

# GSK Public policy positions

## Incremental Innovation

### The Issue

Research literature tends to distinguish between categories of innovation and, in particular, between “radical” and “incremental” innovation. This distinction can be readily applied in the pharmaceutical sector where the development of a “first-in-class” medicine, with a new mechanism of action, will be regarded as radical innovation, and incremental innovation will refer to new drugs in an existing class which have a similar mechanism of action as the first-in-class, but differ in features such as, therapeutic profile, metabolism, adverse effects, dosing schedules and delivery systems.

However, one of the major challenges in Europe and elsewhere is to secure appropriate recognition of, and reward for, “incremental innovation”. Launches of medicines in existing classes have led to a perception that the pharmaceutical industry is focusing its effort on so-called “me-too” drugs that provide little or no added advantage, and therefore do not deserve recognition and reward. This position is misguided. It shows a lack of understanding of scientific processes and ignores the fact that most pharmaceutical R&D is incremental – indeed, incremental innovation is the key to most major advances in the treatment and prevention of disease.

This paper makes the case for supporting and rewarding incremental innovation and argues that if the products of incremental innovation were precluded from the marketplace by restrictive policies, pharmaceutical innovation would be undermined to the detriment of public health.

### GSK's Position

- **Incremental innovation reflects the realities of pharmaceutical R&D.** There is no guarantee that the first drug to market will be the best. Some new medicines will be revolutionary breakthroughs in disease therapy; however, others will deliver incremental benefits over existing treatments, in efficacy, improved tolerability or improved mode of administration. These incremental benefits are important, because they provide the path to more groundbreaking change and because they make a real difference to the lives of patients.
- **Incremental innovation supports therapeutic progress.** Therapeutic progress comes in many forms. There is no guarantee that the first drug to market will be the best possible therapeutic option for all patients. New medicines in an existing therapeutic class (i.e. those which have modifications in their structure or their pharmacological properties compared with “first-in-class”) are not identical and can have significant benefits. They differ in their therapeutic profile, metabolism, adverse effects, dosing schedules, delivery systems, improved formulation, different pharmacokinetic properties and other features.
- **Incremental innovation supports improved therapeutic administration.** More advanced dose delivery systems and dosage forms can bring significant advantages in terms of more sustained therapeutic drug levels, the possibility to administer smaller or fewer doses, or less invasive delivery.
- **Incremental innovation leads to continuous improvement.** The cumulative effect of numerous incremental innovations can sometimes be more transforming than an earlier radical innovation. In fact, a first-in-class has rarely remained the ultimate response to the treatment of a disease. The interaction between technological advances, scientific knowledge, progressively increased understanding of disease mechanisms, the use of drugs in clinical practice and industrial application can all lead to stepwise improvements and the launch of new products. 50% of the drugs on the WHO Essential Drugs List are compounds introduced subsequent to the first in a therapeutic class. Many of the major classes of drugs in current use owe their overall therapeutic effectiveness and clinical significance to important modifications in the first generation of drugs.
- **Incremental innovation improves clinical choice.** Having several alternatives within the same class enables physicians to treat the individual needs of patients and provides options. In many cases, first-in-class are eventually replaced by improved therapies which will show better safety, tolerability and/or efficacy.
- **Incremental innovation can result in new uses.** Existing drugs may be used for new therapeutic areas, for example, through modifications in their delivery system and/or formulation. In other cases, unexpected new indications may have revealed themselves through market use or through deliberate post-marketing research in the existing class.



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- **Incremental innovation drives price competition.** Evidence shows the existence of price competition in different therapeutic areas as a result of having various treatments available that would be substitutable in a majority of patients.
  - **Incremental innovation delivers economic value to healthcare systems.** Many studies have demonstrated the cost-effectiveness of innovative therapeutics in the overall healthcare budget.
  - **Incremental innovation should be recognised in government pricing policies.** A new medicine should be measured and rewarded on the basis of its value in actual therapy instead of a simplistic classification of “breakthrough” versus “me-toos”. The concept of value should encompass a range of different criteria reflecting different perspectives on what can be of value - clinical benefits, patient benefits and societal and public health benefits.
  - **Cost-containment policies that undervalue incremental innovation will discourage research in that therapeutic class.** This may prevent the development of important therapies, dash hopes of particular sub-group of patients with unmet medical need, reduce competition and significantly decrease the chances for successful and cost-effective disease management on a population level.
  - **Incremental innovation that meets established patenting criteria merits IP protection.** It has been suggested that patent protection should not be given to inventions comprising new uses of known compounds, different dosage forms or means of administration. However, the criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. And where patents have wrongly been granted, courts should (and have) corrected those errors.

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