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EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety and innovation

Teleconference meeting between the South Korean Ministry of Food and Drug Safety and DG SANTE B4

15 November 2018

Summary Minutes

Participants:

MFDS: Jaeho Jung, Jiae Kim, Jinyoung Shin

DG SANTE (Unit B4 Medical products: quality, safety, innovation): S. Van der Spiegel, D. Fehily.

1. The meeting participants were welcomed and introduced. The meeting had been organised in the context of the formal evaluation of the European Union legislation on blood, tissues and cells (BTC) that is currently being undertaken by the European Commission [1]. DG SANTE representatives explained that their request for the meeting was part of an effort to consult with some key international regulators in the field of BTC to explore commonalities and differences between the EU regulatory system and those applies elsewhere for these substances.
2. DG SANTE presented the BTC sector in Europe and explained that the legislation that had been adopted in 2002 (blood) and 2004 (tissues and cells) was being evaluated to assess whether it had been effective in meeting its original objectives and if it was still fit for purpose, given the changes that had taken place in the meanwhile.
3. DG SANTE had provided a list of written questions in advance. These were used to structure the discussion.
4. MFDS explained that the Biopharmaceuticals section of their organisation regulates cell therapy, gene therapy, plasma derived medicinal products (PDMP) and tissue banks. They noted that corneas are not included in the definition of tissues (as in the EU). Cornea banking is organised as part of organ transplantation programmes. Demineralised bone is also not regulated as tissue, but under the medical device regulatory framework. There is an ATMP law currently in the process of adoption. Blood components and haematopoietic stem cells are regulated as medicinal products, requiring marketing authorisation. There is currently no national regulation of gametes used for in vitro fertilisation.

[1] https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

5. MFDS explained that Korea does import substances of human origin from the EU, in particular, bone and skin. The conduct inspections of EU tissue banks as part of the authorisation of those imports in the Czech Republic, the Netherlands, Germany and Bulgaria. They work on a 5-year inspection cycle – in contrast to the 2-year cycle required by the EU legislation. They inspect against Korean Good Tissue Practices (KTPs) that are largely based on the United States standards. They find some differences with respect to EU requirements. Notably, they require Nucleic Acid Testing (NAT) for the mandated infectious diseases, while in the EU only anti-body testing is required. There are also some donor eligibility differences and some differences with regard to medication history requirements and recall procedures.
6. Korea imports plasma for PDMP manufacture but only from the United States.
7. Korea does not export blood components from Korean to the EU.
8. In the Korean regulatory frameworks, there are three levels in the regulatory system:
    a. Primary law ~~and enforcement~~ e.g. the Pharmaceuticals Affairs Law, the Human Tissue Act, - need for approval by the National Assembly
    b. Secondary legislation and enforcement e.g. GMP/ GTP - no need for approval by the Assembly
    c. Tertiary legislation in the form of Notifications that are issued directly by MFDS, as needed, and are legal binding.
9. The classification of substances of human origin under the different regulatory frameworks (e.g. Pharmaceuticals Affairs Law, Medical Device law and Human Tissue Act) is carried out within MFDS, where the departments regulating all the different categories of product are located.
10. To ensure sustainability of supply of blood, there is a rule that nationally collected plasma must be used for PDMP manufacture, before any import from other countries.
11. MFDS asked DG SANTE how the traceability of tissues is ensured in the EU when those tissues are used to manufacture ATMPs. It was explained that the Single European Code for tissues must form part of the records of the ATMP manufacturer.
12. DG SANTE thanked MFDS for their valuable contributions to the meeting and to the EU BTC Evaluation.