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EDITORIAL

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BENEFIT/RISK ASSESSMENT FOR NON-PRESCRIPTION DRUG CANDIDATES

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In the middle of 2011, Eric Brass and colleagues[1] proposed a new framework to facilitate regulatory decision making in the assessment of drugs proposed as candidates for non-prescription status. They proposed, *inter alia*, a 'value tree' approach to allow the identification of drug specific attributes within common domains which apply to the benefits and risks of all non-prescription drugs. In doing so they created the components of a potential common language for the evaluation of medicines being considered for non-prescription use.

An endorsement of this approach from regulators came with mention of the value tree in the latest version of the Medicine and Healthcare Products Regulatory Agency (MHRA) guidance to those seeking a change of legal classification for medicines in the UK[2]. This guidance suggests that applicants use the tool early in the evaluation of their candidate drug to identify issues which, for example, may require specific risk minimisation measures.

Working with companies evaluating drugs for 'switch' and preparing for early meetings with regulators, the use of this value tree may provide several positive consequences. First, the framework may allow applicant companies to articulate the benefits of a switch in a structured way. Second, the implicit 'balancing' of the relative values for the benefit and risk attributes of the drug may encourage the quantification of these with data. Whereas companies are usually familiar with ways to quantify risk, they are sometimes inclined to assume that attributes such as 'improved access' can simply be stated. The need to quantify benefits may, for example, encourage companies to present good quality market and behavioural research data to illustrate the consumer benefit which the switch claims to offer. Even if the adoption of a quantitative approach does not lead on to a more formal benefit/risk evaluation, it has the considerable advantage of focussing the attention of regulators and sponsors on evidence; and, if this does not exist, how to generate it rather than to rely on opinions.

But it is in the provision of common domains for discussing the attributes of non-prescription drugs that the framework may add most value. The domains are highly relevant to non-prescription use and cover the possible benefits and categories of risk comprehensively. These domains have counterparts in the current US approach through the 'Switch Considerations' used by FDA to frame deliberations on switch by its advisory committees[3]. Using a common framework approach, drug-specific attributes may be more easily articulated by sponsors and

weighed by regulators. This even raises the possibility of comparing the suitability of drugs for non-prescription status across drug classes and between different regulatory systems (noting nonetheless the need to consider cultural and regulatory disparities), because a common structure is applied to the arguments.

The use of common frameworks in evaluating potential non-prescription drugs could lead to more transparent decisions and perhaps even more consistency between jurisdictions applying supposedly similar criteria. One way to explore the usefulness of the framework to companies and regulators may be to provide detailed examples of how it actually works. *SelfCare* welcomes papers evaluating the benefit/risk attributes of putative switch candidates – possibly starting with the most complex and controversial failed switches of recent years. Perhaps if we can become more fluent in the language of benefit/risk evaluations, we may hope to reap the benefits of the clearer communication that should follow.

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