Finnish Red Cross
Blood Service

18.3.2013

European Commission
Health and Consumers Directorate-General
Health Systems and Products
Medicinal Products – authorizations, EMA

By e-mail to: SANCO-ADVANCEDTHERAPY-REPORT@ec.europa.eu

Submission of comments on Public Consultation Paper on the Regulation on Advanced Therapy Medicinal Products (1394/2007)

Comments from:

Name of organization: Finnish Red Cross Blood Service

The Finnish Red Cross Blood Service is a financially and operationally independent, non-profit unit within the Finnish Red Cross. It is a centralized organization providing nationwide blood services in Finland.

The Finnish Red Cross is a public-law association recognized by the State of Finland. The Finnish Red Cross is the only national association in Finland that belongs to the International Red Cross and Red Crescent Movement. In its operations, it complies with the basic principles adopted at the International Conferences of the Red Cross.

Comments on point 2.3 Hospital exemption

Based on the hospital exemption in Regulation 1394/2007, the Finnish Medicines Agency (Fimea) have published comprehensive guidance on advanced medicinal products (ATMPs) prepared on a non-routine basis according to specific quality standards (Fimea 3/2009). Fimea has given a national authorization based on this exemption guidance for the production of mesenchymal stromal cells (MSCs) in the Finnish Red Cross Blood Service for patients with graft-versus-host-disease (GvHD) non-responsive to steroid treatment (expected mortality 60 – 90%). Our view is that the possibility to produce ATMPs based on a national authorization is of utmost importance for the two following reasons:

1. <u>Unmet medical needs</u>

   In many instances ATMPs that are regulated today have already been used for some time with good success (no safety issues, efficacy expected). In some cases, use of ATMPs may enable treatment of cases where there is an urgent medical need but no traditional/established medical treatment available. It is of great importance that cures based on ATMPs with a profitable benefit/risk ratio can be provided for the patients until adequate marketing authorized medicines become available. Furthermore, development may result in some products/cures that are so rare and individually tailor-made that the national authorization of non-routine production is preferable to marketing authorization.

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2. Development of ATMPs

Research and development of ATMPs is a novel, rapidly increasing and evolving area. An important part of the innovation, scientific research and development is done in hospitals, organizations such as blood establishments and academia where the development is most often driven by the medical needs and science instead of financial interests. Available resources are not comparable to those of the pharmaceutical industry. From the aspect of the needs of patients and healthcare, it is crucial that this not-for-profit driven development is further encouraged and facilitated and that it is done according to the hospital exemption. Only such widely performed innovative early development will enable discovery of potential new ATMPs and give rise to further pharmaceutical development and products reaching marketing authorization leading to safer or more efficacious advanced medicinal products.

Comments on point 2.4 Incentives for the development of advanced therapy medicinal products

In order to support the development of ATMPs, the application of incentives provided in the Regulation, such as certification for quality and non-clinical data, reduced fees and scientific advice, should be extended to cover also hospitals, organizations such as blood establishments and academia.

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