European Association of Hospital Pharmacists (EAHP)

Consultation Response

PUBLIC CONSULTATION PAPER

ON THE REGULATION ON ADVANCED THERAPY MEDICINAL PRODUCTS.

31 March 2013

INTRODUCTION

ATMP: The need for regulatory vigilance and maintenance of GMP requirements

Cautious support for the hospital exemption if accompanied by periodic review

Whilst EAHP has not yet been made aware of significant concerns arising in practice as a result of regulation 1394/2007 on advanced therapy medicinal products (ATMP) the Association is aware of concerns that have been expressed about potential overuse of regulatory exemptions in other fields of medicine e.g. in relation to orphan drugs[1],[2].

Accordingly, EAHP recommend any regulatory exemptions in the area of medicines should be accompanied by systems to monitor its application in practice and any potential misuse of the exemption, or use beyond intended purposes.

On this basis, EAHP gives cautious support to the maintenance of exemptions for ATMP regulation in hospitals, if supported by a process of periodic review of application.

A process for hospitals to "reality check" the application of ATMP exemptions with their relevant national competent authority could be a useful support mechanism for the regulation and should be considered by competent authorities in the context of this regulation.

The need to maintain GMP requirements for ATMP

Further to this EAHP wishes to highlight the need for GMP requirements to be in place for ATMP, as would be the case for other classes of medicinal product.

GMP is an important component in the maintenance of patient safety in relation to any medicine and we are not aware of a strong case for ATMP to be exempt in this regard.

EAHP therefore advise the Commission to satisfy itself that requirements for ATMP GMP are in place across the EU in the context of this consultation exercise.

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[1] Message posted to e-drug, Tue, 20 Aug 2002 available from http://lists.essential.org/pipermail/ip-health/2002-August/003403.html (accessed March 2013)

[2] BMJ 2010;341:c6471 available from http://www.bmj.com/content/341/bmj.c6471.long (accessed March 2013)

Consultation question 1: Are the requirements for marketing authorisation applications set out in the Regulation proportionate and adequate to ensure a high level of public health?

EAHP understanding and experience of these requirements to date suggests the regulation has been proportionate and adequate in the protection of public health.

We refer the Commission to our introductory comments to this consultation response, referring to the need to maintain monitoring arrangements in relation to the ongoing use of the exemption, and the need to ensure ATMP are produced in line with Good Manufacturing Practice (GMP).

Consultation question 2: Are the procedures foreseen in the Advanced Therapy Regulation to assess compliance with the essential requirements of the medical device legislation adequate?

The scope given to the European Medicines Agency's (EMA) Committee for Advanced Therapies (CAT) to oversee this issue appears to the EAHP as reasonable and correct.

As Healthcare Professional (HCP) stakeholders to the EMA, EAHP can see value in both the patient and HCP partners of the EMA being involved in the EMA's ATMP regulatory processes. These stakeholders can provide unique insights, perspectives and elements (and networks) of experience to some of the key questions of medicines regulation.

Consultation question 3: Please provide your views on the application of the hospital exemption

(See introductory remarks)

EAHP gives cautious support to the continuation of the hospital exemption. However, we refer to our two principal points of response:

1) The need to maintain systems of vigilance and monitoring in relation to how the exemption is being used in practice; and,
2) To ensure GMP requirements are being abided by in relation to ATMP production.

Consultation question 4: Please provide your views on the incentives provided for under the Advanced Therapy Regulation

EAHP agrees with the premise set out in the consultation document and the Regulation: that incentives are legitimate in terms of assisting the development of this area of innovation, and that certification for quality and non-clinical data, reduced fees, and scientific advice, are may be legitimate forms of support in this regard.

However, regulation must remain robust in relation to ATMP GMP requirements.

Consultation question 5: Please provide your views on the scope of the Regulation and in particular as to whether the scope should be modified to take account of technical progress

The current scope of the consultation appears correct. However, as developments in areas of cutting-edge innovation can be both sudden and unexpected, it is advisable for either the Commission or EMA to have a process in place to monitor the Regulation's fitness-for-purpose, and periodically consider if the scope should be modified. EAHP suggests this might, for instance, be conducted as an exercise every 5 years.