



EU FOOD AND DRUG UPDATE

The EU Food and Drug Practice of Sidley Austin LLP

Sidley’s EU Food and Drug practice assists multinational companies and trade associations with food, pharmaceutical, biotechnology, medical device, cosmetics and dietary supplement issues in the European Union and its 25 Member States. Our lawyers offer cross-border strategic advice for gaining and maintaining market access. We anticipate governmental actions, advise on approval and submission strategies, and interface with trade associations, consultants and governmental officials. Many major multinational pharmaceutical, biological and medical device companies turn to our group for assistance with compliance issues at European manufacturing sites relating to Good Manufacturing Practice, as well as EU Drug Safety/Pharmacovigilance and Quality System regulations. Our EU Food and Drug lawyers are experienced in matters involving the European Commission, including the Directorate-General for Enterprise, the Directorate-General for Health and Consumer Services, the Commission’s Legal Service and the European Medicines Agency. The EU Food and Drug group forms part of Sidley’s global Food and Drug practice, providing integrated quality legal services to meet our clients’ needs around the world.

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New EU rules proposed for gene, cell and tissue engineered therapies

The European Commission recently proposed a new EU Regulation concerning so-called advanced therapy medicinal products (gene therapy products, somatic cell products and tissue engineered products).¹ The proposed legislation establishes specific rules concerning the authorization, supervision and pharmacovigilance of advanced therapy medicinal products. The approach is based on a single, integrated European regulatory framework for all such products. The legislation, which if adopted will be directly applicable in all 25 EU Member States, will be of importance to innovative companies active in these fields. Stakeholders should monitor and influence the legislative process, which may take a year or more, to ensure that the final version of the EU Regulation is in line with their expectations.

Key elements of the proposal

- *Definition.* Advanced therapy medicinal products are defined as being either gene therapy medicinal products, somatic cell therapy medicinal products (which are both defined in current EU legislation), or tissue engineered products. A tissue engineered product is defined in the new legislation as “a product that: contains or consists of engineered cells or tissues; and is presented as having properties for, or is administered with a view to, regenerating, repairing or replacing human tissue”.
- *Scope.* The proposal addresses all advanced therapy medicinal products falling within the general scope of the Community legislation on medicinal products, i.e. “intended to be placed on the market in a Member States and either prepared industrially or manufactured by a method involving an industrial process”. Products that are both prepared in full and used within a single hospital are excluded from the scope of the proposal.
- *Marketing authorisation requirements.* Advanced therapy products will be subject to the same overarching regulatory requirements as other biotechnology-derived

¹ Proposal for a Regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) NO 726/2004, COM (2005) 567 final, available at http://pharmacos.eudra.org/F2/advtherapies-/docs/COM_2005_567_EN.pdf.

medicines. The type and amount of quality-related, pre-clinical and clinical data that is currently required to demonstrate the quality, safety and efficacy of gene and cell therapy products will also apply to tissue engineered products. In addition, an application for the authorization of a tissue engineered product shall include a description of the physical characteristics and performance of the product and a description of the product design methods. The Commission will draw up detailed guidelines on good clinical and good manufacturing practice for advanced therapy products. It will also lay down technical requirements that are specific to tissue engineered products.

- *Marketing authorisation procedure.* Marketing authorization for advanced therapy products will take place through a centralized EU procedure. The centralized approach is already used for gene therapy and somatic cell therapy medicinal products and will be extended to tissue engineered products. The Committee for Medicinal Products for Human Use ('CHMP') of the European Medicines Agency ('EMA') is responsible for evaluating the advanced therapy products. It will be assisted by a new Committee for Advanced Therapies ('CAT') within the EMA.
- *Pharmacovigilance.* In addition to the requirements for pharmacovigilance that already apply to centrally authorized medicinal products, an applicant seeking marketing authorization for an advanced therapy medicinal product shall detail the measures to ensure the follow-up of efficacy of such products. The Commission can also require, as part of the marketing authorization, that a risk management system be set up or that specific post-marketing studies be carried out. The EMA shall draw up detailed guidelines on post-authorization risk management.

- *Scientific advice regarding pharmacovigilance and risk management.* The EMA shall give scientific advice at a 90% reduced rate on the design and conduct of pharmacovigilance and of risk management for advanced therapy medicinal products.
- *Traceability.* The holder of a marketing authorization for an advanced therapy medicinal product shall establish and maintain a system ensuring that the individual product and its starting and raw materials can be traced through sourcing, manufacturing, packaging, transport and delivery. Traceability data must be kept by the marketing authorization holder for a minimum of thirty years, even if the authorization is suspended, revoked or withdrawn within that period.
- *Ethical Concerns.* In accordance with the subsidiary principle, the Regulation fully respects the national competence to decide on the use or prohibition of any type of cells. For example, advanced therapy medicinal products based on embryonic stem cells cannot be developed or marketed in a member state that prohibits embryonic stem cells and related products. However, within a country which does not prohibit embryonic stem cells and related products, advanced therapy products based on such cells can be both developed and marketed.

The Commission's proposal is now in the hands of the European Parliament and the Council (made up of the EU Member States) who can amend it before deciding whether to adopt it. This legislative process may take a year or more. During this period, stakeholders should monitor and, if necessary, influence the process, so as to ensure that the final version of the EU Regulation is fully in line with their expectations.

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