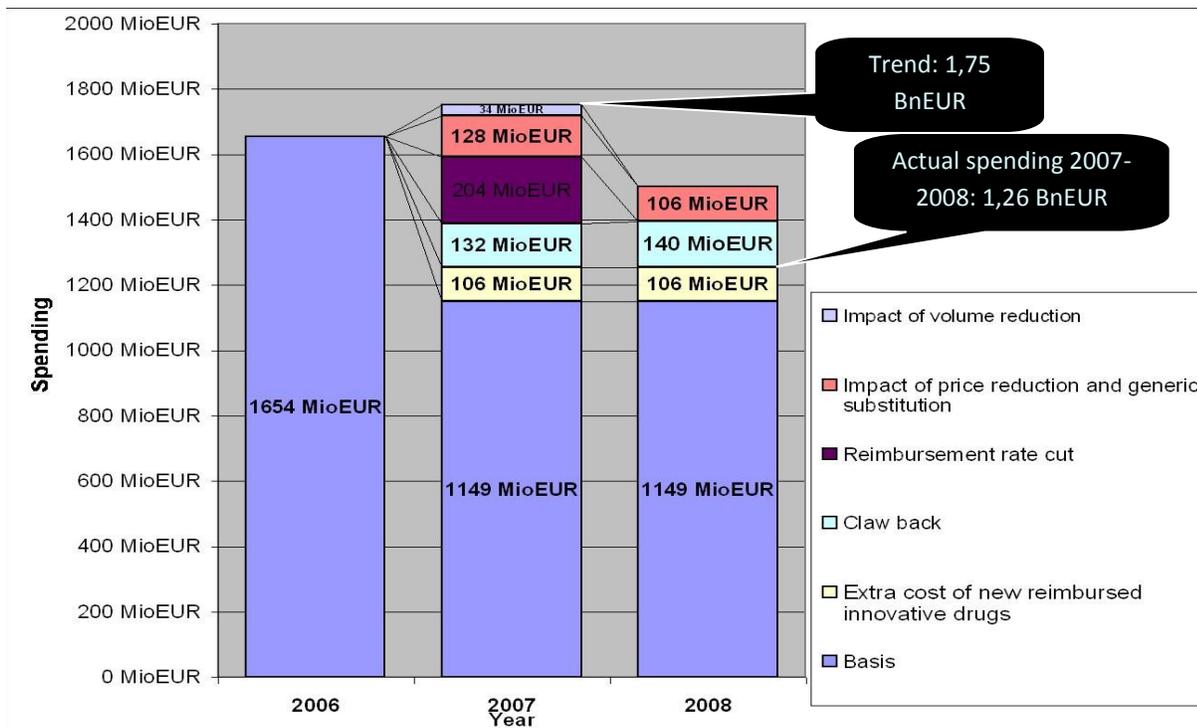
Out of the about sixteen different legislations passed to cut the cost expenditure, it was the four mentioned above that actually impacted the market value and brought down the pharma expenditures to the levels desired by the government. The government had pledged that the cost containment would foster the entrance of innovation in the country –as fund would be readily available thanks to the results of these cost-cutting measures.

The budget spent in 2007 on newly introduced reimbursed ‘innovative drugs’ was 106M € (same value for 2008), about 20% of the total cost cutting. These ‘innovative drugs’ were subject to strong HTA assessments, on what the legislators called a ‘controlled admission to the reimbursement list’. On one hand, the product subject to reimbursement needed to present a full HTA dossier that would be answered within 30 days.

Would the product pass this cut, the reimbursement is granted for a fixed volume agreement contracted for 3-4 years, upon which the product is competitively re-assessed based upon molecule usage, therapeutic treatment paradigms and international reference pricing . There were 47 new products introduced in 2007, for 106M €. That gives a good evidence of the control exerted in the process and the covenants of the agreement. Here is palpable another common misunderstanding of the legislators regarding a very basic concept: the difference between pharma expenditure cost-cutting, cost-containment and cost-effectiveness. Not all innovation can be considered cost-effective on its own; new, targeted treatments are the result of more expensive developments, resulting on more expensive drugs. Taken at face value and as stand alone, very few innovative treatments are cost-effective. ARBs, for example, would have never been approved for reimbursement in

lieu of ACE-inhibitors or beta-blockers if taking the standard paradigm alone – but, how do you measure the long term effectiveness of renal protection, or sexual health maintenance?

Positive reimbursement decisions for innovative drugs, might be tricky if the definition of cost-effectiveness is not properly dimensioned. And this is one of the breaking points on the process of reimbursement. We revert at this point at the original question about sustainable reimbursement systems and decision on innovation interests. In Hungary, the commission (the department of pharmaceuticals of the National Health Insurance, NHIFA) has well established ‘transparency’ directive on the HTA dossier decisions... yet there are deficiencies on the implementation; among others, the decision of the commission is final, and the producer only gets an OK/NOK on the dossier. Would the product not be approved for reimbursement, the reasons for the denial were



kept secret; There are neither open criteria nor scientific or therapeutic reference policies that are available.

There is no open / public definition of cost effectiveness neither measurement procedures or descriptors for it, products might be subject to group-effect procedures, or be classified as ‘special reimbursement’ (with differential financial protocols), but without solid rules of inclusion in the various programs... and this is just the beginning.

Why, after the strong training that pharma economists get in Hungary (through the World Bank Program, the ESKI HTA, the post-graduate courses, the Hungarian HE association and the specialists on the 4th Hurdle), there are such a big amount of deficiencies observed in the process of HTA? These deficiencies are, as expected, very much alike the ones observed in more sophisticated bodies, like the NCE, and are due to the difficulties on establishing explicit thresholds. At this moment, sociology (and anthropology studies) starts playing a role.

Not all the population are patients – but all patients seek maximum pay-back on their social insurance tax contributions. How do you establish which is the ethical and public willingness to pay for a quality adjust life year gain?, i.e., how much can the government (or the society) invest –please notice the choice of verb, and not spend- in maintaining a person alive for long?

This starts becoming a difficult subject, in which finance and ethics collide. Admitting a limit or a threshold on this time-value starts pointing about socially-supported life affordability. In the western cultures, this is very much a taboo subject, and explains part of the ‘lack of transparency’.

There are different ways that the economists have been dealing with the definition of this

‘threshold’. All attempts have been as economically focused and patient-detached driven as possible, for obvious reasons. Among others, the threshold (i.e. the maximum reimbursement limit for a given therapy, considering standard treatment paradigm, and survival rates) are defined as multiples of GDP/capita (as disclosed by the NCE in UK, about 2 or 3 times the annual GDP/capita in UK), or benchmarked vs other countries.

But the thresholds can also be ‘moving’, based on severity of disease, or upon alternative treatment reimbursed therapies. Whatever the choice of threshold –and hence of reimbursement limits- there is an additional element of complexity ingrained on it, which is one of the generators of the differences observed between countries.

This differentiator arises when the countries start considering what is the holistic cost of the treatment, vs the cost of the drug - and how do you quantify the limits of the holistic cost (and hence the reimbursement threshold limits for each part of the treatment).

The different regulatory bodies for health care in Hungary have, probably by now, seized the market response and the impact of the different initiatives, and hopefully will be able to control the growth of the market, and hopefully arrive to a more transparent HTA processes, without, again, rocking the boat.

Hungary was considered as the ‘pilot market’ for testing initiatives – yet, it has been changed this status as to ‘battleground’ in the last years. We only hope that the neighboring countries can understanding holistically the strategy and implication behind this war, and apply the learnings wisely.

For further information on Central & Eastern Europe, please check www.zarzia.com or contact us at office@zarzia.com