INDENRIGS- OG SUNDHEDSMINISTERIET

DANSKE REGIONER

AMGROS

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Terms of Reference for collaboration to promote the development and implementation of advanced therapy medicinal products in Denmark (ATMP Danmark)

1. Background

Rapid technological and scientific developments are progressing advanced therapy medicinal products (ATMPs), covering gene therapies, cell therapies and tissue engineering technologies. These therapies hold great potential for patients. ATMPs can offer patients better and potentially curative treatments for serious and rare diseases where conventional drugs have limited effects and require continuous treatment.

Denmark is well positioned to become a pioneer in the development and implementation of ATMPs thanks to the Danish life science industry and strong professional environments at hospitals and universities within clinical research and personalised medicine.

The first ATMPs have already been implemented in the Danish healthcare system, but experience and analysis have revealed a number of challenges associated with the development and implementation of both commercial and academic ATMPs, making it difficult to realise the full potential. The challenges include regulatory complexity, limited national coordination in the area and the need for new models for collaboration between the healthcare system, the research community and the pharmaceutical industry.

Among other things, these challenges mean that some companies are looking to countries neighbouring Denmark that have already implemented national initiatives to create good framework conditions in the area. This could potentially delay Danish patients' access to new and effective medicines.

In early 2023, Danish Regions and Amgros established a national ATMP working group to share knowledge and coordinate efforts in the area. The working group has helped to uncover some of the challenges and identify relevant action areas to promote the development and deployment of ATMPs in Denmark.

Against this background, the *political agreement on Strategy for life science 2024-2027* of 21 November 2024 allocated DKK 25.5 million for the period 2024-2027 to implement a multi-pronged strategic initiative to promote the development and deployment of effective advanced therapies. The initiative entails establishing a national collaboration structure across the healthcare system, the research world and the pharmaceutical industry, conducting analyses and pilot projects, and establishing improved early regulatory advice from the Danish Medicines Agency on the development and approval of innovative drugs.

These Terms of Reference set out the purpose and deliverables of the strategic initiative as well as the framework for the national collaboration structure for the ATMP area in Denmark.

2. Purpose and deliverables

The purpose is to implement a national strategic initiative to promote the development and deployment of advanced therapy medicinal products (ATMPs) to help ensure that Danish patients have rapid access to the most effective treatments and to develop Danish strongholds within clinical research and life science.

The ambition is for Denmark to be a pioneer in the ATMP area by enhancing the framework conditions for clinical research in order to attract more clinical trials to Denmark, support the transition from research to treatment, and to make marketing ATMPs in Denmark more attractive. The initiative is to focus on

both commercial ATMPs developed by companies and academic ATMPs developed by hospitals and universities.

The ambition is ultimately to establish an ATMP Danmark with a coordination function in the area that can 1) serve as a single point of entry for clinicians, researchers and companies to receive guidance, 2) help establish collaborations on clinical trials, for example, and 3) support networking and knowledge sharing.

The initiative is embedded in a national collaboration structure (governance for ATMP Danmark), see point 3, which will support collaboration and coordination across Regions, universities, the pharmaceutical industry and relevant authorities.

As part of the initiative, analyses and pilot projects will be carried out to identify challenges and possible solution models, including the following:

I. Identify international experience with initiatives and development of organised national or regional ATMP "institutions" to gain inspiration and learning.
II. Identify regulatory conditions in the area in order to clarify regulatory ambiguities and challenges - the output may include guidelines, checklists or similar. This must be coordinated with work by the Danish Medicines Agency on early regulatory advice on innovative medicines, including ATMPs.
III. Describe solution models for collecting real-world data to generate better knowledge about how medicines are used and work in practice by securing regular follow-up on efficacy and safety when deploying ATMPs.
IV. Describe solution models for establishing a coordination function for the area, see above, including a suggested sustainable financing model.
V. Implement pilot projects to develop and test solution models for specific initiatives, such as collecting real-world data and establishing a coordination function.

Furthermore, it may be relevant to identify opportunities for increased collaboration and experience-sharing across the Nordic countries that builds on existing collaboration fora.

In parallel, the Danish Medicines Agency is responsible for establishing better early regulatory advice on developing and authorising innovative medicines ("innovative medicines" covers not only ATMPs, but also new types of medicines in a wider context). The Danish Medicines Agency will involve relevant stakeholders to get input on the form and content of this advice.

3. Collaboration structure

The collaboration structure consists of a steering group to set the strategic direction, formulate objectives and make decisions on initiating analyses, pilot projects, etc. and a reference group to contribute expert knowledge and support coordination and collaboration across the relevant actors in the area. Amgros is responsible for project management and secretariat services for the collaboration structure.

Steering group

The steering group sets the strategic direction, formulates objectives and makes decisions on the initiation of analyses, pilot projects, etc. The steering group will also help ensure progress in the activities initiated and support collaboration in the ATMP area.

The steering group may set up ad hoc working groups to support Amgros in work on the deliverables and involve the relevant expertise.

The steering group is chaired jointly by the Ministry of the Interior and Health and a health director appointed by Danish Regions.

The steering group consists of members appointed by the following organisations:

- Ministry of the Interior and Health
- Danish Regions
- A health director appointed by the Regions
- Amgros
- Three medical directors from university hospitals appointed by the Regions
- Danish Medicines Agency
- Danish Medicines Council
- Universities Denmark
- Danish Comprehensive Cancer Center (DCCC)

The steering group meets four times a year in principle, although more meetings are likely in the start-up phase.

Reference group

The reference group will contribute expert knowledge and input to work on the above deliverables. Members of the reference group will also help to disseminate knowledge and information about the deliverables from the initiative to relevant colleagues and actors to ensure anchoring across Denmark. The reference group will also secure relations with other national projects, organisations and strategies within the ATMP area. Efforts will be made to ensure that members of the reference group have significant insight into the ATMP field, including the development and deployment of ATMPs.

The reference group builds on the ATMP working group established by the Danish Regions and Amgros in 2023 to support knowledge sharing and collaboration coordination on ATMPs in Denmark.

The reference group consists of members appointed by the following organisations:

- Ministry of the Interior and Health
- Danish Regions
- Amgros
- Danish Comprehensive Cancer Center (DCCC)
- Danish Chamber of Commerce
- Confederation of Danish Industry
- Danish Society for Clinical Pharmacology, appointed by the Organisation of Danish Medical Societies (LVS)
- Dansk Selskab for Sygehusapoteksledelse (DSS)
- Danish Patients
- Universities Denmark
- Danish Association of the Pharmaceutical Industry (LIF)
- Danish Medicines Agency
- Danish Medicines Council
- Regions (one from each)
- Danish Health Authority
- Trial Nation

Project management and secretariat

Amgros is responsible for project management for the implementation of analyses, pilot projects, etc. and secretariat services for the collaboration structure. The tasks of Amgros include:

- Completing analyses, pilot projects, etc. as decided by the steering group, within the agreed timetable and the allocated budget.
- Collecting relevant expert knowledge and collaborating with relevant actors in the ATMP area in Denmark and abroad.

- Securing relationships with other relevant projects, organisations and strategies in the ATMP area.
- Supporting knowledge and experience sharing with relevant actors in the ATMP area.
- Preparing and following up on meetings of the reference group and steering group in close dialogue with the two chairpersons and including the Ministry of the Interior and Health and Danish Regions.
- Communicating and disseminating information about the project deliverables to relevant actors in the ATMP area.

In the long term, the goal is for Amgros to develop an ATMP Danmark with a coordination function as mentioned above that acts as a single point of entry for clinicians, researchers and companies to support collaboration and knowledge sharing in the ATMP area.

4. Timetable

The above deliverables are to be implemented with the funds allocated in the Strategy for life science 2024-2027, see point 5, and they must be completed by the end of 2027. The timetable for the individual deliverables will be determined in connection with the steering group's decision to launch.

There is an ambition to continue efforts and collaboration after 2027, and this will require clarification of a funding model between the parties involved.

5. Budget

The political agreement on the *Strategy for life science 2024-2027* of 21 November 2024 allocated DKK 18.5 million for the period 2024-2027 to establish a national collaboration structure and conduct analyses and pilot projects. The funds have been allocated to Amgros for implementation of the above tasks and deliverables, including:

- Secretariat services for the collaboration structure
- Project management and completion of analyses, pilot projects, etc.
- Involvement and collaboration with relevant actors in the ATMP area, including meetings, travel and events
- Communication and dissemination, including knowledge and information sharing with stakeholders in ATMP areas

Additional funding may be sought to implement further activities, e.g. from private foundations. Any applications for additional funding will have to be submitted to the steering group.

Funding for better early regulatory advice from the Danish Medicines Agency is not part of the above deliverables covered by the Terms of Reference.

Funds from the *Strategy for life science 2024-2027* for initiatives to *Promote the development and deployment of advanced therapies*, DKK million

	2024	2025	2026	2027
National collaboration structure, analyses and pilot projects anchored at Amgros	5.0	3.5	5.0	5.0
Better early regulatory advice on innovative medicines from the Danish Medicines Agency (covers more than just ATMP medicines)	1.0	2.0	2.0	2.0