# Medical Devices Containing Human Tissues or Cells

## The Regulatory Framework of Innovative Therapies

**Marcel Boller**
Dr. iur., Attorney at Law, Wenger & Vieli AG, Zurich

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Abstract: Cells and tissues of human origin are used in the treatment of various diseases, such as cancer, diabetes and osteoarthritis. The new regulations regarding medical devices which are in force as of 26 May 2021 cover products containing human tissues and cells to some extent but continue to leave important aspects to national regulations. This article addresses the new rules under Swiss law and gives insights on how the competent authority Swissmedic handles products containing human tissues or cells.

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## I. Introduction

Medical devices are used to prevent, detect, treat or monitor diseases.[1] More and more patients are making use of treatments in which tissues and cells of human origin are used, either directly or after (biotechnological) processing.[2] The use of such cell or tissue preparations in medical care is no longer limited to transplantation.[3] Cells and tissues of human origin are also used in the treatment of various diseases, such as cancer, diabetes and osteoarthritis. In particular, cell therapies are now known and used in oncology.[4] The therapy uses patients' own cells and equips them with new genetic information. As a result of this new information, the cells can specifically detect and destroy certain cancer cells.

A particular challenge is to correctly qualify such products from a regulatory perspective.[5] Occasionally, these novel forms are grouped together as "neuartige Verfahren" ("innovative therapies").[6] The Directive 2001/83 and the Regulation (EC) No 1394/2007 of the European Union (EU) refer to such products as an advanced therapy medicinal product (ATMP).[7] Additionally, some frameworks are particularly shaped for tissue-based products (TBPs).[8] The legislation in the

1 See Federal Office of Public Health (FOPH), Explanatory notes on the total revision of the Medical Devices Ordinance and Ordinance on Clinical Trials with Medical Devices (new Medical Devices Regulation), July 2020, p. 6.

2 See Caroline Veronique Oberweis et al., A Worldwide Overview of Regulatory Frameworks for Tissue-Based Products, in: Tissue Engineering Part B; Reviews, Vol. 26 No. 2, p. 181 et seq., available at https://www.liebertpub.com/doi/10.1089/ten.teb.2019.0315.

3 Anne-Katrin Bock/Emilio Rodriguez-Cerezo/Bärbel Hüsing/Bernhard Bührlen/Michael Nusser, Human tissue-engineered products: Potential socio-economic impacts of a new European regulatory framework for authorisation, supervision and vigilance, p. 8, available at: ftp://ftp.jrc.es/pub/EURdoc/eur21838en.pdf.

4 Marieke Jansen, Bringing CAR-T to Reality, LSR 1/2020, p. 5 et seq.

5 Caroline Veronique Oberweis et al. (fn 2), p. 181 et seq.

6 Swissmedic uses the term "neuartige Verfahren" on its website: https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/besondere-arzneimittelgruppen--ham-/transplantation-products.html; However, this does not seem to be an established terminology as the term is not used in the guidance documents.

7 Art. 1 para. 4a Directive 2001/83 and Art. 2 para. 1 Regulation (EC) No 1394.

8 Caroline Veronique Oberweis et al. (fn 2), p. 181.