



BRITISH GENERIC MANUFACTURERS ASSOCIATION

Tuesday, December 11th, 2012

Paediatric Extensions Costing NHS Hundreds of Millions

- SPC extensions cost NHS nearly £300million
- Figures could rise by a further £500million over five years

Patent extensions being evoked under the EU Paediatric Regulation are disproportionately “rewarding” drug companies and are conservatively estimated to have cost the NHS approximately £300million over the past three years while providing little significant benefit to younger patients.

Research by the British Generic Manufacturers’ Association (BGMA) - the UK trade body representing 90% of the generic supply market - shows that originator companies are generating huge financial returns through extended patents completely out of kilter with the cost and benefit of the work put in.

Unless modifications are made to the EU regulation, it is estimated a further £500million could be unnecessarily spent by the NHS over the next five years before an economic impact report is due to be published in 2017.

Under current EU paediatric legislation, originator companies can apply for an extension to the Supplementary Protection Certificate (SPC), which has already extended the patent period. In order to gain an additional six-months market exclusivity, companies have to research their medicine for use on children and provide information on the results.

The ‘reward’ to the company for carrying out this work is a further six months of overall patent protection from generic competition for the medicine as a whole, not just the paediatric versions. This means companies can achieve returns of hundreds of millions of pounds for an investment of as little as one or two million to carry out the paediatric research.

Warwick Smith, Director General, British Generic Manufacturers Association, said:

“It is morally right that paediatric uses of medicines should be researched and licensed. We do not object to there being a financial incentive, if one is needed, to encourage companies to do this work. It just seems that such a high return on such comparatively low investment is beyond all reasonable scale and proportionality. If unchecked this could cost the NHS a further £500 million over the next five years.

"There are many examples of a pharmaceutical company being granted an extension of patent in exchange for a paediatric trial of a drug and it raises important questions about the regulation and its current parameters.

"This blunt approach to regulation is costing the NHS hundreds of millions of pounds and we believe a more tailored approach is necessary. In cases such as Pfizer's blockbuster Lipitor™ we estimate the extension of patent protection through an SPC cost an additional £150million - all paid for by the NHS and the UK tax-payer.

"And importantly, we do not appear to be seeing many new formulations for children or totally new uses for unmet clinical need. Indeed, most paediatric medicinal versions have the same or similar uses as for adults."

The BGMA has researched SPC extensions granted over the past three years and conservatively estimated that they have cost the NHS a total of £284million. The below table details different examples looking purely at the UK market.

INN name	Brand name	Annual brand value (£)	Date of original SPC patent expiry	Sales for originator during additional SPC extension period (£)	Cost to NHS (£)
Losartan, Tablets	Cozaar™	£85,960,000	September 2009	£42,980,000	£32,235,000
Anastrozole, Tablets	Arimidex™	£67,080,000	August 2010	£33,540,000	£25,155,000
Valsartan, Capsules	Diovan™	£49,170,000	May 2011	£24,585,000	£18,438,750
Valsartan, Tablets	Diovan™	£860,000	May 2011	£430,000	£322,500
Latanoprost, Ophthalmic Solution	Xalatan™	£55,480,000	July-2011	£27,740,000	£20,805,000
Atorvastatin, Tablets	Lipitor™	£429,930,000	November 2011	£214,965,000	£161,223,750
Montelukast (all forms)	Singulair™	£70,971,264	August 2012	£35,485,632	£26,614,224
Total cost to NHS from September 2009 to present					£284,471,724

Warwick Smith added: "We believe that, as an alternative to extending the SPC, different branding and reimbursement regimes may be required to ensure that there is a proportionate and effective incentive."

"This could include an enhanced system of tax credits or bespoke reimbursement regimes, or direct grants. Medicines that may only be used in very low volumes, and are likely to be uneconomic to develop under 'normal' pricing arrangements, could be reimbursed at higher levels to take into account their societal value."

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Notes for Editors:

The British Generic Manufacturers Association represents the interests of UK-based manufacturers and suppliers of generic medicines and promotes the development and understanding of the generic medicines industry in the United Kingdom.

Generic medicines contain the same active ingredient and are as effective as the equivalent brand and cost much less, making the NHS drugs bill affordable. More than two thirds (68.9%) of all medicines dispensed by the NHS are generics yet they cost only xx% of the NHS drugs bill, a saving of more than £10billion* in England & Wales alone. Without generics, the NHS drugs bill would be approximately twice its current level. The average cost to the NHS of a generic medicine is £3.79, whilst the average cost of a branded medicine is £19.73. Competition from generics also stimulates the research based pharmaceutical industry to develop new medicines.

Our 25 members account for around 90% of the UK generics market by volume. Their work keeps medicines affordable for the Department of Health which allows further investment in other healthcare priorities, and promotes innovation in the development of new medicines.

We represent the views and interests of our members and industry to the UK government, the devolved administrations, regulators, other relevant third parties, including where appropriate the Institutions of the European Union.

* The saving of £10bn per year due to generic competition is based on a calculation of what the NHS drugs bill would be if all prescription medicines cost the NHS the average price of branded drugs, i.e. without the impact of lower priced generic medicines.