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Dear Mr. Flanagan

Mylan is a global pharmaceutical company offering a growing portfolio of approximately 1,100 generic pharmaceuticals and several brand medications. Mylan currently employs about 820 people at its facilities in Ireland. The planned expansion of Mylan's operations in Ireland announced on 18th April 2012 by Heather Bresch, CEO Mylan, involves R&D and manufacturing capabilities within the company's respiratory, injectables and oral solids franchises. Through Mylan's investment of up to 76 million euros, which includes funding for expanded research and development (R&D) capabilities, and support from the Irish government through IDA, Mylan committed to more than 500 new positions to its Ireland-based workforce by 2016. One hundred of these jobs were created in the past 15 months. Mylan is currently the largest generics pharmaceutical manufacturer in Ireland and one of the world's leading pharmaceutical companies.[1]

Mylan welcomes the opportunity to contribute to the public consultation regarding the "Potential reference pricing of atorvastatin 10mg, 20mg, 40mg and 80mg" document, and respectfully requests that the current submission be considered when assessing future application of referencing pricing to other generic medicines in the Irish medicines market.

As stressed by the European Generic Medicines Association, *"[External] Reference Pricing (ERP) should not apply to generic*[2] *medicines or to biosimilar*[3] *medicines. In Europe only a very limited number of countries apply ERP on generic medicines, affecting negatively the sustainability of healthcare systems. Generic medicines operate in a very competitive environment; their price level in a given country can only be sustained because of specific conditions, such as the high generic medicines market volume.*

Applying the prices of a given country to another will only distort the generic medicines operation model, driving generic companies out of the market and drastically limiting the savings capacities of healthcare systems, endangering medicines access to patients due to inevitable drug shortages, already prevalent in the countries with low prices."[4]

Furthermore, the World Health Organization stated in their Review Series on Pharmaceutical Pricing Policies and Interventions *"...guarding universal values such as affordability, equitable access of medicines and financial sustainability of the healthcare system and affirms that off patent medicines are not appropriate for an external reference pricing system"* [5] and "in the case of off-patent medicines there are other price control mechanisms, such as internal reference pricing or linking the price of generics to the originators" price, which might be more appropriate to ERP in terms of the level of the technical capacities and information required to apply them." [6]

Irish Health Authorities and payers have other tools much more efficient than ERP to increase competition and savings in the off patent market. In the EGA paper it is suggested to *"promote a dynamic and competitive market environment that generates savings through optimized generic medicines usage by adopting demand side measures that can increase the volume of the generic medicines market. Potential demand creation measures include incentives for prescription of generic medicines and for patients to use generic medicines, and facilitating generic access to the market."*[7]

Specific comments to the HSE understanding of "Potential reference pricing of atorvastatin 10mg, 20mg, 40mg and 80mg"of 20th June 2013:

24.—(1) Subject to subsections (3) to (5) and section 25 and without prejudice to the generality of section 21(3), the Executive may set a price (in this Act referred to as the "reference price") for a relevant group of interchangeable medicinal products in relation only to the listed items which fall within the group.

Generic medicines companies operate in a very competitive environment compared to originators; in Ireland generics are priced 50% below the pre off patent brand price for the 12 months post patent off and then fall to 30% since November 1st 2012. The price linkage between originator and generic medicines means that ERP applied on originator medicines also results in a further price reduction for generic medicines. The generic medicines sector's price dependence on competitors is

[1] Mylan.com - http://investor.mylan.com/releasedetail.cfm?ReleaseID=665180
[2] For more information: http://egagenerics.com/index.php/generic-medicines/introduction
[3] For more information : http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.pdf
[4] European Generic Medicines Association response to EC stakeholders' Consultation - Study on the "External reference pricing of medicinal products: simulation-based considerations for cross-country coordination"
[5] WHO/HAI Project on Medicine Prices and Availability Review: http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf
WHO/HAI Project on Medicine Prices and Availability Review: http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf
[7] European Generic Medicines Association response to EC stakeholders' Consultation - Study on the "External reference pricing of medicinal products: simulation-based considerations for cross-country coordination" referencing Simoens Report 2 - http://pharm.kuleuven.be/pharma_care/documenten/Rapport%20generieken%20EGA%202013.pdf

in itself a threat to sustainability of the industry. This price linkage combined with additional price reductions from ERP further disadvantage generic medicines companies attempting to supply the market.

Faced with the unsustainable pricing environment of referencing lowest price as the standard in Europe, generic medicines companies may not be able to launch their products, as referred by WHO paper[8] *"…The main alleged negative effects [of ERP] include: …delays in the launching of new medicines in countries with low-priced medicines"*. The European Commission Pharmaceutical Sector Inquiry Report also addresses this point by showing that companies tend to launch new medicines in countries where prices are higher[9]. These delays thereby limit competition and reduce long-term savings for the healthcare system.

(2) Subject to section 25, the Executive shall review the reference price (if any) set for a relevant group of interchangeable medicinal products at least once a year but not more than once every 3 months and may, following any such review, set a new reference price for the relevant group of interchangeable medicinal products.

Markets such as Ireland where generic medicines volume is extremely low compared to the European average may end up with prices below their profitability level if EPR is used, as these external prices are referenced from developed medicines markets that can afford to have lower prices due to the high volume penetration of generic medicines. Three months is an insufficient amount of time for generics to develop necessary volumes to sustain lower prices. If EPR is in place, generic medicines companies will need more than three months to achieve a sustainable volume share of the off-market to continue providing safe generic alternatives at affordable prices to patients.

'3) The Executive shall, when setting a reference price for, or reviewing a reference price set for, a relevant group of interchangeable medicinal products take into account—

(a) the ability of suppliers of the relevant listed items to meet patient demand for the relevant listed items,

Despite the atorvastatin market currently being served by a number of suppliers in Ireland, a considerable number of suppliers may be expected to withdraw their medicines from the market resulting from planned administrative price cuts and EPR. Sustainable pricing levels are required to balance price-volume trade off and justify company presence in the market.

In some countries short-term pricing systems have driven down generic prices to unsustainable levels, leading to market withdrawal and major disruptions in the supply chain. It would be detrimental to the quality of health care and to the entire generic medicines sector if prices in these countries were not applied as reference points for Ireland and others.

(c) the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed,

Correct comparison of 'equivalent' prices across Member States requires consideration of several points:

- Pricing and reimbursement systems vary within Europe. When countries apply external reference pricing, pricing and reimbursement decisions made by other countries are transferred to the domestic situation, out of the policy context in which they were created. National policies, e.g. payback schemes, discount systems, profit control systems and risk sharing agreements as well as tenders, can distort external reference price comparison. Prices derived from an average price composition are the result of multiple socio-economic factors, and countries that reference other countries' prices are vulnerable to foreign regulatory changes[10]. Healthcare systems respond to different regulations and population needs, and price comparison between countries does not reflect this context.
- *"It may be difficult to identify the same medicine precisely due to different commercial names, dosage form, strength and packaging. Price comparisons are made much more complex because of the heterogeneous nature of distributors' profit margins, pharmacists, taxes, etc."*[11,12]
- *"When countries use ERP to set prices they are ultimately allowing other countries' pricing policies to determine their own by including approaches obtained from other countries' sets of reference. It is, however, difficult to assess whether the resulting prices will be appropriate, efficient or optimal in accordance with any objective criterion. If reference countries have set their prices too high or too low, then any country later applying the ERP method may run the risk of repeating the same mistake"*[13].
- *"The loss of price transparency is probably one of the most undesirable effects of ERP. Prices represent the market's key mechanism for the efficient allocation of resources. Without known prices, markets simply cannot adjust to an efficient equilibrium."*[14].

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[8] WHO/HAI Project on Medicine Prices and Availability Review: http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf
[9] European Commission. Pharmaceutical Sector Inquiry. 2008.
[10] Impact of cross-reference pricing on pharmaceutical prices: manufacturers' pricing strategies and price regulation, http://www.ncbi.nlm.nih.gov/pubmed/17249840
[11] Dukes MNG, Haaijer-Ruskamp F, Joncheere CP, Rietveld AH. Drugs and Money. Geneva, World Health Organization, 2003.
[12] International pharmaceutical price differences. Australian Productivity Commission study. Melbourne, Canberra, 2001.
[13] WHO/HAI Project on Medicine Prices and Availability Review: http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf
[14] WHO/HAI Project on Medicine Prices and Availability Review: http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf

Diverse pricing and reimbursement policies across Europe, price setting at different levels in the supply chain, and exchange rate changes indicate that a harmonized ERP methodology is unfeasible in the European context.

(d) the relevant prices of therapeutically similar listed items,

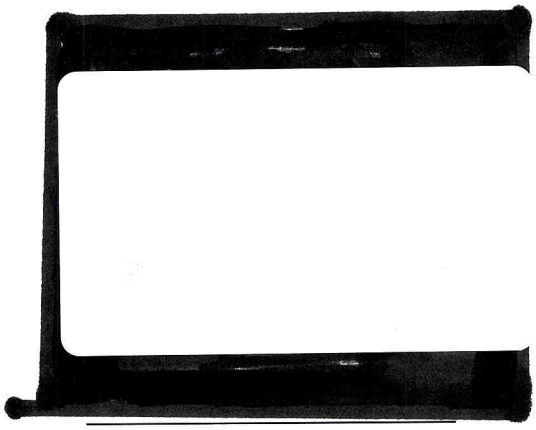
Price comparison between therapeutically similar molecules can distort pricing decisions, as each molecule differs in market maturity. Volume is critical in generic medicines pricing; the high volume level for one molecule may be linked to its lower price, which is not proportional or relevant for a recently off-patent molecule that has not yet obtained high volume levels. Importing prices from different markets is in fact importing other market conditions and dynamics. In addition, before threating the potential savings from generic medicines molecules my comparing therapeutically similar molecules, it is important to set the expectation on the results rights, "Some countries claim to expect price decreases, but this claim is seldom supported by empirical evidence"[15].

(4) The Executive may use a competitive process to set the reference price for a relevant group of interchangeable medicinal products.

Mylan supports the view of the HSE not to use tendering as a measure to create artificial competition, as tendering systems have been shown to drive prices down to unsustainable levels in some countries, potentially causing supply chain disruptions, as mentioned on Professor Panos Kanavos report *"...what is important, however, is that no interruptions to the supply of medicines occur due to tender pricing pressures, or the inability of manufacturers to supply the market with product (which may lead to shortages")* .[16] It would be detrimental for the quality of healthcare and for the generic medicines sector if these countries were used as reference points for other countries.

25.—(1) The Executive shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 4 weeks before the relevant decision takes effect), give notice in writing of the relevant decision, together with its reasons for the relevant decision, to the suppliers of the relevant listed items which fall within the relevant group of interchangeable medicinal products the subject of the relevant decision.

Mylan suggests that Irish Authorities source information regarding interchangeability of molecules from health authorities in other European countries. Generic medicines' interchangeability status is data-based and does not change between countries. Obtaining information from countries already listing the products as interchangeable would result in expedited generic medicines market entry, higher savings to the healthcare system and increased patient access to affordable treatments.



[15] WHO/HAI Project on Medicine Prices and Availability Review: http://www.haiweb.org/medicineprices/24072012/ERPfinalMay2011.pdf

[16] 2009, Kanavos, Tender systems for outpatient pharmaceutical in the European Union: Evidence from the Netherlands and Germany, http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/study_pricing_2007/tendering_systems_en.pdf