



Tokyo, 24 November 2015

NOTE

Subject: First approval of a robotic suit as a medical device by the MHLW: HAL® for Medical Use (Lower Limb Type) by Cyberdyne, Inc. – Opening up the market for personal care and human assistant robotics.

On 10 November 2015 the Medical Equipment and External Diagnosis Subcommittee of the MHLW's Pharmaceutical Affairs and Food Sanitation Council approved of Cyberdyne, Inc.'s HAL® (Hybrid Assistive Limb®) for Medical Use (Lower Limb Type), a robotic exoskeleton developed to assist physically challenged persons, as a new medical device for orphan neural-muscular diseases. The MHLW is expected to officially certify the lower limb type robot suit by the end of this month and take into consideration whether treatments using the device will be covered by health insurance.

After being designated as orphan medical device by the MHLW in December 2014, thus becoming subject to priority review for marketing authorisation and officially applying for it in March 2015, the Council's subcommittee finally gave its consent for HAL® (Hybrid Assistive Limb®) for Medical Use (Lower Limb Type) eleven months later.

Prior to the Japanese approval Cyberdyne's robot suit was issued an EC certificate (CE 0197) for the European market by the German TÜV Rheinland in 2013 following an evaluation under the Medical Device Directive (MDD). Moreover, Cyberdyne Inc. has received the certificate of ISO 13485 (Medical Device) as a manufacturer of robotic medical devices and also became an early adopter of ISO 13842 (application in 2013 while still a draft; published in 2014), the first standard on safety requirements for personal care robots.

EU-Japan Centre's Comments:

- This is the first approval of a wearable robotic suit as medical device by the Health

Ministry, which poses an important step on the way to open up the Japanese market for personal care and human assistant robotics.

- Since Cyberdyne, Inc. has branches in Germany, Sweden, Denmark and the Netherlands it not only maintains a major connection to Europe, but to its most innovative regions. As the company sees itself, according to CEO Dr. Yoshiyuki Sankai, as a leader demonstrating by example and strongly emphasizes the importance of international collaboration, it is likely that the most promising European companies can benefit from Cyberdyne's experiences.
- On the other hand, the company's efforts in early applying for international safety standards, such as ISO 13842, as well as its actual participation in the ISO technical committee responsible for medical robots gives it the ability to better understand the procedures, challenges and benefits. Sharing those experiences with other companies can also be beneficial for pushing market standardisation in the field of personal care and human assistant robotics, thus, for example, lowering entrance barriers.
- In case that treatments using HAL® will be fully or even partially covered by health insurance, this might serve as a further driver for integrating robotics into daily life, similarly promoting acceptance, trust and sales in the long term.

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