Medizinische Hochschule Hannover

Exzellenzcluster REBIRTH
"From Regenerative Biology to Reconstructive Therapy"
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DG Health and Consumers
Unit D5
'Medicinal products – authorizations, EMA'
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Ihr Zeichen	Ihre Nachricht vom	Unser Zeichen	
		FA	27. März 2013

Public consultation on ATMP

Dear Madam, dear Sir,

We refer to the request for public consultation on Advanced Therapy Medicinal Products.

The collaborative project REBIRTH is one of the largest projects in Europe in the field of regenerative medicine. The mission is to develop new regenerative products and apply them clinically. REBIRTH's host university is Hannover Medical School (MHH), which was founded in 1965 and which is today one of the world's leading university medical centers with 7,610 full time equivalent employees, 2,960 students and more than 470,000 patients (in 2011). Hannover Medical School's research and patient care is setting national and international standards. MHH is also part of an excellent regional medical network. The outstanding success in interdisciplinary collaboration both within the MHH and with extramural scientific institutions is reflected in the fact that the MHH is German's medical university with the largest volume of grant funding.

We would like to comment on the following sections:

2.1. Market authorization application requirements for ATMP: The market authorization application for ATMP involves different amounts of data. To ensure public health protection the quality and relevance of the data presented by the manufacturer is of paramount importance. However, ATMPs are not comparable to chemical entities. Due to their heterogeneous applications and their individual characteristics an adapted regulatory perspective is required. Unfortunately, a consensus for the basic requirements defining the quality of ATMPs is currently missing. Therefore, an open discussion with experts in the field including all stakeholders is necessary. In general, we would like to suggest that the quality (and amount) of data required for market authorization for ATMP shall be justified on the basis of risk assessment.

2.3. Hospital Exemption: As part of the freedom of treatment, every physician shall have the option to use non-licensed ATMPs. With respect to patientsafety the use of such non-licensed ATMPs shall be limited to those indications where there is no licensed ATMP of the same efficacy or no other adequate treatment available. The use of such non-licensed ATMPs shall not be limited in number or scope. A restriction would lead to unequal treatment of patients which would not be ethically justifiable. Applicable quality assurance measures shall apply to guarantee product quality and safety.

2.4. Incentives: The current EMA-policy of reduced fees for non-profit organizations and SME for ATMPs shall be continued according to the procedure applied to orphan-drug and children's care indications.

2.5. Extension of scope: Currently, there is no requirement for the extension of the scope of the regulation.

We hope that our comments contribute to a constructive discussion.

Sincerely yours,

Axel Haverich