# ATMP: Belgian legislation at a glance

**About 2 years ago a milestone was set in the Belgian Advanced Therapy Medicinal Products ("ATMP") legislation. The publication took place in October 30th 2018, modifying the law of December 19th 2008 regarding the collection and use of human body material for the purpose of human therapeutic applications or scientific research (hereafter referred to as "the Law"). This law enables progress in the development of new, innovative therapies based upon handling of human cells and tissues for the production of medicines. Discover the most important elements of the law here.**

Since 2016 bio.be, the Belgian federation representing the biotech and life sciences industry, has been advocating to set-up a competitive and performant Belgian legal framework for ATMP's. It's no secret that since the start of these promising cell and gene therapies, Belgium has always been playing a prominent role at the level of R&D and production. Together with Denmark and Switzerland, Belgium attracts proportionally more ATMP clinical studies per capita than other countries, like for instance USA and Canada. The true potential of our country lies in reinforcing the upscaling and biomanufacturing efforts of the biotech spin-offs and start-ups in this domain.

Yet the awareness of the specific demand for the research, development and production of these cell and gene therapies is still a challenge. At the same time this translates itself in the need for an adapted legal framework. After 2 years of extensive preparation and concertation between the Federal Agency for Medicines and Health Products, the cabinet of the Minister of Health, the High Health Council, the Council of University Hospitals in Belgium, the representatives of the banks for human body material and the representatives of the Belgian biopharmaceutical industry, amongst others bio.be, the law of October 30th 2018 modifying the law of December 19th 2008 regarding the collection and use of human body material for the purpose of human therapeutic applications or scientific research, was finally published.

The 2 main changes of the Law concerning ATMP's are the following:

1. As far as the Intermediary Structures are concerned, the Law broadens substantially their action radius by (i) abolishing the prior and burdensome requirement of a contract with a Bank of Human Corporal Material (Hospitals) as pre-requisite for their accreditation by the competent authorities, and (ii) allowing Intermediary Structures to import (from outside the EU) Human Body Material directly, without intervention or transit by a Bank of Human Corporal Material.
2. The Law further regulates, in a transparent and non-discriminative manner, the allocation of autologous Human Body Material collected in Belgium by the Bank of Human Corporal material on the base of previously fixed allocation criteria.

This article has been realized **with the support of bio.be** , the Belgian federation representing the biotech and the life sciences industry. It operates under the aegis of umbrella organisation essenscia. Bio.be's members are part of an effective advocacy and regulatory voice representing the collective interests of the Belgian life sciences and biotechnology community. Bio.be has the tools to help its members' business reach its full potential - from R&D to growth and excellence in biomanufacturing - through advocacy, communications and membership services.

## What's next?

The missing piece in the legislative framework is the publication of the royal decrees, implementing the changed law of December 19th 2008. A change of the Royal Decree of September 28th 2009, regarding the quality and safety norms for donation, collection, obtaining, testing, processing, storage and distribution of human body material, to which the banks for human body material, the intermediate structures for body material and the production facilities need to adhere, urges itself upon. There is a need for the legality of intermediate structures, both at the level of accreditation conditions, as well as import possibilities.

## About the author

Marc Martens is board member of bio.be and partner of Bird & Bird. He is co-head of Bird & Bird's International Life Sciences & Healthcare group and head of Bird & Bird's Regulatory, Public & Administrative Law group in Brussels. He offers both contentious and non-contentious strategic advice to Belgian and international pharma, biotech and medical devices companies, public bodies and national and European industry associations facing complex regulatory frameworks. His areas of expertise cover issues relating to life-cycle management, clinical trials and data, data exclusivity, marketing, price and reimbursement authorisations, and e-health together with data protection, distribution and advertising issues. He provides advice to biotech companies on issues regarding Advanced Therapy Medicinal Products as well as the legal and bioethical issues relating to research and use of human cells and tissues. He regularly represents his clients before the national jurisdictions as well as before the European Court.

Marc Martens holds a law degree from the Vrije Universiteit Brussel (VUB), where he worked for four years as a research assistant, and a degree in public and administrative law from the University of Brussels. Before joining Bird & Bird, he was an expert adviser to the Vice-Prime Minister of Belgium for 3 years.

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which has been organised by at.las and bio.be on **February 9th, 2021**.
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