Public Consultation Paper on the Regulation on Advanced Therapy Medicinal Products

2. CONSULTATION TOPICS

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2.3 Hospital exemption

The application of the hospital exemption for ATMPs should not only be considered as an exception for ATMPs prepared "…*on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient …*" (point n. 6 of the preamble and Art. 28) but the rule for all autologous ATMPs.

Actually, cells from each patients show unique features, their growth in culture should be carry out by a day-by-day procedures, and the process singly adjusted to get the output stated in product specifications, undoubfully generating *a custom-made product for* each *individual patient*.

As a consequence, the need of marketing authorization for autologous ATMPs appears a non-sense.

In our opinion, all autologous preparations in which the receiver donated their own cells or tissues to start the production of their own ATMP, should be excluded *by definition* from marketing authorization.

Moreover, obligation of marketing authorization for autologous preparations violates the sense of declarations stated in point 1 and 7 of the preamble, restricting the real chance for European people to received benefits from "*... new opportunities for the treatment of diseases and dysfunctions of the human body*", and limiting *de facto* the authority of Member States (" … *It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells …*") since only benefits the views of parties worried about ROI (as can transpire from the opinion reported in the Public Consultation Paper advice "*... a too large application of this exemption may discourage the application for marketing authorizations ...*") and not the single patient and medical doctor.

Finally, declarations stated in point 15 of the preamble ("*... human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation …*" and "*... Member States should be urged to take all necessary steps to encourage a strong public and non-profit sector involvement in the procurement of human cells or tissues, as voluntary and unpaid cell and tissue donations may contribute to high safety standards for cells and tissues and therefore to the protection of human health*") are matter of concern as European Community could legally authorized enterprises (i.e. with the release of a marketing authorization for ATMPs) to commercialize products manufactured starting from a gratuity from a donor.

2.4 Incentives for the development

Coherently with most of statements in the preamble of Regulation 1394/2007, non-profit public tissues and cells banks involved in the development of ATMPs for autologous application should receive specifically financial support helping to develop and manufacture advance therapies of the best quality in terms of safety and efficacy.