BIO DEUTSCHLAND

Position paper to current legislation about development and registration of Advanced Therapy Medicinal Products (ATMP)

The development of new therapies (like tissue engineered products and somatic cell - or gene therapy medicinal products) is positively evaluated everywhere and cited as a good example for high tech place Germany. Already the application of cellular therapeutical products leads to an improvement of patients' treatment with certain diseases which have not be treated appropriately so far. Promising new approaches are developing. The new legislation EG 1394/2007 about advanced therapy medicinal products (ATMP) entered into force as from December 30, 2008, determining specific rules for registration and surveillance of medicinal products for new therapies.

The association of biotechnology industry in Germany, BIO Deutschland, explicitly welcomes the ATMP legislation as a clear legal framework for these products. However the new regulation is partly inhibiting innovation, especially for small and medium enterprises (SMEs).

The new legislation demands an obligatory time and cost intensive centralised European authorization procedure. The given transition period to get the central registration approved for companies having already products in the market (some products have been in the market already for years) is so short that in the time given the requested demands cannot be implemented. As a consequence the companies concerned have to take off their products from the market. Sales breakdown has to be expected which especially cannot be compensated by researching SMEs. Most of these companies only have one or a small number of products in the market so that they cannot compensate their originating costs by other projects like in big industry. Furthermore the products having been reimbursed by health insurance so far now have to be delivered at no charge as testing compounds for clinical studies. The cost per testing compound can be in the range of several thousand Euros and SMEs might not afford this without risking the existence of the company.

Already in 2007, with the "tissue law" coming into force (German law about quality and safety of human tissue and cells) converting the EU guideline 2004/23/EG into national law SMEs were stressed by additional bureaucratic efforts inhibiting the development of innovative therapies.

Due to the number of interacting rules and the diversified interpretation by different German federal state authorities the situation is quite diffuse. Tissue or cell sampling being feasible in one federal state might be impossible under the same conditions in another.

Therefore BIO Deutschland claims:

1. To leave registered ATMPs being in the market as long for distribution as it takes to decide about the central registration procedure, if the application for registration had been filed to EMA before the transition period.
2. The support of clinical studies for ATMPs being on the market by compensation of costs for the testing compounds, which were reimbursed by health insurances so far.
3. Provide consistent and uniform rules concerning the "Entnahmestellen" in every federal state.