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Risks to the Stable Supply of Medical Devices from the Perspective of Regulatory Science

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Summary

Various circumstances, such as earthquakes, fires, other disasters, equipment design problems, or manufacturing defects, may threaten the stable supply of medical devices, and therefore manufacturers and their suppliers undertake risk management with the aim of avoiding interruptions of supply. However, aggressive risk management may introduce new and different risks.

In this study, we set out to evaluate the risk associated with changes in the specifications of non-woven polyethylene fabric, which is used in the packaging of medical devices. We found that the responses of governments in the US, Europe, and Japan to these changes have been very different. This is an important issue, because we predict that problems with the supply of sterile pouches could result in a loss of domestic medical devices production amounting to as much as JPY61 billion.

We next developed a formula, using a production model tied to increasable production capacity, that correlates stable supply risk with market share. This formula enables us to calculate relative risk. Products with a high market share and no increasable production capacity face more than five times the risk of other categories of products. Methods of reducing this risk must be considered, and we classify such methods into short-term adjustments (e.g., carrying excess inventory) and long-term adjustments (e.g., improvements to market share balance and distribution of production sites).

Key words

Medical device, Risk management, Stable supply, Regulatory science