British Generic Manufacturers' Association

*Categorically speaking … Warwick Smith, BGMA Director General*

# Commissioning board set to focus on prescribing

It appears the newly formed NHS Commissioning Board intends to hit the ground running in terms of tackling inefficiency in the NHS by looking at the amount of money wasted each month on the unnecessary prescribing of expensive drugs.

The new board takes the financial reins from the Department of Health in April and it is believed one of the early initiatives set in motion will be to look at the prescription costs of GPs and crackdown on those who are out of kilter.

The annual NHS medicines bill is around £9billion and would be more than double that already but for generic competition.

The UK has one of the most mature generic markets in the world. Each year around two-thirds of all items dispensed in England and Wales are done so generically saving the NHS more than £10billion.

Despite this, a recent study - supported by the NHS Commissioning Board - showed that as much as £200million a year alone was being wasted by GPs prescribing just two branded drugs when cheaper and equally effective generics alternatives were available.

With the QIPP agenda driving reforms within the NHS, it seems now that greater focus will be made on inefficient prescribing as a means for freeing up budget which can be allocated elsewhere. Elsewhere our own research at the BGMA has also revealed the cost to the NHS of patent extensions being evoked under the EU Paediatric Regulation which in our view are disproportionally large compared to the benefits to younger patients.

We estimate that over the past three years use of the EU regulation could have conservatively cost the NHS more than £300million.

Unless modifications are made, this could grow by a further £500million over the next five years before an economic impact report is due to be published in 2017.

The way it works is that 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.

## Incentive

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.

We absolutely believe it is morally right that paediatric uses of medicines should be researched and licensed.

We also 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

This rather blunt approach to regulation is costing the NHS hundreds of millions of pounds and we believe a more tailored approach is necessary.

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 takes into account their societal value.

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***Warwick Smith***

If you would like to join the BGMA as an associate member please email info@britishgenerics.co.uk