

**Regulating Risk or Advancing Therapies?
Regulation and sustainability of medicines in a cash-limited economy**

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This paper examines the issue of whether the regulation of medicinal products provides an effective protection against risk, or acts as a barrier to the availability of therapies and to innovation. It considers whether the forces of economic sustainability and disease may justify a revision in individual and societal attitudes to risk.

Medicines are essential for healthcare in advanced countries, and used extensively. Most people not only rely on the safety of these products but also assume that use involves zero risk. Yet many understand little of the sophisticated regulatory mechanisms and complex decisions that are involved in regulating safety.

The regulatory systems that control the safety of medicines in developed nations are extensive, sophisticated, and based on a standardised international approach. There has been continuous development and expansion in the regulatory scheme and requirements since modern controls were introduced in the 1960s. However, the extensive tests and trials that are required to produce sufficient data are very expensive and lengthy. Furthermore, data is required for both safety and economic purposes. Systems for production and evaluation of such data are not always efficiently harmonised so as to minimise delay and cost.

It is becoming increasingly clear that the availability of future medicines, especially innovative products, is threatened by economic factors. Governments and industry are, therefore, considering the need for transformational approaches to the reduction of costs and delay in regulatory and health technology assessment systems, in order to ensure that both healthcare systems and industry remain sustainable.

Two linked developments may offer significant opportunities. First, there is an increasing trend towards strengthening of post-marketing vigilance systems for all product types, notably for medicines in the pharmacovigilance system. Secondly, the harnessing of modern information technology to post-marketing vigilance systems offers the possibility of swift and reliable monitoring of the active use of products in large populations. Taken together, these developments present the possibility of switching emphasis away from the costly pre-market testing of medicines towards complete lifetime monitoring. Thus, medicines might be approved for use earlier than at present.

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However, there are important technical and ethical challenges if such a significant change in approach were to be implemented. Such change would involve a potential but unquantifiable increase in risk for individuals who consume some medicines, but possibly not for global society. On the other hand, such change might lead to the earlier availability of more innovative medicines, and so reduce the risk of disease generally. Perhaps the leading obstacle to such a change would be public reception, driven by the media, of earlier product approval. In this respect, the outcome may be a triumph for fear over rationality.