Advanced therapy medicinal products

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The committee adopted the report by Miroslav MIKOLÁ?IK (EPP-ED, SK) amending - under the 1st reading of the codecision procedure - the proposed regulation on innovative therapies. The key amendments were as follows:

- the committee took up an amendment submitted by the Legal Affairs Committee stipulating that the regulation ?shall not apply to advanced therapy medicinal products that contain or are derived from human embryonic or foetal cells, primordial germ cells or cells derived from those cells". This followed on from an amendment to Recital 6 which pointed out that legislation in force in Member States concerning the use of certain types of cells, such as embryonic stem cells, varies considerably and that the regulation ?should apply only to products made of cells, for which marketing is feasible in the near future and which do not raise major controversies";

- advanced therapy medicinal products prepared in full in a hospital "in a non-profit manner on a one-off basis according to a specific, non-standardised and non-patented process" should also be excluded from the scope of the regulation;

- a number of definitions were clarified: it was stipulated, for example, that tissue engineered products should be medicinal products and, moreover, should not include non-viable human or animal tissues. A combined product should be classified as an advanced therapy medicinal product when it is made of viable cells or tissue, or of components whose action can be considered as primary if they are not viable;

- to ensure the effectiveness of the risk management system, the ?efficacy and adverse reactions? of products should be monitored. The committee also tightened up the wording of the relevant clause so that the Commission would have an obligation, rather than merely opting, to require necessary measures to be carried out when there is a cause for concern;

- a number of amendments sought to strengthen the role, expertise and independence of the future Committee for Advanced Therapies, which will monitor scientific developments in this field and advise the European Medicines Agency (EMEA) when the latter assesses applications to market new products. MEPs said that the European Parliament should be consulted on the appointment of members of the CAT representing physicians and patients? associations. At least two or more members and alternates should have "scientific expertise" in medical devices. One amendment spelled out more clearly that members and alternate members of the committee must "have no financial or other interests in the biotechnology sector and medical device sector". In the case of a combined advanced therapy medicinal product, the entire product should be subject to final evaluation by the EMEA;

- the 90% reduction in the fee payable to the EMEA for scientific advice, which the Commission was proposing in order to boost innovation in the field of advanced therapy medicinal products, should be granted only to SMEs; other firms should get a maximum reduction of 65%. The committee also introduced new articles providing for financial incentives for biotech SMEs, a reduction of 50% in the marketing authorisation fee they pay and technical support for such firms;

- with regard to reporting and review requirements, the committee called for the Commission to assess the impact of technical progress on the application of the regulation and to put forward a legislative proposal, where necessary, to include ?novel therapies which involve neither gene therapy, cell therapy nor tissue engineering?;

- lastly, the committee felt that the two-year transition period proposed by the Commission for existing products to comply with regulation was too short, and proposed a four-year transition period for products other than tissue engineered products.