Methods: Whether or not a medicine is innovative depends on its novelty and the benefits it generates. Novelties require something new, original and perhaps ingenious and is a necessary, but not sufficient, requirement for innovation. Novel pharmaceutical attributes include: new target of pharmacological modulation; new mechanism of action, new chemical structure, improved formulation, improved pharmacokinetics and efficient methods of production. Benefits depend on perspective. Whereas a patient would value health-related quality of life, life expectancy, safety and convenience, payers (e.g. UK NHS) will see value in population health and cost-effectiveness. A society might additionally value non-health benefits such as attracting pharmaceutical company investment in skilled jobs, and social responsibility (e.g. environment, neglected diseases).

Results: An effective vaccine developed in the UK against malaria would be considered highly innovative from a societal perspective, but not from an NHS perspective, as malaria does not affect NHS patients. Conclusion: Health benefits to NHS patients are already rewarded to (and in some cases beyond) the threshold for cost-effectiveness (£30,000 per QALY). There is no incentive for paying an additional premium. However, where benefits of innovation to society exceed the costs, there is an argument for reward. This should not be through price increases, but through taxation and patent laws. The Patent Box, which will decrease the corporation tax to 10% on profits from innovation in the UK, is one such mechanism. Alternatively, a 'sales-based' patenting scheme might vary patent duration according to the benefits achieved, as the clinical evidence matures from the time of licensing. This might benefit patients through the earlier introduction of generics when branded products are made available, and genuinely innovative products, while still allowing the introduction of 'me-toos' to compete on price.

Methods: The long-term success in post-marketing clinical studies is an ongoing market access advice a possible solution to help ensure long-term success in post-marketing clinical studies: cross functional teams or external consultation? Kirpekar S, Mallinson M

Conclusions: Remaining issues with this anti-rebate reform will be explored in this study.

Methods: Manufacturers are under increasing pressure to produce shorter clinical studies in order to bring drugs to market as soon as possible to maximize revenue maximisation before loss of exclusivity. At the same time, authorities from markets across the globe have demonstrated increased interest in post-marketing real-life clinical data in order to help make decisions with regards to reimbursement of drugs as well as their positioning in the treatment pathway.

Objectives: Manufacturers are spending increasing proportion of their budgets to produce this post-marketing clinical data. It is important to ensure if the data that is being produced is close to the needs of the payers. In majority of instances, it is seen that the data being created is quite far from the expectations of authorities to whom benefit it is being created. The data is typically considered for use in payer discussions only at the end of the clinical study when little flexibility is possible in the end-points and outcomes that will be demonstrated. Also, benefits such as considering early data cuts to present on-going benefit of this long term data is not always considered.

Results: Manufacturers and authorities need to think differently. Early data cuts, if shared with the payers, can lead to shorter clinical studies. A closer alignment between the outcomes requested by the authorities and what the industry aims to show will result in better alignment between what is presented to the payers and what the industry is trying to show. Authorities need to take into consideration the importance of the data cuts and the outcomes to be presented.

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