DIN Deutsches Institut für Normung e. V.

DIN

Optics and Presicion Mechanics Standards Committee (NAFuO)

DIN Außenstelle Pforzheim · Alexander-Wellendorff-Str. 2 · 75172 Pforzheim

European Commission,
DG Health and Consumers,
Unit D5 'Medicinal products – authorisations, EMA'

SANCO-ADVANCEDTHERAPY-REPORT@ec.europa.eu

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Comments on Public Consultation
Public Consultation Paper on the Regulation on Advanced Therapy Medicinal Products

Dear Sir or Madam,

Please find attached the Comments on the Public Consultation Paper on the Regulation on Advanced Therapy Medicinal Products.

These comments are submitted by DIN Deutsches Institut für Normung e.V. on behalf of the German National Standards Committee NA 027-02-21 AA, responsible for Medical products utilizing Tissue Engineering Technologies and the secretariat of CEN/TC 316 "Medical products, utilizing cells, tissues and/or their derivatives".

In order to facilitate the further electronic processing of the comments, we enclose the comments in a word-file.

Yours sincerely,

DIN German Institute for Standardization
Optics and Precision Mechanics Standards Committee (NAFuO)

Elisabeth Leitner
Secretary of CEN/TC 316
NAFuO Standards Committee Manager

Petra Bischoff
Project Manager NA 027-02-21 AA

- Comments see next page -

Comments on
Public Consultation Paper on the Regulation on Advanced Therapy Medicinal Products

To Consultation Topic
2.1 Marketing authorization application requirements for advanced therapy medicinal products

The Market authorization Application for ATMP includes a varying amount of data. To ensure public health protection the quality of the data presented by the manufacturer is paramount.
However, due to the heterogeneity of potential applications and the specific characteristics of ATMPs that are not comparable to conventional chemically defined pharmaceuticals an adapted regulatory perspective is required.
Currently a consensus for the basic requirements defining the quality of ATMPs is missing. A broad discussion with experts in the field incl. medical practitioners, patient organizations, scientists and manufacturers is urgently needed. It would be most beneficial to pursue this task while recognizing the knowledge obtained with cell-based products that are already on the market.

To Consultation Topic
2.2 Requirements for combined advanced therapy medicinal products

No comments

To Consultation Topic
2.3 Hospital exemption

ATMPs are the products of innovative research on the potential of living cells to regenerate, replace or improve healing of tissues and organs. Due to the novelty of this product, group experiences obtained by their application result in many cases in the detection of improvement potential. The lifecycle of ATMPs is within 3 to 5 years from market introduction to development of an optimized product with improved performance characteristics. Compared to conventional, chemically defined pharmaceuticals with lifecycles of more than 10 years this is a very short timeframe.

The so-called hospital exemption is currently the best solution for a smooth translation process. The application of ATMP products under the hospital exemption must be based on a careful risk/benefit analysis considering benefits and drawbacks of other treatment options.

To Consultation topic
2.4 Incentives for the development of advanced therapy medicinal products

For SMEs and Start-ups further fee reductions for the Market Authorization Application are to be considered. In addition, scientific advice should be available for considerably lower costs.

To Consultation topic
2.5. Scope and adaptation to technical progress

Currently there is no requirement for the extension of the scope of the Regulation.