GSK Public policy positions

Information to Patients about Prescription Medicines

The Issue

There are many differences in the ways that countries approach the provision of information to patients about prescription medicines. These may be for social, cultural and historical reasons and often result in different legal frameworks, as is currently the case across the EU compared with the US. GSK respects these differences whilst maintaining that the certain principles should always apply.

GSK's Position

– Patients should be able to readily access high quality up-to-date user-friendly information about their medicines.

– Information about prescription medicines for patients should be regulated to ensure accuracy and quality.

– Pharmaceutical companies should, like other sources, be free to supply accurate and balanced information about prescription medicines.

– Regulatory regimes should avoid unnecessary disproportionate and costly bureaucracy, which provide no additional benefit for patient.

We believe there is no evidence that allowing patients to access high quality information on their medicines would increase demand or healthcare costs. On the contrary, we believe that a better informed patient is likely to be more compliant with a prescribed treatment and may help healthcare systems save resources in the long run.

Background

The European Union

In many European countries patients are unable to readily access high quality up-to-date user-friendly information about medicines. The internet is increasingly the primary source of such information. This can expose patients to unregulated information from an enormous variety of sources. The only source that cannot provide this information on the internet in many European countries are the medicines' manufacturers themselves, as under current legislation this provision is often considered as direct to consumer (DTC) advertising, and is therefore illegal.

The internet, of course, has no borders. Patients can access the internet. They can therefore source information on medicines from outside the EU where different regulatory standards relating to patient information will often exist. This information, however, could be unreliable, even if coming from a pharmaceutical company's non-European website, as the licence in Europe may differ from the licence from where the internet site originates.

The way forward needs to address this situation. A harmonised solution is needed across all EU countries which would permit manufacturers to provide written and web-based, high-quality and regulated information on their products so all EU patients have access to such information in their own language.

In some European countries there are already excellent models of good information provision on medicines, with pharmaceutical companies playing an active role along with national regulatory bodies. Examples include the FASS- the Swedish Medicines Information Engine and the UK Medicines Guides.

GSK supports increased patient access to high-quality non-promotional information about medicines from manufacturers which we believe would directly benefit European patients and public health. GSK supports the highest standards of regulating this information provision.

Emerging Markets and Asia Pacific

GSK believes that patients in all Emerging Markets and Asia Pacific (EMAP) countries should also be able to access high quality non-promotional information on prescription medicines from multiple sources including pharmaceutical companies in line with the principles outlined in this paper. In the vast majority of EMAP countries pharma companies are not currently able to provide any information about their prescription medicines to the public currently.

USA

Many believe that the cultural and socio-economic context in Europe and most countries in EMAP are not suited to *DTC advertising* of prescription-only medicines by pharmaceutical companies. GSK accepts this assessment. In the US however DTC advertising of prescription medicine is legal and widely accepted within strict legal boundaries. Pharmaceutical companies are therefore able to advertise prescription medicines to patients including through television, print advertisements and the internet. In addition to DTC advertising, manufacturers are permitted, and for some products required under US law, to distribute FDA-approved patient labelling. Although less extensive than the FDA-approved professional labelling and written in words that consumers will understand, FDA-approved patient labelling provides risk and benefit information that is material to the decision by the patient (with the involvement of a health care professional) to use a prescription medicine.

Because of the stringent laws that apply, GSK has a detailed internal approval process for advertisements in the US, which includes review by medical, regulatory and legal specialists. US law gives the US Food and Drug Administration (FDA) the authority to *". . . require the submission of any television advertisement for a drug . . . not later than 45 days before dissemination of the television advertisement."*

GSK goes further than this as in addition, the industry code[1] and company policy require that all new television advertisements about prescription medicines must be submitted to the FDA for review and comment prior to broadcast. Further, the Industry code and company policy require GSK to spend an appropriate amount of time educating healthcare professionals on new medicines or indications before launching advertising directed at patients. Finally, the industry code and GSK policy also state that such advertising should:

– Be designed to responsibly educate the public not just about the medicine but also, where appropriate, about the condition for which it is prescribed,
– Be accurate and supported by evidence in accordance with FDA regulations,
– Include information on the risks and benefits of treatments,
– Provide information on other treatment options such as diet and lifestyle changes where appropriate,
– Be targeted to avoid audiences who are not age appropriate, specifically only placing TV and print advertisement with content not appropriate for children in programs or publications that are reasonably expected to draw an audience at least 80 per cent of whom are adults.

While patients must consult with their physicians about their condition and the appropriateness of a prescription medicine, and obtain his or her consent, before receiving such medicines, responsible and regulated pharmaceutical advertising is widely recognised as an additional useful source of health information.

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[1] See the Pharmaceutical Research and Manufacturers of America Guiding Principles for Direct to Consumer Advertisements About Prescription Medicines effective March 2, 2009.