POLICY BRIEFS
No. 04/2013
ISSN 1653-8994

PRICE TAGGING THE PRICELESS: International reference pricing for medicines in theory and practice

Lisa Brandt *(lisa.brandt@ecipe.org), a Trade Policy Analyst at ECIPE*

Piggy banks around Europe are operating on an empty stomach these days, especially the ones belonging to the public healthcare sector. In times of austerity, the healthcare sector has been subject to significant budget cuts or measures that have stopped expenditure from increasing. But at the same time, policymakers seem cautious about prescribing too harsh medicine to a sector that is, admittedly, not in rude health. Tempted by the idea of quickly reducing healthcare costs with minimal efforts, politicians are currently kicking major incremental healthcare reforms down the road. Instead, the attention is drawn to reducing the amount of money spent on external expenditure items, notably medicines.

In price-regulated pharmaceutical markets, two common methods to determine drug prices are so-called health technology assessments (HTA) and international reference pricing (IRP). At first glance, international reference pricing might resemble Mary Poppins's magic formula of a spoonful of sugar that helps the medicine go down; it is a relatively inexpensive policy instrument insofar as it presents governments in single-payer systems with no extra costs as they seek to quickly curb expenditure on pharmaceuticals. IRP basically builds on systematic price comparisons with other countries and aims at fixing low reimbursement levels for drugs covered by the public health insurances. However, when high-income countries such as Germany set their reimbursement prices in comparison to prices in other countries that are implementing severe austerity measures, like for instance Greece, something suggests the system is not working quite right.

There are in fact serious concerns as to whether international reference pricing is an adequate instrument in terms of reconciling the immediate need to reduce healthcare spending with the objective of fostering a

SUMMARY

International reference pricing (IRP) has become a popular policy instrument in Europe. As government seeks to curb healthcare costs and notably reduce expenditure on medicines, the use of IRP has arguably prompted price convergence. Reference pricing may reduce drug prices and promote generic market entry in the short term. In the long run however, IRP risks causing negative dynamic effects. This is due to the fact that the operation of the price mechanism is set out of play. The IRP as an instrument is not designed to improve productivity and efficiency in the pharmaceutical market. Instead of basing prices on an assessment of the added therapeutic value of a new medicine, IRP focuses solely on cutting costs. As pharmaceutical companies react to policy incentives, launch delays have been observed as well as higher prices on branded drugs as firms try to compensate for foregone sales. Ultimately, by dampening the price competition and by discouraging incremental innovation, IRP may in the long run defeat its purpose and lead to increased medical expenses for the public healthcare sector.

dynamic and innovative atmosphere for health technology improvements. IRP may enable public authorities to economise in the short run. It is however a blunt instrument when it comes to assessing the welfare, or indeed the therapeutic value, of a new medicine. In comparison to health technology assessment, which typically is a more holistic method that takes the cost-effectiveness as well as the total costs of a medical treatment into account, reference pricing focuses on the price only.

The problems are rooted in the fact that IRP is underpinned solely by the idea of reducing costs rather than enhancing productivity or providing value for money in the healthcare sector. Policymakers may rejoice as the prices on medicines become lower almost overnight. However, lower costs in the short term must be juxtaposed with negative long-term ramifications that may result from the fact the IRP sets the operation of the price mechanism out of play. This might entail serious consequences on innovation, competition, market structures, and prices as well as on the availability of drugs, ultimately affecting patients.

The objective of this paper is to discuss the benefits and drawbacks of international reference pricing. Building on existing research and literature, the aim is to identify known effects and provide greater understanding of possible unintended consequences of IRP, particularly with respect to market distortions. The risk that IRP may backfire and increase the aggregate costs for medicines in the future is particularly examined.

DIFFERENT METHODS OF CALCULATING REIMBURSEMENT PRICES

In recent decades, international reference pricing has become a widely used policy instrument to contain public expenditure on medicine. IRP refers more precisely to "the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country".[i]

IRP does not regulate the actual retail price of the product, but the amount that is reimbursed by the public healthcare insurances. Companies are free to set a price at any level above the reference price, but the so-called out-of-pocket-payments from the patients are then going to be higher. For the vast portion of the market for prescribed medicines, IRP is *effectively* a price regulation.

The methodological advantages of IRP - the fact that is it relatively easy and not too costly to calculate, implement and administer - are also the major source of critique against it. The reference price is not a given unit but depends on the method of calculation, which varies from country to country among the 24 out of 27 EU Member States that currently apply some form of IRP. The different ways of administering IRP in Europe are related to the fact that healthcare policy is a member state competence, even though directives on the procedures for market approval and harmonisation of the reimbursement procedures have been adopted at EU level.

To begin with, the reference price for the reimbursement level depends on the number of countries that are included in the so-called country basket. A country basket includes approximately 4-8 reference countries, and these are usually selected from the same geographical region. The composition of the country-basket varies depending on where relevant price information is available and in which countries the drug has been launched.[1]

Because of price comparisons, prices in certain countries may have disproportionate influence on drug prices internationally, although there can be no guarantee that the price in one country correctly represents the value of a medicine in the first place. The United Kingdom, for instance, represents around 4% of the global pharmaceutical market but the countries[ii] that include the UK in their reference clusters together represent around

[i] International reference pricing should not be confounded with internal reference pricing; "the practice of using the price(s) of identical medicines or similar products or even with therapeutically equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of reimbursement of the products in a given country". (WHO/HAI, 2011) This paper addresses exclusively international reference pricing.

[ii] Countries that refer to the UK include Japan, France, Italy, Canada, Belgium, Switzerland, Poland, The Netherlands, Finland, Hungary, Norway and Mexico.

25% of the global demand. The UK itself does not apply a reference price system *per se*. Instead, its Pharmaceutical Price Regulation Scheme consists of a profit control regulation specifying the maximum level of profit that companies can make from the drugs they supply to the National Health Service (NHS). In addition, a price control mechanism limits the possibility of raising the price of a medicine, although companies can freely set the initial price when a new medicine is launched.[2]

Second, the international reference price depends on the type and the number of drugs included in the group of medicines that it applies to. The basket can include generics[iii] (generic reference pricing) or both patented products and generics (therapeutic reference pricing). Within each category, respectively, medicines can be grouped together depending on their chemical equivalence (chemical substances in the molecules), pharmacological equivalence (interaction between the chemical and the body system) or therapeutic equivalence (effect of the drug). While clustering drugs together according to their active substances or molecules is rather straightforward, it is a more complicated exercise to define criteria for 'similar' drugs based on therapeutic equivalence.[3] By way of example, in Germany, reference pricing applies only to off-patent drugs (generic reference pricing), which are divided into three categories; chemically equivalent products; drugs with similar therapeutically and pharmacologically active ingredients; and drugs with similar comparable therapeutic effect.[4] Italy introduced genetic reference prices in December 2001 and groups off-patent drugs into clusters according to their active ingredients. Prices are then calculated on the basis of the minimum prices on the market.[5]

Third, the IRP depends on when the price comparisons are made and on whether the reference price is calculated based on the lowest price in the basket, the simple average or the weighted average. Different packaging, names of the medicines and dosage forms may also complicate comparisons. Admittedly, IRP calculations are sometimes made difficult by pharmaceutical companies' deliberate strategy of making effective price comparisons difficult. Price comparisons are in some cases also further complicated by differences between ex-factory prices, wholesale prices and retail prices as well as currency fluctuations and exchange rate volatility.

Fourth, the indicated prices might not reflect the actual prices at which pharmaceutical companies sell the drugs to public authorities. Confidential discounts in the contracts are common. This might however change as the Commission's new proposal for a review of the Transparency Directive aims to make full disclosure of all price information mandatory. Companies are however anxious about preserving their freedom to operate under commercial confidentiality. Rebates represent for instance 2-7% of total expenditure on medicines in Germany; 3.5% in Ireland and around 3% in France.[6] Other types of price arrangements used in for instance Hungary, France and Italy include pay-back mechanisms for risk-sharing, which, if applied, oblige companies to return parts of the profit if sales exceed a pre-determined level. Similarly, Spain has a general discount system in place where drug companies must return a certain level of their annual profits to the Ministry of Health.[7]

Against this backdrop, it becomes clear that IRP is not designed for the purpose of determining the optimal price of a medicine.[8] Critics point out that there is neither any room for assessing the actual added therapeutic value of a drug, nor for taking patients' or doctors' views on the innovativeness of a new medicine into account. There is no mechanism to assure that prices set by regulators in other reference countries are appropriate and fair. Instead, pricing mistakes might easily be repeated.[9]

Price regulations in general and international reference pricing in particular illustrate the fact that medicines are not treated like any other product by regulators. Actually, the entire pharmaceutical market displays a number of particularities which imply that the price mechanism alone cannot serve to determine a sustainable equilibrium between supply and demand in the same way as it generally does in a perfectly competitive market.

First, pharmaceutical companies need to charge higher prices than the marginal costs of production if they are to

[iii] "A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights" (WHO)

recuperate their costs for research and development. In the EU, pharmaceutical companies spend over € 26bn on R&D activities annually, or the equivalent of 17% of total investment in the private sector.[10] Patents for molecules thus serve as a safeguard to make sure that companies are compensated for the significant R&D costs involved in the developing of a new medicine, which can take around 12 years. For generic drugs the time to produce a new drug is shorter, but still around 3 to 5 years. While patents or exclusive rights serve to encourage innovation, they effectively place the patent holders in a monopolistic position. Patents are normally valid during a time period of 20 years in accordance with the agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) in the World Trade Organization.

Second, the launch and marketing of new medicines is strictly regulated. Even if most pharmaceutical companies operate globally and can choose where to launch their products, there are tendencies of price distortions because of monopsonic situations. In other words, public authorities have the power to influence the price by virtue of often being the single purchaser due to the way in which national healthcare systems are administered.

Third, in all cases, it is not entirely up to pharmaceutical companies to independently decide the price for the medicines that they launch because of price and reimbursement regulations. Pharmaceutical companies have traditionally negotiated different prices for their products in different markets, depending on the purchasing power of countries and of patients. By differentiating their prices, companies can charge higher prices in high-income countries while offering lower prices in countries where the willingness or capacity to pay is lower. Differential pricing can in this way enhance social welfare if it permits the introduction of a greater variety of pharmaceutical products in low-income markets, notably in developing countries[11]. It should also be mentioned that differential pricing has prompted parallel trade, implying imports of medicines sold in low-price countries to high-price markets. Parallel trade is more common within the EU market than elsewhere, but it is still estimated to concern only 2% of the drugs on the EU market.[12] There have been signs of a growing market for parallel trade, though.

A fourth aspect that characterises the pharmaceutical market is the relatively inelastic demand for medicines. People are obviously in need of medicines when they are sick, but this is also linked to the fact that subsidies and universal health insurances render people insensitive to prices. There is in other words a form of moral hazard involved since patients only pay a small share of the actual costs. This may potentially lead to overconsumption.

Fifth, the market for pharmaceuticals is characterised by an intrinsic problem of information asymmetry. Physicians act as agents recommending and prescribing drugs to their principals – the patients, who for natural reasons are not in a position to test and chose whatever medicines they like.

In sum, for all the reasons mentioned above, the supply as well as prices of pharmaceutical products does not function in the same way as they would normally do in a perfectly competitive market.

THE EFFECTS OF IRP IN THE SHORT TERM VS. LONG-TERM IMPACTS

Immediate price drops, then what?

It follows from the fact that the pharmaceutical market already is extensively regulated that when public authorities around Europe are under pressure to tighten their belts, one of the first methods that comes to mind is to change the policies for reimbursement. Indeed, public healthcare spending in OECD countries is currently increasing at a faster rate than economic growth. On average, health expenditure increased from 8.8% of GDP in 2008 to 9.5% in 2009.[13] Medicines account for around 1/3 of total health expenditure, or approximately 1.5% of GDP.[14]

International reference pricing can be rather efficient in the short term with respect to the objective of containing public expenditures on medicines.

In terms of immediate or static effects, studies confirm that IRP has led to lower prices in OECD countries.[15] Reductions of expenditure on medicines of up to 50% have been observed, implying significant cost savings in the short term.[16]

As a result, there are signs of price convergence in Europe. Lower prices have been observed in high-income countries whereas low-income countries have to pay relatively more in relation to their GDP/capita. The price convergence appears to derive from international reference pricing and parallel trade, although it is difficult to isolate the causal factors. Notwithstanding such tendencies, drug prices still vary across Europe. For a basket of 150 medicines, prices differ about 25% between different Member States. Price differences can be up to 4:1 for individual patent-protected medicines, or even 16:1 in the off-patent market.[17]

In so far as price drops have been observed, such tendencies depend on several factors, notably on competition. As a rule of thumb, the greater the intensity of generic competition, the greater the downward pressure on prices.[18] Also, if prices on branded drugs are high prior to the introduction of a reference price, a greater number of generic competitors are likely to enter the market, particularly in market segments where a successful patented drug has been selling in big volumes.[19] Moreover, the downward pressure on prices also tends to be stronger the bigger the number of medicines included in the group of drugs that the reference price is applied to, since the competition then is more intense. Also, if there are large price differences within a specific market segment prior to the introduction of an IRP, the effect on prices is likely to be more significant.[20]

However, all that glitters is not gold. The effect on prices actually seems to fade out over the course of a couple of months. According to a study on reference pricing in Germany during 1994-2005, market prices were reduced by approximately 14% following the introduction of reference pricing, the greater part of the reduction occurred during the first month. The same study showed that a 1% decrease of the reference price led to a 0.27% decrease in market prices during the first month and a 0.03% decrease in the second month. Thereafter, there was no significant effect and the prices instead remained constant.[21] This indicates that IRP does not provide any competitive incentive for pharmaceutical companies to lower prices below the reference price.[22]

Larger market shares for generics in the short term

Generics have generally captured greater market shares in terms of volume in OECD countries following the introduction of IRP. But the effect on the market structures depends largely on the strategies of branded drugs firms.[23]

Companies producing the original drug can engage in defensive pricing strategies in order to preserve their market share after patent expiration. By lowering the prices on branded drugs, launching new dosages/formulations or substituting drugs still under patent protection, they may try to offset the impact of IRP on sales.[24]

However, another tendency is actually being observed, the so-called generic paradox. It implies that former patent holders maintain a high price on the branded drug, or even increase the price. This is a way for companies to compensate for foregone sales and launch delays while counting on consumer loyalty.[25] According to a recent study, the generic paradox has been observed in the UK, Sweden and the Netherlands, where prices of originator product actually increased following generic entry.[26] Similar tendencies have also been observed in France, where prices of the original branded drugs tended to remain largely unchanged despite the introduction of reference pricing.[27] In relation to this, two German studies have also showed that prices on drugs not subject to reference pricing increased significantly, indicating how companies raise prices on drugs not covered by IRP in order to compensate for lower profits on products subject to IRP.[28]

In sum, although immediate price reductions have been observed following IRP introduction, these effects may be wiped out over time as a result of the counter-strategies of companies that produce the originator drug. This also indicates that price reductions in the short term may come at the expense of negative dynamic effects for the pharmaceutical sector as a whole in the long term as companies react to the incentives provided by regulators.

DYNAMIC EFFECTS

Launch delays hindering access to medicines

In terms of dynamic effects of international reference pricing, several empirical studies point at launch delays in low-income markets as companies adapt their marketing strategies according to the use of international reference pricing among public healthcare authorities.[29]

Like other profit-making companies, pharmaceutical firms base their launch strategies on estimations about price, competition and market shares. Companies tend to look with a jaundiced eye on international reference pricing since it makes it difficult for them to differentiate prices between countries. Firms might thus prefer to wait before launching a product in a low-price market in order to avoid a relatively low price influencing reimbursement prices elsewhere.

Consequently, access to medicines risks being delayed, especially in low-income countries. According to a study[iv], only 55% of all potential drug launches actually take place. The greatest number of launches takes place largely in high-income countries like the U.S., Germany and the UK.[30]

Moreover, IRP can lead to postponement of launches more generally because of administrative delays, for instance if cumbersome regulations impede generics from entering the market once patents expire. Price-controlled markets like France, Spain, Italy and Japan experience delays in generic launches and low rates of generic market penetration (less than 20%) in the off-patent segment. In comparison, the rate of generic penetration in the U.S., which does not apply reference pricing, is over 70%.[31]

Launch delays may cause welfare losses, the extent of which depend on the added value and the cost-effectiveness of the new medicine.[32] Companies might put up with opportunity costs in terms of foregone sales so as to avoid low prices from spilling over. Patent protections continue to run, however, even if a product is not introduced on the market. For patients, being denied access to medicines can be particularly troublesome if the new drug is expected to be more effective than the dominant standard of cure.[33]

Disrupting the competition on the pharmaceutical market

In the short run, reference pricing may increase the competition from generics, resulting in lower prices overall and bigger market shares for generics. Over time however, IRP risks distorting the functioning of the price mechanism and obstructing the development of a competitive environment.

IRP implies that profit margins in high-income markets are set low by regulators already at the time of the expiration of a patent, when profit margins would normally be high. In theory, price regulation might weaken the market powers of patent holders. However, fixed reference prices diminish the incentive for competition as companies have little to gain from lowering their prices below the level of the reference price. IRP thus interrupts the natural price erosion that would normally occur over time, due to inflexibilities in its design.[34]

While research shows that reference pricing can prompt significant price reductions of up to 50% in the short run, the average price decline is relatively small in the long run, only between -1.4% and -2.7%, according to a study by Kanavos, Costa-Font and Seeley (2008). The decline in generic prices is actually more noticeable in countries that do not apply IRP, like in the UK and the U.S., where more flexible price regulation permits stronger price competition.[35]

For society as a whole, a lack of generic competition may imply substantial opportunity costs for the public healthcare systems. It represents a foregone opportunity to improve the cost efficiency on the pharmaceutical market.[36] Generics currently represent around 14% of the total value of global sales of pharmaceuticals. The market share of generic drugs varies between countries, however. Generics represent more than 40% of the total number of

[iv] Funded by AstraZeneca

products sold in the U.S., Germany and the UK, whereas they only account for 10% of the market share (volume) in for instance Italy, Belgium, Spain and Portugal.[37] Lower generic market penetration is generally associated with higher aggregate costs for the public healthcare systems, and a less dynamic pharmaceutical market.

Disincentive to innovate

The impact of international reference pricing on R&D and innovation may be serious although the full impact of this type of price regulations will not be measurable until many years from now. In all cases, there is a risk that reference pricing will have a dampening impact on the intensity of the research within the industry as a whole. By reducing profit margins, IRP might also have ramifications on the type of innovations that the pharmaceutical industry produces in the sense that it skews the allocation of resources for new research projects. Moreover, the incentive to develop new drugs may be reduced if reimbursement levels for new medicines are determined only on the basis of the added medical value in comparison to the existing standard of cure, which is often a generic product. This might impede progress and lead to a situation where the incremental innovation ends once there is an efficient generic medicine on the market. While policymakers have been working feverishly to curb expenses, the risk is that there may be one standard of cure, full stop, has probably not occurred to them.

Subsequently, instead of investing in incremental improvements of existing medicines, pharmaceutical companies might spend more resources on R&D to develop pioneer drugs that replace existing medicines, for instance by developing orphan drugs to treat rare diseases, for which profit margins are higher.[38] Also, it is likely that companies will focus on developing drugs mainly for the most important reference markets, thereby meeting the needs of patients in large high-income markets rather than the needs of patients in countries with a lower capacity to afford medical treatment.[39]

Innovation is obviously not a self-fulfilling goal, but is important in order to improve access to efficient medical treatment and to assure the availability of a great variety of drugs that can meet the different needs of individual patients. However, instead of enhancing innovation and cost-effectiveness in the pharmaceutical sector, the focus of the IRP on cost-containment only may end up causing a splitting headache for the public healthcare sector. IRP might raise pharmaceutical expenses in the future and discourage incremental innovation. This is basically a result of the fact that pharmaceutical companies react rationally to incentives created by IRP in their quest to maximise profits in the absence of price competition.[40]

CONCLUDING DISCUSSION

The pharmaceutical market features a number of particularities that prevents it from functioning as a regular competitive market. On the supply side, extensive amounts of time and resources are required to develop a new medicine. Therefore, patent systems and data protection rules are in place to grant exclusive rights to innovators in order to preserve competition and encourage investment in R&D. On the demand side, public healthcare agencies play a dominant role. Not only do they have a strong influence on the market structure by way of administering the public health insurances, they also have significant control over the price levels by being the dominant buyers of medicines.

Notwithstanding this exceptionalism, assuring a regulatory environment that provides for a well-functioning and dynamic pharmaceutical industry is absolutely crucial for the future. While healthcare is perceived a right rather than a commodity in Europe, it is essential to find ways to reconcile the objectives of reducing healthcare expenses and at the same time encouraging competition and development of medical treatments.

Currently, there is a tendency to lower drug prices and price convergence in Europe, arguably as a result of the use of international reference pricing among public agencies. Research shows that IRP can be effective in terms of lowering the prices of drugs in the short term and increasing the competition from generics. Short-term cost savings must however be seen in contrast to the adverse effects that IRP may have on the pharmaceutical market in the long run.

The aspect that nobody seems to consider is the fact that this type of price regulation puts competition out of play. International reference pricing is based purely on a cost containment philosophy. Such an instrument could potentially work, if we were still in an era of pharmaceutical blockbusters. Times have changed, however. Excessive profits are rather the exception than the rule. Many pharmaceutical companies are nowadays under pressure to make profit and far from all drugs are bestsellers.

The problem comes down to the features of IRP as a policy instrument. In view of achieving static effects in the form of price cuts, public agencies are pursuing a policy that is effectively undermining the competition on the pharmaceutical market. Eventually, public healthcare agencies may get a taste of their own medicine as the dynamic effects of reference pricing become visible. By destroying dynamic competition, causing launch delays and discouraging R&D, IRP might generate increased aggregate costs for the healthcare sector in the long run. The adverse effects of IRP are already becoming evident. Pharmaceutical companies are withdrawing medicines or even calling off launches as part of their strategy to avoid prices from spilling over from low-income markets to other markets because of IRP.

It will be essential to improve productivity and cost efficiency in the healthcare sector in the years to come. IRP is not the instrument that is going to do the trick though. It is simply not designed for that purpose. Now, high-income countries are obviously not pleased about paying more for the same drugs that low-income countries pay less for. But in the interest of promoting a dynamic and innovative pharmaceutical market in Europe, the most feasible solution seems to be to allow some form of differential pricing.

In the end, all efforts should not be devoted to reducing the costs of medicines. A vast array of inefficiencies must be addressed, including the administration of hospitals and medical services. Improving cooperation between different regions and municipalities with respect to sharing resources and equipment will also be important.

Policymakers may prefer to introduce painful reforms in small doses. It will nonetheless be essential to build a solid foundation for the future, in order to improve efficiency in the healthcare sector overall. Admittedly, there is no special formula that can sweeten the pill and make such reforms easy, quite the contrary. It will be challenging, especially in comparison to simply setting a low reimbursement price for a medicine.

BIBLIOGRAPHY

- Augurzky, B.; Göhlmann, S.; Gress, S. (2006) 'The Effects of Reference Pricing on Ex-factory Prices of Rx Drugs in Germany. A Panel Data Approach', Rhine-Westphalia Institute for Economic Research, RWI: Discussion Papers, No. 46
- Bardey, D.; Bommier, A., Jullien, B. (2010) 'Retail price regulation and innovation: Reference pricing in the pharmaceutical industry', *Journal of Health Economics*, Vol. 29, pp. 303-316
- Brekke, K.; Holmas, T.H.; Straume, O.R. (2011) 'Reference pricing, competition, and pharmaceutical expenditures: Theory and evidence from a natural experiment', *Journal of Public Economics*, Vol. 95, pp. 624-638
- Brekke, K.; Königbauer, I., Straume, O.D. (2007) 'Reference pricing of pharmaceuticals', Journal of Health Economics, Vol. 26, pp. 613-642
- Costa-i-Font, J.; Varol, N.; McGuire, A. (2011) 'Does pharmaceutical price regulation affect the adoption of generic competition? Evidence from the OECD, 1999-2008. CESifo working paper, no. 3441. CESifo Group, Munich, Germany
- Danzon, P.M.; Towse, A. (2003) 'Differential Pricing for Pharmaceuticals: Reconciling access, R&D and Patents', *International Journal of Health Care Finance and Economics*, Vol. 3, pp. 183-205
- Danzon, P.M.; Wang, Y.R.; Wang, L. (2005) 'The impact of price regulation on the launch delay of new drugs – evidence from twenty-five major markets in the 1990s', Health Economics, Vol. 14, pp. 269-292
- Drummond, M.; Jönsson, B.; Rutten, F. (2011) 'Reimbursement of pharmaceuticals: reference pricing versus health technology assessment', *Health Economics*, Vol. 12, pp. 263-271

- European Generic Medicines Association, EGA, (2009) 'How to Increase Patient Access to Generic Medicines in European Healthcare Systems', A Report by the EGA Health Economics Committee, Contributing Authors: Bonger, F. and Carradinha, H.
- Friederszick, H., Tosini, N., de Véricourt, F. Wakeman, S. (2010) 'An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in the Pharmaceutical Industry'. European School of Management and Technology GmbH, Berlin, Germany, ESMT White Paper
- Ghislandi, S. (2010) Presentation: Effects of Reference Pricing in Pharmaceutical Markets: a Review, ECHE 2010, Helsinki, Finland, 7-10 July, 2010
- Ghislandi, S. (2011) 'Competition and the Reference Pricing Scheme for pharmaceuticals', *Journal of Health Economics*', Vol. 30, pp. 1137-1149
- IHS Global Insight (2011) 'Healthcare Forecasts Amidst Global Economic Turmoil: Recession-Proof or Leaking Roof?' World Markets Healthcare Forecasting Special Report. Report Author: Jing Zhang
- Innovative Medicines South Africa, IMSA, (2011) 'Reference Pricing – Background information and IMSA position'
- Kanavos, P.; Costa-Font, J.; Seeley, E. (2008) 'Competition in off-patent drug markets: Issues, regulation and evidence', *Economic Policy*, July 2008, pp. 499-544
- Kanavos, P; Nicod, E.; Espin, J.; van den Aardweg, S. (2010) 'Short- and Long-Term Effects of Value-Based Pricing vs. External Price Referencing'. The London School of Economics and the Andalusian School of Public Health, report commissioned by the European Commission, DG Enterprise
- Kanavos, P.; Vandoros, S. (2011) 'Drugs US: are prices too high?', *Significance*, Vol. 8, Issue 1, pp. 15-18
- Kanavos, P.; Vandoros, S. (2013) 'The generics paradox revisited: empirical evidence from regulated markets', *Applied economics*, Vol. 45, Issue 22, pp. 3230-3239
- Kanavos, P.; Vandoros, S.; Irwin, R.; Nicod, E.; Casson, M. (2011) 'Differences in costs of and access to pharmaceutical products in the EU'. Study requested by the European Parliament's Committee on Environment, Public Health and Food Safety. ENVI. IP/A/ENVI/ST/2010-12
- Koenig, P., MacGarvie, M. (2011) 'Regulatory policy and the location of bio-pharmaceutical foreign direct investment in Europe', *Journal of Health Economics*, Vol. 30, pp. 950-965
- Magazzini, L., Pammolli, F., Riccaboni, M. (2004) 'Dynamic competition in pharmaceuticals. Patent expiry, generic penetration, and industry structure', *European Journal of Health Economics*, Vol. 5, pp. 175-182
- Miraldo, M. (2009) 'Reference pricing and firms' pricing strategies', *Journal of Health Economics*, Vol. 28, pp. 176-197
- Garau, M.; Towse, A.; Danzon, P. (2011) 'Pharmaceutical pricing in Europe: Is differential pricing a win-win solution? Occasional Paper 11/01. London: Office of Health Economics
- Office of Fair Trading (2007) 'The Pharmaceutical Price Regulation Scheme. An OFT market study'. London: February 2007
- Organisation for Economic Co-operation and Development (2008) 'Pharmaceutical pricing policies in a global market', OECD Health Policy Studies, Directorate for Employment, Labour and Social Affairs, Health Division
- Organisation for Economic Co-operation and Development (2011), Health data: 'Spending continues to outpace economic growth in most OECD countries'
- Varol, N., Costa-Font, J., McGuire, A. (2011) 'Does Pharmaceutical Price Regulation Affect the Adoption of Generic Competition? Evidence from the OECD 1999-2008', CESifo Working Paper Series No. 3441
- Yadav, P. (2010) 'Differential Pricing for Pharmaceuticals. Review of the current knowledge, new findings and ideas for action', A study conducted for the U.K. Department for International Development, August 2010
- World Health Organization and Health Action International (2011) 'WHO/HAI Project on Medicine Prices and Availability. Review Series on Pharmaceutical Pricing Policies and Interventions. Working Paper 1: External Reference

ENDNOTES

1 World Health Organization and Health Action International (2011)

2 Office of Fair Trading (2007)

3 cf. Drummond, Jönsson and Rutten (2011)

4 Galizzi, Ghislandi and MIraldo (2011)

5 Galizzi, Ghislandi and MIraldo (2011)

6 OFT (2007)

7 WHO/HAI (2011)

8 Innovative Medicines South Africa (2011)

9 WHO/HAI (2011); Friederiszick et al. (2010)

10 Kanavos, Vandoros, Irwin, Nicod and Casson (2011)

11 Yadav (2010)

12 OECD (2008)

13 OECD (2011)

14 OECD (2008)

15 Galizzsi, Ghislandi and Miraldo (2011); Kanavos, Costa-Font and Seeley (2008); Augurzky, Göhlmann and Gress (2006); Drummond, Jönsson and Rutten (2011)

16 Galizzi, Ghislandi and Miraldo (2011)

17 Kanavos, Vandoros, Irwin, Nicod and Casson (2011); WHO/HAI (2011)

18 Gizlandi (2010); Brekke, Holmas and Staume (2011)

19 Brekke, Holmas and Staume (2011)

20 Drummond, Jönsson and Rutten (2011)

21 Augurzky, Göhlmann and Gress (2006)

22 Drummond, Jönsson and Rutten (2011)

23 Ghislandi (2010); Brekke, Holmas and Staume (2011); Kanavos, Costa-Font and Seeley (2008)

24 Galizzi, Ghislandi and Miraldo (2011)

25 Augurzky, Göhlmann and Gress (2006); Friederiszick et al. (2010); Galizzi, Ghislandi and Miraldo (2011); Costa-i-Font, Varole and McGuire (2011)

26 Kanavos, Vandoros (2013)

27 Kanavos, Costa-Font and Seeley (2008)

28 Galizzi, Ghislandi and Miraldo (2011)

29 WHO/HAI (2011); Costa-i-Font, Varole and McGuire (2011); Garau, Towse and Danzon (2011); Danzon, Wang, Wang (2005); Varol, Costa-Font and McGuire (2011)

30 Danzon, Wang and Wang; (2005)

31 Costa-i-Font, Varole and McGuire (2011)

32 WHO/HAI (2011)

33 Danzon, Wang, Wang (2005); WHO/HAI (2011)

34 cf. Ghislandi (2011)

35 cf. Brekke, Holmas, Staume (2011); Kanavos, Costa-Font, Seeley (2008); Magazzini, Pammolli, Riccaboni (2004)

36 Varol, Costa-Font, McGuire (2011)

37 OECD (2008)

38 Bardey, Bommier and Jullien (2010); OECD (2008); Friederiszick et al. (2010); Garau, Towse and Danzon (2011)

39 Friederiszick et al. (2010)

40 Bardey, Bommier and Jullien (2010); OECD (2008); Friederiszick et al. (2010)

LATEST PUBLICATIONS:

Mixing Apples and Oranges: The Limitations of Trade Policy in Mitigating Climate Change
ECIPE Bulletin No. 03/2013
By Lisa Brandt

One Year After the Foul Expropriation of YPF: Argentina's Road to Ruin
ECIPE Bulletin No. 02/2013
By Fredrik Erixon

On Camels and the Making of EU Biofuels Policy
ECIPE Bulletin No. 01/2013
By Fredrik Erixon

Openness in Public Procurement Markets: Time for a Reality Check
ECIPE Policy Brief No. 03/2013
By Patrick Messerlin

A fibre-rich diet for Europe: Is the EU's Next Generation Access strategy compromising on competition?
ECIPE Policy Brief No. 02/2013
By Lisa Brandt, Hosuk Lee-Makiyama

Pariah in the World Economy: How Should Countries Respond to Argentina's Return to Economic Nationalism?
ECIPE Policy Brief No. 01/2013
By Fredrik Erixon, Lisa Brandt

Life Beyond Reciprocity: Why Competition in Public Procurement is in the EU's Own Interest
ECIPE Bulletin No. 10/2012
By Lisa Brandt

A EU-Taiwan Trade Accord from EU Member States Perspective: Rebalancing regional trade
ECIPE Policy Brief No. 13/2012
By Hosuk Lee-Makiyama, Michal Krol

The Renminibi on the Internationalization Trail
ECIPE Working Paper No. 01/2012
By Sylvain Plasschaert

Back to Basics: Economic Reforms and EU-China Relations
ECIPE Bulletin No. 09/2012
By Fredrik Erixon

Whither Global Rules for the Internet?
ECIPE Policy Brief No. 12/2012
By Hosuk Lee-Makiyama, Rohan Samarajiva

Upholding Europe's mandate on trade: The EU-Japan FTA
ECIPE Policy Brief No. 11/2012
By Hosuk Lee-Makiyama

Europe and the Asia Pacific
ECIPE Policy Brief No. 10/2012
By Brendan Nelson

Aid for Trade: Chronicle of a WTO Attempt at Coherence
GEM Policy Brief
By Jean-Jacques Hallaert

The Economics and Political Economy of Going beyond the GATS
GEM Paper
By Erik van der Marel, Sébastien Miroudot

Property rights, Consumption Growth and Consumption Volatility: Evidence from a Land Reform in Vietnam
GEM Paper
By Hosuk Lee-Makiyama, Niels Kemper, Luu Viet Ha

The European Centre for International Political Economy (ECIPE) is an independent and non-profit policy research think tank dedicated to trade policy and other international economic policy issues of importance to Europe. ECIPE is rooted in the classical tradition of free trade and an open world economic order. ECIPE's intention is to subject international economic policy, particularly in Europe, to rigorous scrutiny of costs and benefits, and to present conclusions in a concise, readily accessible form to the European public. We aim to foster a "culture of evaluation" – largely lacking in Europe – so that better public awareness and understanding of complex issues in concrete situations can lead to intelligent discussion and improved policies. That will be ECIPE's contribution to a thriving Europe in a world open to trade and cross-border exchange.

www.ecipe.org
Phone +32 (0)2 289 1350 Fax +32 (0)2 289 1359 info@ecipe. org Rue Belliard 4-6, 1040 Brussels, Belgium