

## S11-2 The Life Cycle Management Strategy of Drugs

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It is common pathways of drugs that patent expiry leads to the entry of generics (GEs) and sharp decline in their drug prices, low motivation among medical representatives and ultimately plunge in the sales of drugs. In the US and the EU, in particular, use of GEs is more strongly recommended and market share of brand drugs decline rapidly after their patent expiries. In addition, as to blockbusters, their me-too drugs enter market before GE entry, threatening blockbusters' market position.

Global development and sales of drug are key drivers for business growth and huge R&D expenditure of ¥100bn per one product is required. It may no exaggeration to say that global new drug development becomes extremely high-risk business. To reduce such risk is a role of Product Life Cycle Management (LCM) and there exist two patterns: LCM of new product and LCM of existing products.

Basic concept of LCM of drugs and the significance of pharmaceutical technology (new drug formulation) are described for further discussion of the role of pharmaceutical technology among participants.