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Annex No. 11 to the MU Directive on Habilitation Procedures and Professor Appointment Procedures

PUBLIC LECTURE EVALUATION

Masaryk University	
Faculty	Faculty of Medicine
Procedure field	Pharmacology
Applicant	doc. MUDr. Regina Demlová, Ph.D.
Lecture date	17. 6. 2026, 13:00 hod.
Lecture topic	The Role of Clinical Pharmacology in Advanced Therapy Medicinal Products (ATMPs): from Development to Patient Access
Persons present (number)	38 (see attached list of attendees)
Designated evaluators (board members)	prof. PharmDr. Petr Babula, Ph.D. prof. MUDr. Ondřej Slanař, Ph.D. prof. MUDr. Jiří Vítovec, CSc. doc. MUDr. Kateřina Kopečková, Ph.D. Prof. Jacques Demotes-Mainard, MD, PhD

The public lecture delivered by doc. MUDr. Regina Demlová, Ph.D., provided a comprehensive, scientifically rigorous, and highly relevant account of the role of clinical pharmacology in the development, evaluation, regulation, and clinical implementation of Advanced Therapy Medicinal Products (ATMPs). The topic addressed by the lecture represents one of the most rapidly developing and conceptually challenging areas of contemporary biomedical research, with considerable relevance to academic medicine, translational research, regulatory science, and healthcare systems.

The lecture was logically structured and guided the audience from the fundamental principles of ATMP classification through the specific pharmacological characteristics of cell- and gene-based therapies to the regulatory, clinical, and societal aspects of their implementation. Dr. Demlová clearly delineated the differences between conventional medicinal products and ATMPs, with particular emphasis on the concept of "living drugs" and on the need to adapt classical pharmacological paradigms to the assessment of their efficacy, safety, persistence, and long-term clinical effects.

A particular strength of the lecture was the integration of established pharmacological principles with contemporary therapeutic technologies. Dr. Demlová demonstrated a profound understanding of the pharmacokinetic and pharmacodynamic specificities of ATMPs, including cellular kinetics, persistence, biodistribution, exposure–response relationships, immunological interactions, and the requirements for long-term safety monitoring. These complex scientific and methodological issues were presented with clarity and precision, while maintaining an appropriately high academic standard.

The lecture also convincingly linked theoretical knowledge with clinical experience and translational research. Of particular relevance were the examples of investigator-initiated clinical studies conducted at Masaryk University and University Hospital Brno, including dendritic cell-based immunotherapy for paediatric malignancies and mesenchymal stromal cell therapy for epidermolysis bullosa. These examples illustrated the translation of basic scientific findings into innovative therapeutic approaches and documented Dr. Demlová's substantial contribution to the field of advanced therapies.

The presentation further addressed the regulatory framework governing ATMP development in Europe and internationally, including the requirements of regulatory authorities, long-term follow-up obligations, and challenges associated with manufacturing, quality control, reimbursement, and patient access. Dr. Demlová demonstrated a comprehensive understanding of the entire development pathway of advanced therapies, from preclinical research and clinical evaluation to post-authorisation surveillance. The discussion of future developments, including gene-editing technologies, next-generation CAR-based therapies, and the establishment of ATMP Centres of Excellence, provided a forward-looking perspective and underlined the strategic importance of this field for modern clinical pharmacology.

From a pedagogical perspective, the lecture was delivered with clarity, confidence, and an excellent command of the subject matter. The presentation was supported by well-prepared visual materials and demonstrated the lecturer's ability to communicate highly specialised scientific information to an expert audience in a structured, comprehensible, and academically appropriate manner. Throughout the lecture, Dr. Demlová demonstrated broad interdisciplinary knowledge, scientific maturity, and a clear vision for the further development of clinical pharmacology in the era of advanced therapies. All questions raised during the subsequent discussion were answered in a highly competent, precise, and comprehensible manner.

The public lecture demonstrated outstanding scientific expertise, extensive research experience, and excellent pedagogical competence. Dr. Demlová presented a highly complex and rapidly evolving field in a coherent and intellectually mature manner, effectively linking fundamental pharmacological principles with current developments in cell and gene therapies. The lecture reflected her significant contributions to translational and clinical research, her recognised standing in the field, and her ability to contribute substantially to the development of innovative therapeutic approaches from experimental research to clinical application.

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Conclusion

The lecture delivered by doc. MUDr. Regina Demlová, Ph.D., entitled "The Role of Clinical Pharmacology in Advanced Therapy Medicinal Products (ATMPs): from Development to Patient Access" and delivered as part of the professor appointment procedure, **demonstrated** sufficient scholarly qualifications and pedagogical capabilities expected of applicants participating in a professor appointment procedure in the field of Pharmacology.

Date: 17.6.2026

prof. PharmDr. Petr Babula, Ph.D.	signature
prof. MUDr. Jiří Vítovec, CSc.	signature
prof. MUDr. Ondřej Slanař, Ph.D.	on-line
doc. MUDr. Kateřina Kopečková, Ph.D.	on-line
Prof. Jacques Demotes-Mainard, MD, PhD	on-line