JONES DAY | **Alert**
May 2015

JONES DAY

ALERT

Recent Developments in Regulations Governing the Manufacturing and Marketing of Induced Pluripotent Stem Cells

Japan continues to develop regulations governing induced pluripotent stem ("iPS") cells.

It is now permissible to launch regenerative products for medical use in humans or animals, including iPS cells, by using the fast-track approval process. As we explained in our December 2014 *Commentary*, "Amendment to Drugs and Medical Devices Law in Japan Takes Effect," the Pharmaceutical and Medical Device Law ("PMDL") established a new approval process for regenerative medicinal products. In this new approval process, the efficacy of the regenerative medicinal product is assumed (it is not required to be demonstrated) if the product is heterogeneous, and if the safety of the regenerative medicinal product is demonstrated through clinical trials and the efficacy of the regenerative medicinal product is assumed (it is not required to be demonstrated), the applicant may launch the regenerative medicinal product subject to certain conditions for a fixed term (the applicant then needs to obtain unconditional approval during the fixed term by demonstrating the product's efficacy).

It is also possible for an entity to provide a service to cultivate or otherwise process human or animal cells, including iPS cells, for a medical organization under the Act on Safety Assurance of Regenerative Medicine, etc., which became effective last November (the same date as the amended PMDL). Under this Act, an entity may provide such service to a medical organization if the entity obtains

CONTACTS

Scott Jones
Tokyo

Mitsutaka Okano
Tokyo

Masatoshi Adachi
Tokyo

QUARTERLY LIFE SCIENCES CONFERENCE
Enforcement and Compliance Trends in the Life Sciences Industry

September 17, 2015
Izumi Garden
Tokyo, Japan

■ Details

Beginning in September 2015, Jones Day will host quarterly video-conferences in Tokyo covering a number of key

authorization to cultivate or otherwise process human or animal cells from the Minister of the Ministry of Health, Labour and Welfare. The entity may not, however, provide such service for iPS cells derived from human blood due to restrictions under the Act to Secure the Stable Supply of Safe Blood Products in Japan. Under this Act, human blood may be used only for blood transfusions or academic research. Currently, iPS cells used for research are usually derived from human skin. The use of human blood, however, is a less invasive way to cultivate or otherwise process such iPS cells. But for the above reason, a medical organization needs to manufacture iPS cells derived from human blood at its own site.

On January 27, 2015, however, the Council on National Strategic Special Zones indicated that it is considering establishing a policy to permit an entity to sell iPS cells derived from human blood within certain special zones for testing purposes at a research organization. If this policy is formalized, an entity may collect human blood and manufacture and sell the iPS cells created therefrom for the purpose of testing at a research organization within the special zones that the government will specify. It is expected that research on iPS cells at research organizations in Japan will accelerate as a result, due to the time and labor saved by the research organization in not having to manufacture iPS cells derived from human blood at its own site. The relevant laws to implement this policy are planned to be submitted to the ordinary session of the Japanese Diet in 2015.

日本語版につきましては、こちらをクリック願います。

issues facing our clients engaged in the life sciences sector throughout the world.

These videoconferences will be free of charge and, other than the first conference, will be held at our office in Tokyo.
The first conference, titled "**Enforcement and Compliance Trends in the Life Sciences Industry**," will be live and will be held at Izumi Garden at 14:00 on September 17, 2015.

Should you or your colleagues wish to attend, please send an email to seminar@jonesday.jp.

Follow us on:

Jones Day is a legal institution with 2,400 lawyers on five continents. We are One Firm Worldwide℠.