

# On new medications, market access and Malta's health system



PHARMACEUTICAL RESEARCH-BASED INDUSTRY MALTA ASSOCIATION

## INTERVIEW WITH MARK MALLIA



The recently announced Malta Budget 2014 included a key health-associated proposal that assured that new medications shall be introduced on the Government Formulary List in the coming year specifically targeting the treatment of multiple sclerosis, ADHD and diabetes. The announcement comes just a few hours prior to an interview with Mark Mallia, a pharmacist and President of PRIMA (Pharmaceutical Research & Development Industry Maltese Association). He shares some invaluable insight and concerns regarding the current situation on medicines and their availability in Malta.

“As PRIMA our priority mission is market access and we welcome any addition to the Government Formulary List (GFL) of available medications. However the regular access to innovative medications is listed in the EU charter for patients' rights and if our country is to abide with EU legislation, Malta should ascertain that it respects the set timelines by when our patients should have access to such drugs.”

Mr. Mallia voices strong concerns over Malta's innovation deficiency in terms of pharmaceutical products. He pinpoints a number of incongruencies in the system.

“Malta has not and is not abiding with the EU Transparency Directive, (Directive 2013/50/EU) mainly in terms of respecting the time frames within which new products are placed on the GFL (if introduced at all!). Variations are not simply days or weeks, but months and in some cases, years. There are specific conditions for which generic medications were introduced, when the proprietary medication was never introduced. This is unacceptable since it deprives patients of innovative solutions to their health concerns. Then again, some innovative medications are only available to the few who can afford to buy them from the private market.”

Mr Mallia adds:

“We must acknowledge the improvements that have been made to the quality of public health care in Malta, but investing in infrastructure and equipment is not enough. Restricting the introduction of better innovative medicines defeats the whole scope of providing high standard health care.”

But isn't it all about costs involved and sustainability? PRIMA has a hands-on approach to this issue.

“Significant cost increase? Not necessarily. We need to make the system more efficient and sustainable. We need to introduce more accountability on the use of medications, consumables and medical procedures through more defined protocols of use. We need better forecasting and purchasing systems, improved storage and distribution systems and improved market access. If innovative drugs are introduced on the Government Formulary in line with EU regulations, this would result in more competitive pricing for the government through increased availability of products. This would also provide the medical profession with more tailored treatment choices which are very often more cost-effective than older remedies. It would also benefit pricing in the retail market for those patients who might not fit the protocol criteria for the free innovative drugs. This can be achieved by adopting, where appropriate, policies and systems used in the great majority of other healthcare systems in the EU.”

Scientific innovation has led to an increased life expectancy and a subsequent significant increase in the elderly population. The interview harnesses on the topic of sustainability of the system.

“With the common political decision that all health services are to remain 'free' or rather as is the reality, paid for by our taxes, sustainability of the health system will be very difficult to achieve and maintain due to the exponential increase in demand. A sustainability problem, besides limiting availability of new medications, also contributes to out-of-stock situations. This may cause poor control of the patient, which in turn may result in increased use of other health services, such as increased admissions to the general hospital at an overall higher cost.”

PRIMA believes that within the current scenario, significant improvements may still be made through the revision of certain policies and practices. Mr. Mallia goes on to explain immediate reforms which may be implemented.

“PRIMA suggests that the National Formulary should be revised and old medicines which have become obsolete be removed. Cost-saving should be reinvested in innovative drugs to bring the national formulary in line with that of other EU countries.

Part of the savings achieved from switching originator medicines to generic medicines should be reinvested into innovative medicines”.

PRIMA estimates that over recent years the Maltese government has saved at least 10 million Euros per year following patent expiration.

“As a research & development industry, our focus is on ensuring that patients who avail themselves of medicines locally, find ready availability medications which are the most advanced and of the highest standards possible.”

Mr. Mallia explains the entire process through which medications end up on the market, starting from the lengthy, costly and risky research and development process conducted by the pharmaceutical companies.

“By the time a product reaches the market, an average of 12 to 13 years will have elapsed since the initial synthesis of the new active substance. The cost of researching and developing a new chemical or biological entity has been estimated at Euro 1,172 billion in 2012. On average, only one or two of every 10,000 substances synthesized in laboratories will successfully pass all the stages to become marketable products. The invention and introduction of major life-saving, therapeutic, revolutionary treatments only makes sense if market access regulations/laws and procedures are adhered to. This benefits the long-term sustainability and profitability of the industry and of health systems alike, and ensures that investments benefit society through innovative and better health outcomes.”

“Our country is blessed with excellent human resources including some of the best medical professionals in the world as well as excellent hospitals and health facilities ... we want to be part of a state of the art health system which remains sustainable for present and future generations.” §

