

## Novartis Position on Competitive Off-Patent Markets

The primary goal of a sustainable healthcare system is to provide the best possible care for any individual patient, while ensuring access for all patients to healthcare treatments through the efficient and appropriate use of resources. Both access to medical progress, as well as sustainability can be fostered through the respective contributions of originator and generic medicines. In shaping the rules for competition in off-patent markets a key question is how responsible substitution<sup>1</sup> should be enabled.

### Novartis Position

We believe that the enabling environment for competitive off-patent markets should be guided by key principles:

- Effective use of intellectual property promotes innovative research by providing a limited period of market exclusivity to recoup research & development investment. Patents should not be violated and generics should not be denied immediate market access after intellectual property expiry.
- In efficient off-patent markets where medicines are available from multiple high quality sources prices should not be subject to regulation but result from competition in the market supported by appropriate incentives on the demand side. Off-patent brands should compete under the same rules.
- Patients need to be informed about available treatment options. Manufacturers, prescribers, pharmacists and authorities have a shared responsibility to educate patients concerning characteristics of generic medicines and appropriateness of generic substitution including options for the use of the original product.
- Savings generated through increased competition and high-quality generics have to be passed on to society to fulfill the potential of lower healthcare costs and free up resources for innovative medicines.
- Patented and generic compounds should not be clustered in therapeutic reference price groups, since this weakens the incentives for incremental innovation in a therapeutic class. Such price linkage of a generic medicine to a still patented compound interferes with competition on price after patent expiry. The underlying assumption of full therapeutic equivalence of different compounds works to the detriment of individual patient therapy.

*Last updated on December 2008*

<sup>1</sup> We refer to our position on "responsible substitution" on how lawful substitution should be done.