European Commission
DG Health and Consumers
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SANCO-ADVANCEDTHERAPY-REPORT@ec.europa.eu

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UNITED KINGDOM GOVERNMENT RESPONSE TO THE EUROPEAN COMMISSION PUBLIC CONSULTATION ON THE REGULATION ON ADVANCED THERAPY MEDICINAL PRODUCTS

Please find the attached the United Kingdom Government response to the European Commission's consultation on the Regulation on advanced therapy medicinal products (1394/2007/EC).

Yours sincerely,

Jonathan Mogford
Director of Policy

1. The MHRA welcomes the opportunity to comment on the European Commission's consultation on the operation of the Regulation on advanced therapy medicinal products (1394/2007/EC). Our experience is that much of the activity on ATMPs so far is still at relatively early, developmental stages, notably around clinical trials, so our experience of some aspects of the Regulation has been relatively limited. Because of this, our view is that further time/experience will be needed before a more informed and comprehensive assessment of the Regulation can be made.

Requirements for combined advanced therapy medicinal products

2. Some stakeholders in the UK have commented that further clarity of the co-ordination that exists between the Committee for Advanced Therapies (CAT) and the notified bodies would be helpful to the sector.

Hospital exemption

3. The UK has implemented a scheme under the hospital exemption (laid down in Article 3 (7) of 2001/83/EC). To date, one licence has been granted to operate under the UK's national scheme. We are aware that there have been calls from some quarters for harmonisation of the

arrangements that exist in Member States under the exemption. We are not currently convinced that there is a need for harmonisation of those arrangements. The specific parameters that apply under the exemption are laid down in the Regulation. During the negotiations on the Regulation, there was acknowledgement that it would be difficult to introduce harmonised arrangements given the wide range of healthcare arrangements that exist in Member States.

Scope and adaptation to technical progress

4. Some stakeholders in the UK have commented that in this complex, innovative area there are issues around the boundaries with other legislative instruments. For example, some of the products that may be developed in this area may be for the treatment of orphan conditions and so there are linkages with the Regulation on orphan medicines. We would suggest that this needs to be kept in mind going forward. Likewise, developing technologies of this kind raise important questions as to how the boundaries between pre and post authorisation regulatory activity are drawn and best operated in the interests of patients.

Conclusion

5. As mentioned previously, this is a relatively new developing area and experience is limited with only two products authorised under the centralised procedure to date. Nevertheless, interest and focus on this innovative area of medicines is increasing. As the area further develops, it will be important to monitor the issues that emerge in order to fully assess the impact of the legislative framework. Overall, we detect a strong interest among interested parties in ensuring that channels of dialogue and advice at both European and national level are operating effectively in order to help operators navigate their way through an inevitably complex regulatory environment.