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Induced Pluripotent Stem Cell Therapies in Poland from a Public Health Perspective: Regulatory Deficit and the Untapped Potential of Pharmacists

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Abstract

A substantial part of this study consists of an analysis of the legal framework governing advanced therapy medicinal products (ATMPs), including the hospital exemption mechanism. The author highlights the lack of uniformity in the regulatory framework across the European Union and the differences in the approaches adopted by jurisdictions such as the United States, Japan and Switzerland. The aim of the paper is to evaluate Polish regulations against the international background and to identify possible directions for their further development, particularly in the context of planned legislative changes and the potential role of the pharmacist within the system.

Keywords: induced pluripotent stem cells (iPSCs), pharmacist, advanced therapy medicinal products (ATMPs)

Introduction

This year marks the 20th anniversary of the discovery of induced pluripotent stem cells (iPSCs), which represent one of the most rapidly developing areas of regenerative medicine. Stem cells possess unique capacities for self-renewal – understood as repeated cell division leading to the generation of daughter cells with identical characteristics – as

well as the ability to differentiate into specialised cell types that may be used for therapeutic purposes (Lin et al., 2013). Pluripotent stem cells can differentiate into cell types derived from all three germ layers: ectoderm, mesoderm and endoderm. However, unlike totipotent cells, they are not capable of generating an entire organism (Sobhani et al., 2017). Depending on their origin, stem cells are classified as embryonic, foetal or somatic (adult-derived) (Wrześniewska-Wal, 2016).

Shinya Yamanaka and Kazutoshi Takahashi's discovery of iPSCs (Sipp, 2011), derived from adult cells, broadened the spectrum of potential therapeutic applications while reducing some of the ethical dilemmas associated with the use of embryonic and foetal cells (Marei, 2025). iPSCs are generated by reprogramming somatic cells into a pluripotent state. Under laboratory conditions, pluripotent cells may be maintained in culture for prolonged periods while retaining an undifferentiated state and proliferative capacity (i.e. through passaging) (BobisWazowicz, 2025).

The dynamic development of stem cell research, including research on iPSCs, is opening new avenues for regenerative medicine (Wrześniewska-Wal, 2025). In clinical practice, iPSC-based approaches have been explored in the context of bone marrow transplantation for haematological disorders such as lymphomas, leukaemias, myelomas, anaemias and severe immunodeficiencies, owing to their capacity to restore blood formation through haematopoietic stem cells (Pecyna & Dulak, 2022). The use of iPSC-derived retinal pigment epithelial cells for the treatment of macular degeneration has also shown promise in clinical studies (Marei, 2025). At the same time, despite their considerable therapeutic potential, the safety and feasibility of stem-cell-based therapies continue to raise concerns, particularly with regard to the risk of immune rejection, tumorigenicity and other biological hazards (Herberts, 2011).

The biological nature of these products, which are based on living cells, distinguishes them from conventional medicinal products and is associated with specific regulatory challenges (Sipp, 2011). In the European Union, they are classified as advanced therapy medicinal products (ATMPs). The legal framework governing ATMPs has been shaped primarily by Directive 2001/83/EC (2001) and Regulation No. 1394/2007 (2007), which establish specific rules for marketing authorisation and safety oversight. Likewise, in 2024 the European Parliament adopted a proposal for a directive on the Union code relating to medicinal products for human use, which would repeal Directive 2001/83/EC. The proposed changes will also affect stem cell therapies, including iPSC-based ones, which do not fall within the ordinary regulatory pathway, but are instead subject to the mandatory centralised procedure for authorising ATMPs. In parallel, a distinct pathway is provided through the AMTP hospital exemption mechanism (ATMP-HE). The current EU framework in this area is general in nature and leaves Member States considerable discretion in implementation. As a result, the rules governing the use of the ATMP-HE vary substantially across Member States.

The aim of this paper is to analyse Polish regulations governing ATMPs, with particular emphasis on the ATMP-HE, in comparison with selected nonEU systems (the

United States, Japan and Switzerland). An additional objective, in light of the proposed introduction of the Union code relating to medicinal products for human use, is to identify potential directions for reform, including the better use of pharmacists' professional competencies. The analysis reveals significant regulatory fragmentation and demonstrates that strengthening oversight mechanisms and expanding the role of the pharmacist could improve the safety and effectiveness of iPSC-based therapies in clinical practice.

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Materials and Methods

The study is based on a comparative analysis of the EU regulatory framework governing ATMPs, including the ATMP-HE, Polish regulations in this area and, comparatively, the regulatory frameworks of the United States, Japan and Switzerland. The analysis also takes into account legal scholarship concerning inconsistencies in the implementation of the ATMP-HE in Poland. In addition, the paper draws on the theses presented in the author's conference poster, entitled "Between Law and Practice: Poland's Regulatory Deficit in iPSC Therapies and the Pharmacist's Untapped Potential", which was presented at the 6th Central European Biomedical Congress, "Integrating Neuropharmacology and Bioinformatics with AI" (Wrześniewska-Wal, 2025).

International Standards for Stem Cell Therapies

The biological specificity of stem cell therapies means that there are no uniform or universally accepted standards for assessing their quality, safety and efficacy. There is likewise no international consensus on the relevant legal framework, and the available guidance remains fragmented and often overly general. An important harmonising role is played by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), whose objective is to reduce the duplication of clinical trials and to harmonise registration requirements. The ICH was established on the initiative of five jurisdictions (Japan, the United States, Canada, the European Union and Switzerland). It develops technical guidelines intended to support the development and registration of safe, effective medicinal products (International Council, n.d.). Nevertheless, despite the ICH's activities, significant regulatory divergence persists, particularly with regard to cell-based therapies. As a consequence, legal systems such as those of the United States, the European Union, Japan and Switzerland have developed

their own distinct regulatory models, based on national product classifications and risk assessment. Under European Union pharmaceutical law, the general rule is that a medicinal product must obtain marketing authorisation before it can be placed on the market.

The product development process, from preclinical studies through clinical trials (including Phases II and III) to the granting of marketing authorisation, usually takes between 10 and 20 years and entails substantial financial costs (Carpenter, 2017). While conventional medicinal products may follow various authorisation pathways (national, decentralised, mutual-recognition and centralised procedures), ATMPs are characterised by a high degree of technological innovation, which justifies subjecting them to a specific regulatory regime. EU law therefore provides for an exclusive centralised procedure for the marketing authorisation of ATMPs. The Committee for Advanced Therapies (CAT) participates in the assessment and scientific evaluation of these products within the framework of the European Medicines Agency (Pecyna, 2024). Regulation No. 1394/2007 establishes specific rules governing marketing authorisation and post-authorisation safety oversight for these products, including requirements relating to pharmacovigilance quality systems, obligations to monitor data in EudraVigilance and the conduct of post-authorisation safety studies. Given the time-consuming nature of placing an ATMP on the market through the ordinary authorisation pathway, the EU legislator recognised that in certain exceptional circumstances the use of an ATMP may be justified, thereby ensuring that the patient can access innovative technologies which may be life-saving or health-preserving, while still safeguarding standards for safety and ethics (Pecyna, 2024).

This is the rationale underlying the ATMP-HE, which permits the individual use of such products within a single Member State, subject to quality and oversight requirements equivalent to those for centrally authorised products. The institution of the ATMP-HE is established in Article 28 of Regulation No. 1394/2007. That provision concerns a product intended for a specific patient and manufactured on a non-routine basis, according to an individual medical prescription. Its use is limited to a hospital setting, within the territory of the Member State in which it was manufactured, and under the exclusive professional responsibility of the attending physician.

In the United States, clinical trials designed to demonstrate the safety and efficacy of stem-cell-based products are regulated by the Food and Drug Administration (FDA). The regulation of cell-based therapies is based on the legal model established under the Public Health Service Act (2026), which distinguishes human cells, tissues and cellular and tissue-based products (HCT/Ps) according to their level of risk and degree of biological manipulation. A key distinction is drawn between products regulated under section 361 versus section 351 of the Act. Products meeting the criteria of minimal manipulation, homologous use and absence of systemic effect are classified as "361 HCT/Ps" and are subject to a simplified regulatory regime. By contrast, products that do not meet these criteria are classified as "351 HCT/Ps" and are treated as biological products, which

entails the requirement to obtain authorisation through the Biologics License Application pathway and to undergo full pre- and post-authorisation evaluation. Unlike EU law, the US system does not provide a formal hospital exemption mechanism; however, it serves a functionally similar role through a simplified regime for products that meet the criteria set out in section 361 of the Public Health Service Act. This framework is supplemented by Title 21, Part 1271 of the Code of Federal Regulations (n.d.), which establishes quality standards, donor eligibility requirements, oversight of manufacturing and distribution and measures to prevent the transmission of communicable diseases with respect to human cells, tissues and cellular and tissue-based products. The 21st Century Cures Act of 2016 introduced the category of Regenerative Medicine Advanced Therapies (RMAT), which enabled accelerated regulatory pathways for innovative therapies intended to treat serious or life-threatening diseases (Reis, 2029). The RMAT designation allows the FDA to formally identify the most innovative cell- and gene-based products that may substantially improve the treatment of serious conditions. In practice, RMATs perform a role that is functionally similar to the ATMP-HE, although in the United States RMATs constitute a formal federal regulatory designation rather than an exception to the requirement for marketing authorisation.

In Japan, stem cell therapies are governed by two statutes: the Act on the Safety of Regenerative Medicine (2022) and the Act on Securing Quality, Efficacy and Safety of Products, Including Pharmaceuticals and Medical Devices (PMD Act; 1960). The initiation of therapy involving stem cells, including iPSCs, requires the prior submission of a detailed health care provision plan. The plan is subject to review by a certified regenerative medicine committee (Article 28 of the Act on the Safety of Regenerative Medicine). The system is based on a risk-tiered approach (Classes I–III), meaning that the higher the risk, the more stringent the regulatory requirements. Under Japanese law, stem cell products constitute a distinct regulatory category alongside pharmaceuticals and medical devices, and they are subject to a separate approval pathway (Articles 23–25 and 23–37 of the PMD Act). In practice, products based on stem cells may be granted conditional approval, meaning that regulatory decisions may be taken on the basis of limited clinical data before full evidence on safety and efficacy becomes available. At the same time, the legislature has imposed specific obligations on entities manufacturing and using such biological products in the context of conditional approval. These obligations include the traceability of product flow, the identification of recipients (such as hospitals or physicians) and the maintenance of patient documentation.

In Switzerland, stem-cell-based products are registered within the framework established by the Therapeutic Products Act (2000), which also covers biological products and advanced therapies. As a rule, such products are classified as medicinal products of a biological nature, and placing them on the market requires prior authorisation by the Swiss Agency for Therapeutic Products (Swissmedic). The authorisation procedure is based on the demonstration of quality, safety and efficacy, taking into account the

specific nature of the biological material and the manufacturing process. Applicants are required to submit full documentation, including preclinical and clinical data, together with a detailed description of the manufacturing process in compliance with good manufacturing practice. Swiss law treats biological products, including ATMPs, as medicinal products subject to the general rules on marketing authorisation and regulatory oversight, without establishing a separate hospital exemption category. In practice, this means that every ATMP must either be assessed and authorised by Swissmedic or used for clinical research which adheres to the strict requirements governing clinical trials and ethical oversight. There is no automatic exception pathway allowing use in individual hospitals without full authorisation; any procedural simplifications are based on pre-authorisation access mechanisms and research-related decisions rather than on a separate legal category equivalent to the ATMP-HE.

Table 1. Comparison of the EU framework for ATMP hospital exemption with the regulatory approaches adopted in the United States, Japan and Switzerland

Country / Name of product	Regulatory framework	Competent authority	Procedure
United States / Biological products (HCT/Ps)	Public Health Service Act; 21 CFR Part 1271; FDA guidance	Food and Drug Administration	Accelerated pathway: Regenerative Medicine Advanced Therapy (RMAT) designation
Japan / Regenerative medicine products	Act on the Safety of Regenerative Medicine (2022); PMD Act (Pharmaceuticals and Medical Devices Act)	Pharmaceuticals and Medical Devices Agency	Conditional approval may be granted on the basis of incomplete clinical data, where there is an urgent medical need; mandatory post-authorisation surveillance lasts approx. 5 years.
Switzerland / ATMPs	Therapeutic Products Act (HMG) (2002); Swissmedic guidance	Swiss Agency for Therapeutic Products (Swissmedic)	Swissmedic is responsible for the authorisation and oversight of advanced therapies, including iPSC-based therapies.
European Union and Poland / Advanced therapy medicinal products	Regulation (EC) No. 1394/2007; national legislation	European Medicines Agency	iPSC-based therapies must be authorised by the EMA through the centralised procedure, using full preclinical and clinical data.

Polish Regulations

EU legislation in this field is framework-based and general in character, leaving Member States a margin of regulatory discretion as regards the use of ATMPs under the ATMP-HE. Pursuant to Article 2(33b) of the Polish Pharmaceutical Law (2001), a product under the ATMP-HE is an advanced therapy medicinal product within the meaning of Article 2(1)(a) of Regulation No. 1394/2007, prepared within the territory of the Republic of Poland on a non-routine basis, in accordance with quality standards, and

used in the course of hospital services provided within Poland, under the exclusive responsibility of a physician, in order to fulfil an individual prescription for a medicinal product for a given patient. However, the criteria in the Pharmaceutical Law for classifying a product under the ATMP-HE are not sufficiently precise. In particular, the provisions do not clearly indicate the scope of permissible non-routine manufacturing, the criteria for assessing "custom-made" preparation or the distinction between hospital exemption and industrial manufacturing. This may lead to inconsistent interpretation and application of the regulations in practice.

The key element distinguishing the ATMP-HE category from industrial manufacture is the absence of mass production, referred to in the legal definition as non-routine manufacture. In Polish regulations and guidance, however, there are no precise criteria that would allow this notion to be defined unambiguously**, for example, by reference to the number of patients, the number of batches or the duration of manufacture, which may encourage an overly broad application of the ATMP-HE beyond genuinely individual and exceptional situations**. The literature indicates that it would be desirable to introduce provisions that more clearly emphasise the individualised nature of the ATMP-HE (Pecyna, 2024).

In Poland, quality standards applicable to ATMPs have been implemented only partly through provisions relating to good manufacturing practice (GMP). However, therapies involving iPSCs generate specific risks requiring particular precision, such as validating the reprogramming, controlling the genomic stability and following procedures for batch releases. At present, there are no national regulations corresponding to the solutions provided for in Articles 14 and 15 of Regulation No. 1394/2007, which concern pharmacovigilance oversight (including the monitoring of adverse reactions and post-authorisation risk management) and product traceability systems, respectively. The supervisory obligations arising from Article 36g of the Pharmaceutical Law apply only to marketing authorisation holders, and therefore do not cover products used under the ATMP-HE (Pecyna, 2024). In this context, the model adopted by Swissmedic, which publishes guidance on GMP standards, deserves consideration.

In Polish law, the scope of the ATMP-HE has been specified by reference to "hospital services" within the meaning of the Act on Medical Activity, which gives the mechanism a systemic character and ties it to the national organisation of health care delivery. However, this formulation may lead to a restrictive interpretation and may potentially exclude some forms of treatment delivered outside formal hospital services, even though they might fall within the broader EU understanding. EU law emphasises that such products are used "under the exclusive professional responsibility of a medical practitioner", which underscores the professional character of the liability associated with the exercise of a medical profession. The Polish provision uses the simplified wording "under the exclusive responsibility of a physician"; however, this difference is primarily linguistic and does not lead to any substantial normative divergence.

Table 2. Comparison between Polish and EU regulations concerning hospital exemption

Aspect	European Union	Poland	Assessment
Element distinguishing hospital exemption from industrial manufacture	Non-routine manufacture	Non-routine manufacture	They are fully aligned, but in Poland there are no detailed guidelines on the number of patients, number of batches or duration of manufacture, for example.
Quality and oversight; GMP guidance	"in accordance with specific quality standards"	"in accordance with quality standards"	The Polish regulation is less precise.
Hospital setting	"used … in a hospital"	"within hospital services within the meaning of the Act on Medical Activity"	In Poland the scope of application is defined systemically. This may lead to a restrictive interpretation, for example, by excluding certain forms of treatment provided outside formal "hospital services".
Responsibility	"under the exclusive professional responsibility of a medical practitioner"	"under the exclusive responsibility of a physician"	EU law emphasises the professional character of liability; the Polish wording is linguistically simplified but substantively convergent.

Authorisation by the Chief Pharmaceutical Inspector

Under Polish law, the manufacture of a product under the ATMP-HE requires prior authorisation from the Chief Pharmaceutical Inspector, preceded by a permit issued by the Minister of Health for activities involving the procurement, testing, processing, storage and distribution of tissues and cells, which constitutes a prerequisite for the subsequent administrative procedure. In Poland, authorisation to manufacture products under the ATMP-HE is granted by means of an administrative decision issued by the Chief Pharmaceutical Inspector. The applicant submits documentation in accordance with the template laid down in the Regulation of the Minister of Health of 5 February 2019, including information on manufacturing sites, a list of products and designated competent persons (Regulation of the Minister of Health of 5 February 2019). The authority conducts both a formal and substantive review of the submitted documentation and issues its decision within 90 days of the filing of a complete application, although the time limit is suspended where the applicant is requested to provide additional information or where the proceedings are stayed (Article 38a(6)–(7) of the Pharmaceutical Law). The Chief Pharmaceutical Inspector then issues a decision either granting or refusing authorisation. Following the former, the authorisation is provided to the applicant either by post or in person.

Importantly, this authorisation does not constitute approval for a medical experiment or for the provision of a health care service. The opinion of a bioethics committee is a separate component of the procedure. The authorisation issued by the Chief Pharmaceutical Inspector is therefore limited to a formal administrative permit to manufacture

a product classified under the ATMP-HE. Complying with GMP requirements constitutes a significant organisational and financial challenge for hospitals and for the development of iPSC-based therapies in Poland. Where authorisation is granted for a product under the ATMP-HE, the manufacturer is required to employ a competent person who simultaneously meets the following criteria:

- holds a relevant Master's degree, medical degree or equivalent qualification (including a diploma recognised under the applicable legal provisions) in biological, chemical, pharmaceutical, medical or veterinary sciences
- possesses knowledge and experience relevant to the specific type of ATMP being manufactured
- has sufficient command of the Polish language to perform the duties associated with this role

The Role of the Pharmacist

Advanced therapy medicinal products manufactured under ATMP-HE must comply with quality standards equivalent to those applicable to medicinal products that hold marketing authorisation. Product quality is the foundation of the safety and efficacy of ATMP-based therapies; accordingly, the manufacturer is responsible for implementing and maintaining a comprehensive pharmaceutical quality control system, including procedures, human resources, documentation and mechanisms that comply with GMP.

Within this system, a pharmacist may serve as the professional responsible for ensuring that the manufacturing process complies with GMP requirements, including oversight of aseptic conditions and documentation. The Swiss model, characterised by high quality standards, may serve as a useful reference point. Pharmacists should also participate in the development of national regulatory guidance on GMP. At the same time, pharmacists play a key role in coordinating testing related to product identity, purity and potency, as well as assessing genomic stability and microbiological safety, while ensuring continuity of the chain of identity and compliance with the quality management system. In the context of the ATMP-HE, product traceability is equally important. The regulatory models adopted in Japan and Switzerland demonstrate that early access to therapy can be combined with robust post-authorisation oversight.

The competencies of a pharmacist should also encompass participating in pharmacovigilance systems, including the maintenance of registries, the analysis of adverse events and the design of post-authorisation surveillance plans. In products derived from iPSCs, batch-release procedures and long-term follow-up – particularly in relation to tumorigenicity and ectopic differentiation – are particularly important. This involves maintaining registries, analysing adverse events and designing surveillance strategies tailored to cell-specific risks.

In clinical practice, pharmacists may also provide educational support to patients, including assessing the risks and benefits, monitoring drug interactions (including those involving immunosuppressive therapies) and participating in the informed consent process in accordance with the principles governing the ATMP-HE. Such support may include educating patients concerning risks, benefits and post-administration follow-up obligations, overseeing medication reconciliation (for example, interactions with immunosuppressive therapy) and using standardised informed-consent forms.

Conclusions

Poland has a sufficient legal basis to introduce iPSC-based therapies in a safe, effective manner; however, practical deficits relating to the definition of the ATMP-HE, GMP requirements specific to iPSCs, consistency of oversight, financing and workforce preparedness create a gap between law and practice. Narrowing and harmonising the ATMP-HE, strengthening quality standards and pharmacovigilance requirements and systematically incorporating the pharmacist as a key actor responsible for quality and safety would accelerate the development of credible innovation and improve patient protection.

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Conflict of interest: The authors declare that there is no conflict of interest related to the publication of this study.

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