Interview with Kate Lynch, CEO, Generic Medicines Industry Association (GMiA)

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In trying to be an effective association and positively influence the environment for your members, what have been the main achievements and milestones since you were appointed in 2008?

We have been focusing on several strategic priorities over the past four years, firstly on creating a viable commercial environment for our members in terms of getting market access for generic medicines. We are presenting a clear message to the government that generic medicines are an equal choice and present the opportunity for significant savings to the reimbursement schedule.

Moving more volume from the originator to the generic brand is a good outcome for the community. The Australian price disclosure mechanism means that the government will claw back savings for the public that are delivered to the market over time and this will ensure that the reimbursement price most closely reflects the market price.

By definition the originator brand has 100 percent of the market when the first generic enters. In order to get foothold in the market, the market model in Australia is that the sponsors of generic medicines discount to the pharmacy to get a share of the market. Those discounts are clawed back by the government, and after twelve months of data collection, the reimbursed price paid by the government is reset to the actual market prices. The more uptake of generic medicines, the lower the weighted average price will be at the end of the reporting period, yielding a lower new reimbursed price paid by the government.

Government supports the uptake of generic medicines. In the 2010 Commonwealth budget the government allocated money to an independent but government-funded body, the National Prescribing Service, that delivers education and information to the consumer about good use of medicine. Monies were directed to the NPS to deliver a community campaign to increase consumer confidence to choose a generic medicine.

One of our big successes is in the registration process. In 2008 we reached a crisis situation with the Therapeutic Goods Administration (TGA) in terms of evaluation of generic medicines. We saw back then a large increase in the number of generic medicines seeking registration, which reflected the number of molecules going off patent and the increase of international generic players entering the Australian market. The systems and processes of the TGA were not equipped to deal with that, which led to a large backlog of applications and increased evaluation times. We implemented a streamlined submission process, and this led to two successes: the backlog is now gone, and the new process is back on track for the efficient delivery of regulatory existence.

Looking at the PBS, last April we saw one of the biggest single reductions in PBS history. Can you outline the significance of the current regulation to the industry and in particular the impact it has on GMIA’s members?

April 1, 2012 saw the single largest price cut across the portfolio of generic medicines in the history of the PBS. This was part of the 2010 reforms, so the market knew it was coming. The actual mechanism was designed to reflect the market price. The actual price reduction was different across different products ranging from no change to around 75% reduction and consequently impacted different businesses in a different way, depending on the amount of competition for a certain molecule. The government reports that the reduction was on target, but our members are reporting a higher impact, up to 32 percent. It led members to look at their business in a focused way: every line item is under review and scrutiny to ensure that each is delivering profitability.

Generics currently represent only 34% of the market in terms of volume and 14% in terms of value; how would you explain this fairly low market share?

The numbers demonstrate that generic medicines are very good value to the community and to the government. The relatively low market share of course create opportunities for our sector. We do have slow switch from originator to generic in this market because there is no price difference from a consumer point of view between choosing the originator or generic brand. We hope that the government can pick up on that to realize further savings are possible if we further drive the use of generics.

With international competition from countries in the region like South Korea, India, and China, how will Australia stay ahead of the curve in terms of remaining a destination for pharmaceutical manufacturing, also taking into account strong Australian dollar puts pressure on exports?
We have a large base of domestic activity. Our members employ 2.500 people, and we export over 550 million dollars on a total of 4 billion pharmaceutical exports. We have seven manufacturing and R&D sites, although two of those will be rationalized soon. These sites have traditionally been developed to service the Australian market but as a sector we are now looking more to the regional market. As Australia becomes a low-cost market through price disclosure, it is a fact of life that medicines can be sourced at a lower cost from offshore. Still, the high reputation of the Australian industry and our regulator give us a competitive advantage when exporting to the Asian region.

What is your vision for the Australian pharmaceutical industry in the next 5 to 10 years and what role will GMiA play in realizing that future?

The role of the generic medicines industry is critical to the sustainability of government funded medicines, particularly in a country such as Australia with a subsidized Pharmaceutical Benefits Scheme. The generic sector will play an increasingly critical role in sustaining this Scheme. GMiA plays an important role in ensuring that we get the balance right and that we do not introduce competition into a highly regulated market without ongoing review and monitoring on what the impact of that competition is. We need to find that balance where we find the best price for the Australian people and at the same time ensure the viability of the entire sector. We have all the building blocks in place in Australia; it is now all about creating a viable and vibrant pharmaceutical sector across all parts of the life cycle.

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