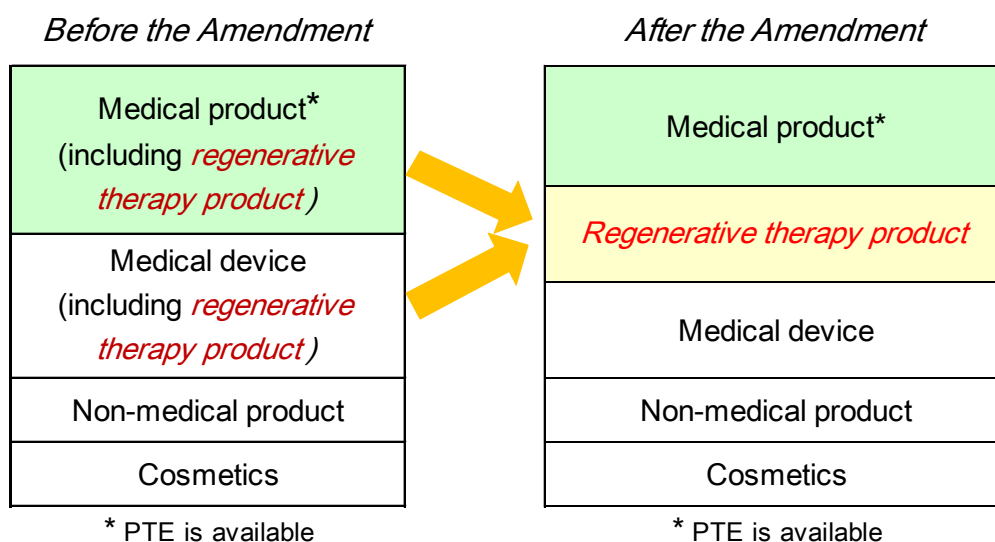

Patent Term Extension Moves to Cover Regenerative Therapy Products

Patent term extension (PTE) has become available for regenerative therapy products such as “cell sheets” and “cartilage regenerating product containing cells” in Japan. This was decided by “The Working Group for Study of PTE for Regenerative Therapy Products” set up under the Industry Structure Council, and was announced by the Ministry of Economy, Trade and Industry on February 26, 2014.

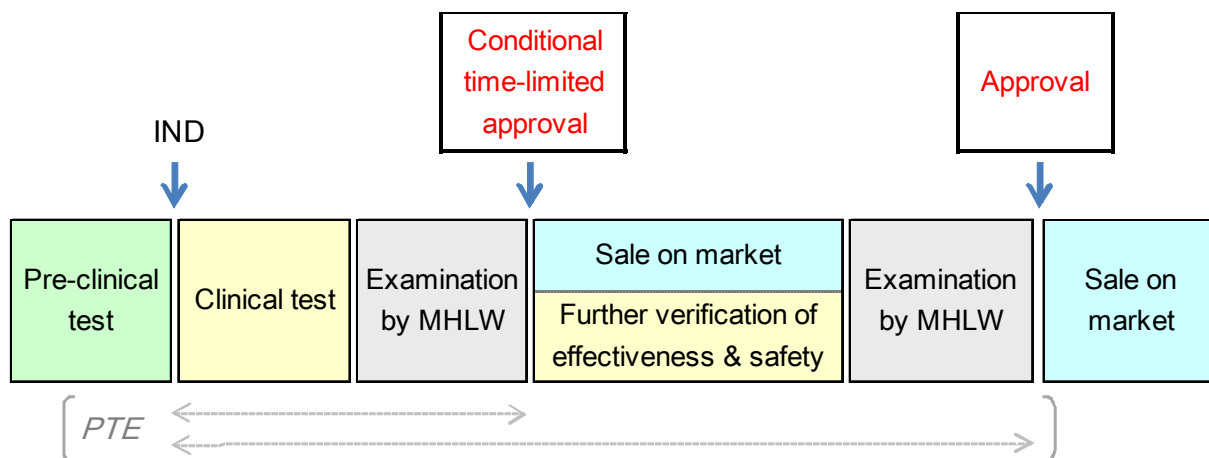
1. Background

The reason for this change in PTE is due to a recent amendment of the Drug Affairs Law. The bill for amendment of the Drug Affairs Law was passed in November 2013, and the amendment is expected to be enforced in November 2014. Two major changes in the amendment which will affect PTE are:

- (1) A new category “Regenerative Therapy Product” is created under the Drug Affairs Law. The regenerative therapy product consists of:
 - (a) “A product manufactured by processing a human or animal cell (e.g. cell sheets, cartilage regenerating product containing cells)” for which PTE has not been currently available, and
 - (b) “A product containing a gene which is introduced into a human or animal cell and is expressed (e.g. gene therapy)” for which PTE has been currently available.



- (2) “Conditional time-limited approval system” will be introduced for quicker approval of a new regenerative therapeutic product.



The PTE system must be adjusted to the amended Drug Affairs Law in terms of both of the above.

2. Agreed Change of the PTE system

“The Working Group for Study of PTE for Regenerative Therapy Products” held discussions and agreed as follows.

(1) The category “Regenerative Therapy Product”

PTE will be available for all regenerative therapy products”.

(2) “Conditional time-limited approval system”

The PTE term will be the period between an IND (Investigational New Drug) application and the time-limited conditional approval by MHLW (Ministry of Health, Labour and Welfare).

By this change of the PTE system in Japan, PTE will be available for "Medicine", "Regenerative Therapy Products" and "Plant Protection Drugs". The coverage of PTE will become similar to the European SPC (Supplementary Protection Certificate).

3. Future plan

(1) When the change will come into effect

The enforcement ordinance of the Patent Law will be amended and become effective at the same time as the amendment of the Drug Affairs Law, in November 2014.

(2) Transitional Provisions

The amendment of the enforcement ordinance will apply to applications for PTE filed on or after the enforced date of the amendment in November 2014.

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