Regenerative Medicine

Review

わが国の再生医療実用化促進の規制整備と世界での位置づけ

New Japanese Regulatory Challenges towards Progress of Regenerative Medicine and Their International Impact

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Summary

To ensure that regenerative medicines using relevant cell-based products contribute more to human health care, it is essential that suitable measures be taken by the regulatory authorities and manufacturers regarding prompt and safe application of these products to patient care. In Japan, a new legal framework was recently established as the principal law covering this field– namely, the Regenerative Medicine Promotion Law. In line with this legal framework, the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Law– renamed the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act came into force in November 2014. This paper describes the scope, specific features, and significance of the new Japanese regulatory framework in comparison with those in Europe and the US, and also represents a perspective of development, evaluation and control of various innovative cell-based products using existing various scientific and technical guidelines. It is expected that regenerative medicine in Japan can be advanced efficiently, effectively, and reasonably through the use of currently established regulatory mechanism and relevant guidelines. The newly proposed approach “Minimum Consensus Package” together with the Add-on package in an individual case would be challengeable.

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