IN GENERAL

Comment 1:

The ATMP Regulation should urgently be revised to focus on delivering affordable therapies to all those who are in need, without necessarily "placing these products on the European market". The most rapid and elegant way to achieve this would be for the European Commission to publish an interpretative document on what is understood by the "placing on the market of ATMPs", by analogy with the Medical Devices[1]. This document should guarantee that tailor-made and niche ATMPs are kept outside of the scope of the Medicinal Products Legislation and that, by doing this, the availibility of these products / these therapies to the patients remains assured.

[1] *European Union | European Commission (DG Health and Consumers) | Interpretative document of the Commission's services:* ***Placing on the market of medical devices****; 2010. http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/placing_on_the_market_en.pdf.*

IN RELATION TO "HOSPITAL EXEMPTION"

Comment 2:

According to the ATMP Regulation itself, ATMPs which are 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 (generally referred to as the "Hospital Exemption") should not fall within the scope of the ATMP Regulation[2].

[2] *Regulation (EC) No 1394/2007 (ATMPs)*

Whereas:

(6) This Regulation is a lex specialis, which introduces additional provisions to those laid down in Directive 2001/83/EC. The scope of this Regulation should be to regulate advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, in accordance with the general scope of the Community pharmaceutical legislation laid down in Title II of Directive 2001/83/EC. Advanced therapy medicinal products which are 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, ***should be excluded from the scope of this Regulation*** *whilst at the same time ensuring that relevant Community rules related to quality and safety are not undermined.*

Furthermore, since these products are not intended to be placed on the market and are not prepared industrially or manufactured by a method involving an industrial process, these products are not covered by the scope of the Medicinal Products Directive 2001/83/EC either[3].

[3] *Directive 2001/83/EC (MPs)*

Title II | Scope| Article 2

1. This Directive shall apply to medicinal products for human use ***intended to be placed on the market*** *in Member States* ***and*** *either* ***prepared industrially or manufactured by a method involving an industrial process****.*

Comment 3:

The ATMP Regulation is a *lex specialis* inside the Medicinal Product Directive (2001/83/EC), it addresses all ATMPs falling within the global scope of Community legislation on Medicinal Products. Therefore, if these types of products are not falling within the scope of the Medicinal Products Directive 2001/83/EC they cannot be considered as ATMPs either (Bredin-Prat Lawyers 2012[4]).

[4] Bredin-Prat Lawyers (2012) Treatment with Keratinocytes in View of the European Community Medicinal Product Legislation. Legal Advice to the Queen Astrid Military Hospital, Brussels, Belgium | Ref. 20 03 2012:1-8

Comment 4:

Obviously, these products also need to be regulated and since they are not regulated through the European Medicinal Products Directive or the ATMP Regulation (see previous motivations), they remain regulated (in full) through the European Cell and Tissue Directive (2004/23/EC) of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[5]. "In full" means the "the full scope of the Cell and Tissue Directive" ("from donation to distribution").

[5] Directive 2004/23/EC (C&Ts)

Chapter I | General Provision | Article 2 | Scope

1. This Directive shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications. **Where such manufactured products are covered by other directives**, this Directive shall apply only to donation, procurement and testing.

Comment 5:

When previous argumantation is not followed by the European Commission, at least the following sentence (see furher) should be added to Point (6) of Regulation (EC) No 1394/2007 (ATMPs):

[2] *Regulation (EC) No 1394/2007 (ATMPs)*

Whereas:

(6) This Regulation is a lex specialis, which introduces additional provisions to those laid down in Directive 2001/83/EC. The scope of this Regulation should be to regulate advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, in accordance with the general scope of the Community pharmaceutical legislation laid down in Title II of Directive 2001/83/EC. Advanced therapy medicinal products which are 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, should be excluded from the scope of this Regulation whilst at the same time ensuring that relevant Community rules related to quality and safety are not undermined. ***These products remain fully regulated through the* European C&Ts Directive 2004/23/EC.**

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