Engagement

WP 6 deliverable:

Cross-border medical logistics via drones: Concept Paper on Technical and Legal Considerations

EDEN-Medical

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Executive Summary

Background

Medical logistics are increasingly challenged by time-critical delivery requirements, limited availability of essential medical supplies, and a strong dependence on conventional ground-based transport infrastructure. These vulnerabilities become particularly evident in crisis situations such as natural disasters, pandemics, or large-scale emergencies, when infrastructural damages, congestion, or border-related constraints can significantly delay the delivery of vital goods. Advanced Air Mobility (AAM) and drone-based transport systems offer a promising and resilient alternative. This potential is especially pronounced in cross-border regions such as the Meuse-Rhine region, where healthcare institutions in neighboring countries are located in close geographical proximity. A cross-border AAM-network for the transport of medical goods can strengthen regional healthcare resilience and disaster preparedness.

EDEN-Medical

Against this backdrop the project EDEN-Medical was initiated to facilitate cross-border cooperation between hospitals and relevant stakeholders in the region and identify barriers and regulatory gaps that currently stand in the way of transporting medical goods across borders via drone technology.

Objectives of the Concept Paper

This Concept Paper aims to highlight the medical necessity for such a cross-border medical drone-transport network by presenting the perspectives of relevant clinical and pre-clinical stakeholders, outlining the transport requirements of different medical goods and demonstrating technical and operational feasibility. Furthermore, it identifies necessary adaptations and developments with regard to drone systems, their integration into hospital infrastructure, and telemedical platforms connecting end-users with drone operators. After establishing medical necessity and technical feasibility, the main objective is to present the current status quo of administrative and legal frameworks and to identify core barriers and regulatory gaps that hinder the implementation of such a cross-border network. Finally, based on these findings, concrete recommendations are formulated for policymakers to advance regulatory conditions.

Target Audience

The target audience of this Concept Paper includes clinical stakeholders such as hospitals, healthcare networks, pharmacies and general practitioners, as well as pre-clinical stakeholders like emergency departments and fire brigades. It also addresses medical laboratories and other suppliers of medical goods and services, as well as small and medium-sized enterprises that are active in healthcare logistics or drone technology. On the regulatory level, the paper is directed at authorities, policymakers and legislative bodies at EU, national and regional level.

Current Landscape of Medical Goods Logistics

To gain direct input from clinical stakeholders structured interviews were conducted with 24 representatives of different departments in three hospitals located in the neighbouring countries of Germany, Belgium and the Netherlands (Ziekenhuis Oost-Limburg, Zuyderland Medical Center, University Hospital RWTH Aachen). The interviewed departments included pharmacy, pathology, transfusion medicine, laboratory services, crisis response teams, anaesthesiology, intensive care, emergency medicine, surgery and trauma teams, logistics departments, cornea bank, and flight operations. Based on these interviews, a list of medical goods was compiled, including information on the type of medical good, the typical weight and dimension and required temperature conditions during transport. In total, 24 different medical goods were identified as potentially suitable for drone transport. These include medical equipment (Automated external defibrillators, rescue buoys, telemedical devices, specialised catheters, paediatric surgical sets, emergency surgical sets, ventilator tubing and pneumothorax drains), laboratory samples (blood, semen, urine, faeces, breast milk and saliva), tissue samples (variable tissue samples, frozen section), blood products (whole blood units, frozen plasma, platelets), medication (Dantrolene, antidotes, other emergency medication) and transplants (corneal tissue, other organ transplants).

Across the different departments, medical goods are typically transported on a daily basis, often multiple times a day. These routine transports account for the majority of medical logistics activities. Even in these routine cases, however, time is often critical, as analyses and examinations depend on timely delivery and their results directly inform clinical decision-making, with implications for patient treatment and outcomes. In emergency situations, timely delivery becomes even more critical, often requiring ad-hoc transport solutions. While such emergency transports occur less frequently, and are inherently unpredictable, they currently heavily rely on taxi services, which are both costly and time-consuming.

In some cases, the limiting factor in medical logistics is not the transportation itself but the availability of urgently needed supplies. For example, the head of pharmacy at the University Hospital Aachen reports up to 700 delivery bottlenecks per year. Although strong cooperation with other pharmacies across Germany often allows these shortages to be mitigated, this typically involves transporting medication over long distances, even when supplies may be available just across the border. All interviewed stakeholders reported that cross-border transport of medical goods remains very limited due to restrictive national regulations, high administrative burdens, and unresolved reimbursement issues.

A focus group survey involving 14 pre-clinical and clinical stakeholders from all three countries validated the findings from the structured interviews. Participants emphasised the medical necessity for fast and reliable transport solutions and stressed that this need is not limited to exceptional crisis scenarios.

Technical and Operational Requirements

Medical goods vary considerably in weight, dimensions and transport requirements. A drone system must therefore be capable of carrying different payloads and accommodating varying sizes. Environmental and temperature requirements must also be considered, as some goods are sensitive to vibration or require strict temperature control. Continuous temperature monitoring and documentation in accordance with regulatory standards are mandatory. In addition, safety-related aspects such as packaging and positioning within the drone are critical, particularly for dangerous goods or biological materials, which may require specific packaging solutions (e.g. tear-resistant bags, shockproof containers, locking mechanisms to prevent unauthorised access) or upright transport. At present, no standardised cargo container exists that can be used across different medical goods and drone platforms.

Different drone systems offer distinct advantages and limitations, and selecting the most suitable system depends on the intended use case. There are three main types: multirotor systems enable vertical takeoff and landing (VTOL) and therefore do not require runways, making them well suited for short-distance transport despite their limited speed and range. Fixed-wing systems, by contrast, require runways but can cover longer distances at higher speeds, though their inability to hover makes them less suitable for confined environments. These systems are best suited for long-distance transports. Convertiplanes or hybrid aircrafts combine features of both system types, allowing VTOL while transitioning to fixed-wing flight during cruise, making them suitable for medium- to long-range missions.

For flight control and flight path planning, a high degree of automation is essential to ensure safe flights beyond the visual line of sight (BVLOS), which are monitored from a Ground Control Station (GCS). Ideally, such a GCS should be capable of managing flights of various drone types irrespective of the manufacturer.

Automation is equally important for integration into hospital infrastructure and logistics. Processes such as loading and unloading should require minimal personnel involvement. Ground infrastructure must be easily accessible, safe and interoperable with different drone systems. For hospitals with helipads, it is also crucial that drone operations do not interfere with helicopter traffic.

To connect the various stakeholders involved in operating, maintaining and using such systems and to ensure smooth integration into hospital processes, a digital platform is required. A dedicated telemedical platform can serve as the central technical infrastructure, integrating drone operations with hospital information systems and offering an intuitive, multilingual user interface. Hospital end-users could use the platform to order medical goods, check availability, and receive real-time delivery updates, while drone operators could manage and monitor flight operations. Beyond logistics, such a platform also offers potential for future extensions, including cross-border knowledge exchange.

Legal and Administrative Framework

Preliminary legal analysis indicates that the most significant barriers to establishing a cross-border drone (emergency) transport network for medical goods are legal constraints, regulatory gaps, and lengthy administrative procedures.

Drone regulations have been harmonised at the EU level with operations classified into three risk-based categories: open, specific and certified. Flights conducted within the visual line of sight fall under the open category and generally do not require authorisation. BVLOS operations, however, typically fall under the specific or certified categories and require flight authorisations or approval in each Member State involved. This creates a substantial administrative burden for cross-border operations. Authorisation procedures are often time-consuming, complex and further complicated by language barriers, fragmented national rules and the absence of a single procedure for cross-border operations. Moreover, no high-urgency procedures currently exist to enable expedited authorisations for time-critical operations. Due to the increased interest in and use of drones, aviation authorities are experiencing a high volume of applications, leading to longer processing times. Additional challenges arise from national differences in airspace management and lack of legally binding, harmonised geo-zone maps. This makes it burdensome for cross-border operators to combine multiple maps, understand local requirements and plan coherent flight routes across the cross-border region.

The legal framework governing cross-border transport of medical goods is similarly complex. Despite the EU principle of free movement of goods, significant restrictions continue to hinder the cross-border exchange. Regulations follow a risk-based approach and largely depend on the category of medical goods being transported. As of now there is an absence of clear guidelines, although the upcoming EU Regulation 2024/1938 on “substances of human origin”, which will apply from 7 August 2027 onwards, shows potential to improve harmonisation. Furthermore, the transport of infectious materials (such as blood samples) introduces an additional regulatory layer, as it may affect the type of authorisation required for drone operations or necessitate separate approval for the transport itself.

Other relevant legal considerations include insurance, liability, data exchange and reimbursement. Adequate insurance and liability arrangements must be ensured, particularly as they are a prerequisite for flight authorisation. However, uncertainties remain regarding liability in BVLOS operations and insurance coverage of transported medical goods. While data protection regulations govern the collection and processing of personal data, national differences in implementation continue to complicate cross-border health data exchange - an issue also relevant for digital platform development. Finally, financial questions related to reimbursement of medical goods and operational costs, must be clarified and agreed upon between hospitals, health insurance providers and drone operators.

Stakeholder Engagement and Institutional Cooperation

Identifying barriers for the establishment of network on cross-border drone medical logistics is only a first step. Translating these findings into impact requires clear strategies for stakeholder engagement, institutional cooperation and practical follow-up. Piloting projects such as EDEN-Medical pave the way for future progress. Projects and initiatives need to identify and target several relevant stakeholder groups, including end-users, operational actors, regulatory and policy stakeholders, industry actors and comparable initiatives. Structured engagement formats are essential to reach these groups effectively. EDEN-Medical has already employed structured interviews and focus group surveys to involve end-users early on and hereby support co-creation. Planned next steps include workshops with peer initiatives and industry actors to foster knowledge exchange, as well as policy- and administration-focused events aimed at informing regulatory bodies and achieving tangible impact. An evidence-based position paper bringing together insights from different initiatives, pilot projects and industry stakeholders will present findings and recommendations to lawmakers and support transferability to other regions.

Policy Recommendations

Based on these preliminary findings the following policy recommendations are proposed:

- **Harmonisation of EU and National Legal Frameworks:** Future policy efforts should focus on strengthening harmonisation between EU-level regulations and national legislation, with the aim of reducing legal inconsistencies and improving legal certainty for operators involved in cross-border medical drone transport.

- **Unified Approaches to Airspace Management and Geo-Zones:** Policymakers should work towards more unified and interoperable approaches to airspace management, including harmonised geo-zone classifications and up-to-date digital maps accessible across borders.

- **Establishing a Single Cross-Border Flight Authorisation Process:** Ideally, this would take the form of a single application procedure. From the drone operator's perspective, this would function as a "one-stop shop" through which the application could be submitted. This would contrast with the current process, under which authorisation must first be obtained from one country, followed by separate approvals from other countries. A single procedure would therefore substantially reduce the administrative burden for cross-border drone operators. As an initial step, such a one-stop-shop system could be established between neighbouring countries with significant cross-border activity, for example within the Benelux or at a cross-border regional level (e.g. the Meuse-Rhine region).

- **Expediting Authorisation Processing Times:** Currently, aviation authorities are under significant pressure due to a high volume of applications and insufficient human resources. This has resulted in application backlogs and lengthy processing times, ranging from several weeks to several months. Member States should therefore invest and allocate adequate financial resources to increase administrative capacity. Moreover, as no dedicated high-urgency (emergency) authorisation procedure currently exists, the system makes it difficult to implement initiatives in response to healthcare emergencies or other public emergencies, such as fire response. This challenge is particularly acute for cross-border and ad hoc operations, where a general operational authorisation cannot be requested well in advance due to urgent needs, or where flights fall outside the scope of an existing authorisation (for example, deviations from predefined routes, such as flights to or from emergency locations rather than between pre-approved hospitals).

- **Strengthening Cross-Border Cooperation Between Aviation Authorities:** Improving cooperation between national aviation authorities includes closer alignment of approval procedures, shared understanding of operational requirements and regulation on airspace, and improved communication channels such as joint working groups or formal coordination mechanisms. Currently, such cooperation largely exists under the EU umbrella, notably through EASA. However, some of our project policy recommendations such as the introduction of a single authorisation procedure could be more effectively promoted through more intensive cooperation between neighbouring countries (Belgium, the Netherlands and Germany) and cross-border regions (e.g. Meuse-Rhine region).

- **Creating Clear Guidelines on Cross-Border Transport of Medical Goods:** Understanding which rules apply to the cross-border transport of medical goods (whether for aviation-based drone logistics or road transport) is highly complex. The relevant legislation is fragmented at the national level and largely depends on the category of medical goods being transported. To support both emerging medical initiatives and existing forms of cooperation, such as ambulance services, hospitals, and other healthcare organisations, there would be significant value in developing clear and harmonised guidelines. For example, guidelines established jointly between the Netherlands, Belgium, and Germany could help stakeholders understand which rules they must comply with when transporting medical goods across borders.

Outlook and Roadmap

Establishing a cross-border AAM-network for medical goods transport has the potential to strengthen healthcare systems in the entire region in terms of cooperation, resilience and disaster preparedness. The population in the Meuse-Rhine region would benefit from improved cooperation between hospitals both in regard to exchange of goods and knowledge. Importantly, its added value extends beyond individual use cases and should be understood within the broader context of national and international strategies for disaster resilience, digital health, telemedicine, and cross-border emergency response systems. Looking ahead, technological, regulatory and institutional developments can be anticipated that will further enable such cross-border operations. The long-term vision is the establishment of a permanent, cross-border medical AAM network operating not only in emergency situations but also as part of routine healthcare logistics. To ensure sustainability, two cross-cutting aspects must be addressed from the outset: economic viability and environmental sustainability. This includes achieving high system utilisation through a combination of routine and emergency operations, day- and night-time flights, and the avoidance of cargoless flights, as well as conducting comprehensive economic and sustainability analyses in line with circular economy principles.

The roadmap below (see Figure 1) outlines the key milestones and phased steps for implementation of such a cross-border medical AAM-network.

Short-term **0 – 2 years**	**Preparation of Enabling Conditions** • Pilot projects: limited number of hospitals and specified use cases • Close cooperation with aviation and health authorities to streamline cross-border authorisation processes and develop pragmatic procedures for high-urgency transports • Establishing technical foundations for interoperabiity with different drone systems
Mid-term **2 – 5 years**	**Harmonisation and Scaling** • Scaling: adding more hospitals, broadening the range of medical goods and extend operational areas • Regulatory efforts: reducing fragmentation, harmonising international airspace management, establing high-urgency procedures • AAM operations embedded in regional emergency and disaster response frameworks
Long-term **> 5 years**	**System Integration and Routine Operations** • Transition from project-based initiatives to fully integrated, sustainable system • Development of EU-wide standards on cross-border medical AAM operations • Alignment of liability and reimbursement frameworks • Integration into routine healthcare logistics • Add advanced applications: centralised stocking strategies, use of AI-predictive models

Figure 1. *Roadmap for Implementation of a cross-border medical AAM-network.*

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Abbreviations

AAM	Advanced Air Mobility
AED	Automated external defibrillator
AI	Artificial intelligence
BVLOS	Beyond the visual line of sight
EASA	European Union Aviation Safety Agency
EU	European Union
GCS	Ground control station
GDPR	General Data Protection Regulation
SME	Small and medium-sized enterprises
SoHO	Substance of human origin
TFEU	Treaty on the functioning of the European Union
UAS	Unmanned aerial system
UAV	Unmanned aerial vehicle
UI	User interface
VLOS	Visual line of sight
VTOL	Vertical takeoff and landing

1. Introduction

1.1 Background and Relevance of AAM in Medical Logistics

Medical logistics face a range of challenges, including time-sensitive deliveries, limited availability of critical medical supplies, and dependency on conventional transport routes[1,2]. In crisis situations—such as natural disasters, pandemics, or large-scale emergencies—these challenges intensify[2,3,4]. Infrastructure may be damaged, roads blocked, or traffic congestion may severely delay the delivery of vital goods. Under such conditions, Advanced Air Mobility (AAM) and drone-based transport offer a highly resilient and efficient alternative[5,6,7].

Studies and pilot projects have shown that drone transport can achieve significantly shorter and more predictable delivery times compared to ground transport, even under challenging conditions[8,9,10]. Beyond emergency scenarios, AAM also holds great potential to strengthen the resilience and responsiveness of healthcare systems in everyday operations.

Particularly in cross-border regions such as the Meuse-Rhine region, where hospitals and healthcare institutions of three neighboring countries are located in close proximity, drone transport can unlock new synergies. In urgent situations, medical goods available just across the border could be delivered faster by air than from distant domestic locations. This approach harnesses geographical proximity to improve the timeliness and reliability of medical logistics, thereby enhancing regional healthcare resilience and cooperation.

1.2 EDEN-Medical Project

Against this backdrop the EDEN-Medical project was initiated to address current regulatory and administrative challenges related to the cross-border transport of medical goods using AAM[11]. The

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project examines the existing legal and operational frameworks, develops concepts for future implementation, and formulates recommendations for policymakers and local authorities.

The core objective of EDEN-Medical is to establish a cross-border AAM-enabled network of hospitals that facilitates the rapid exchange of urgently needed medical goods and associated medical information in emergency situations. To support this objective, the project is developing a digital platform that enables real-time information exchange between hospitals, medical service providers and drone operators.

Ultimately, EDEN-Medical seeks to strengthen resilience of healthcare systems across the participating countries within the programme area. To ensure long-term impact, the project brings together hospitals, small and medium-sized enterprises, local authorities and universities in a collaborative framework designed to sustain project outcomes beyond its duration.

The consortium includes the University Hospital RWTH Aachen as the lead partner. Further hospital partners are Zuyderland Medisch Centrum and Ziekenhuis Oost-Limburg. The participating SMEs are Docs in Clouds TeleCare GmbH, DronePort Sint-Truiden, and flyXdrive GmbH. Academic partners include the Institute for Flight System Dynamics, RWTH Aachen University and the Maastricht University Institute for Transnational and Euregional Cross-Border Cooperation and Mobility. Local authorities are represented by the Aachen Fire Brigade, acting on behalf of EMRIC.

1.3 Objectives of the Concept Paper

The objective of this Concept Paper is to assess the potential of cross-border Advanced Air Mobility (AAM) solutions for the transport of medical goods and to examine the conditions under which such systems can meaningfully contribute to resilient healthcare logistics. It aims to highlight the medical necessity for efficient logistical solutions and to outline the transport requirements of different medical goods. On this basis, the paper assesses the technical and operational feasibility of drone-based transport and identifies necessary adaptations of drone systems, hospital infrastructure and supporting digital platforms. A central objective is to present and analyse the current status quo of administrative, logistical, and legal frameworks governing cross-border AAM transport of medical goods. It identifies the preliminary findings made in the first year of the EDEN-Medical project on existing barriers, regulatory gaps, and operational challenges while proposing comprehensive concepts to address and improve these aspects.

One of the key objectives of the EDEN-Medical project is to foster collaboration with relevant authorities and stakeholders to support the development of a harmonised and efficient legislative framework. This concept paper lays a basis for such stakeholder consultations in order to inform bodies such as the European Union Aviation Safety Agency (EASA) and local authorities, as well as companies, other drone projects and other interested stakeholders about the current status quo. Furthermore, the concept paper seeks to advance regulatory conditions that enable both regular and ad-hoc cross-border drone transports. Ultimately, the Concept Paper aims to support the establishment of swift and reliable cross-border delivery of medical goods, as well as telemedical exchange of expertise and to strengthen preparedness for emergency and crisis situations. It outlines the potential of a streamlined cross-border AAM transport framework, promoting adaptability, responsiveness, and sustainability in future healthcare logistics. While the analysis is grounded in the specific context of the Meuse-Rhine region, the concepts and considerations presented are intended to be transferable to other cross-border regions.

As the concept paper presents early findings from the project, it discusses only preliminary observations, and the results should therefore be interpreted as provisional.

1.4 Reader Guide

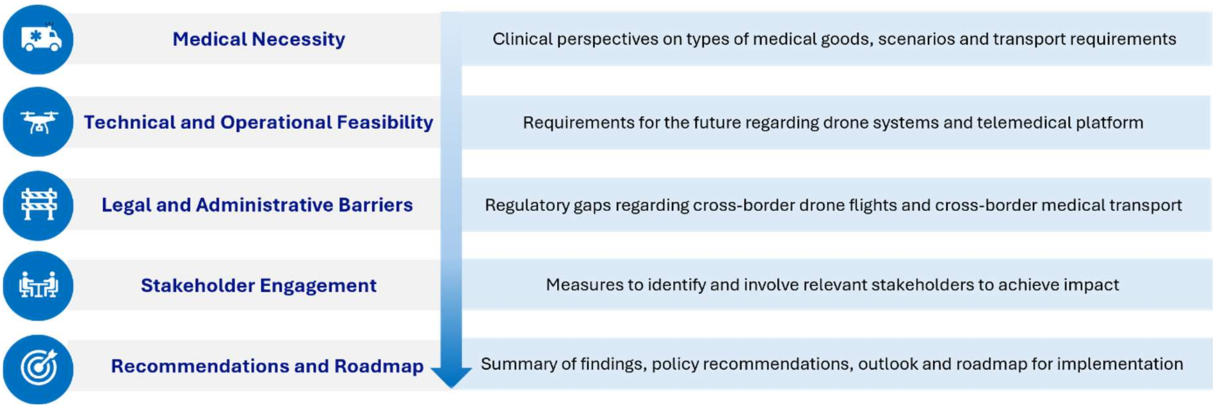

Figure 2: *Visual overview of the Concept Paper's structure and argumentation.*

Given the scope and length of this Concept Paper, Figure 2 provides a visual overview of the paper's storyline and argumentative flow. It is intended as a reader guide to support orientation and to make the logical progression of the analysis transparent.

Following this introduction, Chapter 2 outlines the current landscape of medical logistics and cross-border healthcare cooperation, drawing on insights from interviews and focus groups with preclinical and clinical practitioners. This chapter establishes the medical necessity for improved logistical solutions and highlights the specific challenges of time-critical medical transports in cross-border regions.

Chapter 3 examines the technical and operational feasibility of drone-based medical transport. It outlines system requirements, operational concepts, and current limitations, demonstrating that cross-border medical AAM operations are technically achievable, while also identifying areas requiring further development to enable reliable, scalable, and sustainable deployment.

Building on this, Chapter 4 analyses the legal and administrative frameworks governing cross-border drone operations. This chapter represents the analytical core of the paper, identifying regulatory fragmentation, administrative barriers, and legal uncertainties as the primary obstacles to implementation.

Recognising that regulatory change requires coordinated action, Chapter 5 focuses on stakeholder engagement and institutional cooperation. It identifies key stakeholder groups and outlines approaches for structured dialogue, co-creation, and policy-oriented exchange to translate identified barriers into actionable reform processes.

Finally, Chapter 6 summarises the key findings, formulates concrete policy recommendations, and presents a roadmap for implementation. The roadmap outlines short-, mid-, and long-term steps toward establishing a sustainable, cross-border medical AAM network.

1.5 Target Audience

The Concept Paper is designed for a broad range of stakeholders involved in medical logistics, healthcare delivery, and regulatory governance. This includes:

- Hospitals and healthcare networks
- Medical laboratories and suppliers of medical goods
- Emergency departments and fire brigades
- Small and medium-sized enterprises (SMEs) active in healthcare logistics or drone technology
- Pharmacies and general practitioners
- Regional and local authorities engaged in emergency preparedness and healthcare coordination
- National aviation authorities
- Policymakers and legislative bodies on the European Union (EU), national and regional level

By addressing these audiences, the paper seeks to foster cross-sector collaboration and raise awareness of the potential benefits and requirements for implementing cross-border AAM transport solutions in the healthcare sector.

2. Current Landscape of Medical Goods Logistics

This chapter presents findings from the conducted requirements analysis in regard to cross-border transport of medical goods via drones. On the basis of interviews and focus group surveys with clinical and pre-clinical stakeholders it identifies medical goods suitable for this type of transport, their transport requirements and different transport scenarios. Clinical examples from all three countries highlight the medical necessity of a fast and reliable cross-border medical logistics solution.

2.1 Types of Medical Goods and Transport Scenarios

The term “medical goods” encompasses a wide range of different products, including medical equipment, pharmaceuticals, and biological samples. A detailed overview of the various categories and medical goods suitable for transport via drone identified in project EDEN-Medical through interviews and focus group surveys with clinical and pre-clinical stakeholders is provided in Table 1 below. These individual use cases are further elaborated in Deliverable D1.1, “Report on Schedule of Requirements and Demonstration Flight Planning Framework”.

Table 1: Overview of all relevant medical goods identified in project EDEN-Medical

Medical goods	**Weight of load**	**Dimensions(max.) in cm**	**Temperature conditions**
Medical equipment			
Automated external defibrillators (AEDs)	5 kg	30x30x20	-
Rescue buoys (water rescue service)	<5 kg	60x30x20	-
Telemedical devices	<2 kg	30x30x20	-
Specialised catheters	377 g	35x31x3	-
Paediatric Surgical Set	400 g	1-2 shoeboxes	-
Emergency Surgical Set	6-12 kg	60x30x15	-
Ventilator tubing	2 kg	30x25x12	-
Pneumothorax Drain	1-2 kg	30x20x8	-

Laboratory samples			
Blood samples	20 g	2x2x15 (per sample)	+4°C
Semen	20 g	10x10x15	Room temperature
Urine	50 g	10x10x15	+4°C
Faeces	20 g	10x10x15	+4°C
Breast milk	20 g	10x10x15	+4°C
Saliva	20 g	10x10x15	Room temperature
Tissue samples			
Tissue samples	variable	variable	Room temperature
Frozen Section	< 100 g	variable	Room temperature
Blood products			
Whole blood unit	400 g	20x20x20	+2°C to +6°C
Frozen plasma	300 g	20x20x20	+2°C to +6°C
Platelets	400 g	20x20x20	+20°C to +24°C
Medication			
Dantrolene	330 g	12,5x18x8	Room temperature
Antidotes	variable	variable	+2°C to +8°C Or +15 to +25°C
Emergency medication	variable	variable	+2°C to +8°C Or +15 to +25°C
Transplants			
Corneal tissue	270 g	10x5x5	+10°C to 40°C
Organ transplants	variable	30x30x20	+4°C to +40°C

Some medical goods require a more specific differentiation. Blood samples for laboratory analyses consist of numerous tests with different medical indications and are subject to varying requirements regarding transport urgency, frequency, and conditions. These include, for example, blood samples used for diagnostic purposes, such as in cases of myocardial infarction, where time-critical decisions must often be made.

Additionally, blood samples for blood group determination are of high relevance, as they are crucial for selecting the appropriate type of blood transfusion and can help to avoid the need for emergency universal transfusions. Moreover, blood samples for pathogen diagnostics play an essential role, for instance in identifying the causative agents of meningitis or sepsis, to enable adequate patient treatment. Without the identification of the pathogen, targeted therapy cannot be initiated.

The same is true for tissue samples that are analysed by the department of pathology. There is equally a wide range of different types of tissues, that oftentimes need to be handled differently and include samples of all sizes, having different transport requirements. It also needs to be noted, that while not every tissue analysis is as time-critical as a frozen section analysis, where the pathologist is obligated to share the analytical result with the surgeon within the timeframe of 30 minutes, most pathological examinations are considered urgent. Therapeutical decisions on which medications a patient should receive and what the further line of treatment should be are dependent on the result of the pathological analysis. Any delay in the pathological examination, e.g. due to transport delays, has an immediate effect on the patients' therapy and may delay the start of effective treatment and thus have an impact on outcome and survival.

A substantial body of literature has investigated the feasibility of drone-based transport for various categories of medical goods. For most of the items listed in Table 1 - including medical equipment, laboratory samples and tissue samples, blood products, medication and even organs - evidence suggests that drone transport is viable under defined conditions, provided that specific requirements are met. Multiple studies have focused on the delivery of medical equipment in emergency settings, such as AEDs for cardiac arrests, demonstrating the improvements in response times and, in some cases, patient outcomes[12,13,14]. The feasibility of transporting blood samples for laboratory analysis via drones has likewise been confirmed in several studies[15,16]. Research on blood products indicates no clinically relevant degradation when predefined temperature ranges and vibration thresholds are maintained, while transportation times are significantly reduced compared to conventional logistics[17,18,19]. Drones have also been shown to offer particular advantages for the delivery of time-critical medication, especially in emergency situations or remote areas[20,21]. Notably, even the transport of whole organs has been examined, with studies demonstrating that unmanned aerial vehicles (UAVs) can safely deliver donor organs while preserving temperature control and structural integrity[22] including cases of successful transplantation following drone-based transport[23,24].

2.2 Real-life Examples

Real-life examples illustrate the urgency and importance of the rapid transport of medical goods. One example is the time-critical transport of an automated external defibrillator (AED) to a person suffering from cardiac arrest. Across the Interreg-EMR programme area, cardiovascular diseases

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[23] Scalea JR, Pucciarella T, Talaie T, et al. Successful Implementation of Unmanned Aircraft Use for Delivery of a Human Organ for Transplantation. Ann Surg 2021. 274(3):e282-e288. https://doi:10.1097/SLA.0000000000003630

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remain a leading cause of death. In Germany, approximately 339,000 people died from diseases of the circulatory system in 2024[25], compared to about 38,000 deaths in the Netherlands (2024)[26] and more than 27,000 deaths in Belgium (2022)[27]. Many of these events are associated with acute cardiac emergencies, including cardiac arrest, where timely access to an AED can be life-saving. Although there are numerous stationary AED installations across the countries, laypersons often lack information about their exact locations. This problem is particularly pronounced in rural areas (which often includes border regions), where AED density is considerably lower.

Another example concerns the transport of corneal transplants. Keratoplasty is a common and highly successful type of transplantation in which a diseased, scarred, injured or opaque cornea is replaced with a clear, healthy one. The donor corneas originate from deceased organ donors and are stored in so-called cornea banks. Prior to transplantation, the cornea is transferred to a special medium and prepared for transport. The Cornea Bank Aachen, for instance, serves a large area within North Rhine-Westphalia, as well as other regions in Germany and even internationally, e.g. Belgium and Austria. Approximately 700 cornea transports are conducted annually by car, train or occasionally by airplane. Of these transports approximately 6% were emergency transports.

Another illustrative example of new potential through UAV-based medical goods transport are intraoperative frozen sections — small tissue samples taken during tumour surgery and immediately examined by a pathologist to determine whether the tumour has been completely removed. Currently, this is only feasible in large centres or with longer transport times, which results in prolonged surgeries and increased risk for patients. Through new collaborations extending beyond local hospital networks, rapid pathological frozen section diagnostics could become feasible for additional hospitals, thereby optimising surgical resources and improving population healthcare coverage in the programme area.

2.3 The Status Quo: Clinical Perspectives on Frequency, Urgency, and Predictability

The current transport frequency of medical goods by car varies greatly depending on the type of goods. What all transport types have in common, however, is that they often occur on a daily basis and are frequently time-critical.

At the beginning of the EDEN-Medical project, we aimed to assess the current status quo of transportation needs across the three partner hospitals: University Hospital RWTH Aachen[28], Zuyderland Medical Center[29], and Ziekenhuis Oost-Limburg[30]. To adequately interpret the transport frequencies at these hospitals, it is essential to briefly describe their size and level of healthcare provision.
University Hospital RWTH Aachen is a large university medical center and tertiary referral hospital, providing the full spectrum of maximum and highly specialised care and closely integrated with research and medical education. Zuyderland Medical Center is one of the largest non-university hospitals in the Netherlands and serves as a regional secondary-to-tertiary care provider, offering a broad range of specialised clinical services across multiple sites. Ziekenhuis Oost-Limburg is a major

[25] https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Gesundheit/Todesursachen/_inhalt.html#235880
[26] https://opendata.cbs.nl/#/CBS/en/dataset/7233ENG/table?ts=1767875410687
[27] https://statbel.fgov.be/de/themen/bevoelkerung/mortalitaet-lebenserwartung-und-todesursachen/todesursachen#panel-13
[28] https://www.ukaachen.de/
[29] https://zuyderland.nl/
[30] https://www.zol.be/

regional acute care hospital in Belgium, functioning as a secondary care center with extensive specialised services and playing a central role in healthcare delivery in the Limburg region.

Structured interviews were conducted with 24 experts from various departments across all three partner hospitals to determine department-specific transport frequencies. The departments included pharmacy, pathology, transfusion medicine, laboratory services, crisis response teams, anaesthesiology, intensive care, emergency medicine, surgery and trauma teams, logistics departments, cornea banks, and flight operations.

For example, the central laboratory at University Hospital RWTH Aachen reports sending collected blood samples for specialised analysis to external laboratories three times per day. Similarly, the pathology department reports receiving two to three transports with tissue samples per day from hospitals across Germany, as well as at least weekly international transports. Zuyderland Medical Center reports daily collection of blood samples from its 15 local sites for analysis at the central laboratory. Its pharmacy additionally reports two to three routine transports per day, while emergency deliveries are commonly handled via taxi services. Ziekenhuis Oost-Limburg reports at least five daily transports of blood samples between laboratory facilities at different campus locations, as well as additional transports to specialised laboratories and local partners such as general practitioners and smaller health centers.

In the context of pharmaceutical logistics, true emergency transports are comparatively rare. Ziekenhuis Oost-Limburg, for example, reports only one to two emergency medication transports per year, primarily involving the delivery of antidotes in cases of rare intoxications.

The pharmacy of the University Hospital RWTH Aachen, which serves as a major regional provider supplying medications to several smaller hospitals as well as to the emergency services of the municipalities of Aachen and Heinsberg, and which also operates the emergency depot ("Notdepot") of the Chamber of Pharmacists of North Rhine-Westphalia, reports emergency transports of urgently needed medications approximately twice per month.

Most emergency situations can be managed using medications from these emergency depots, which smaller hospitals keep in stock. These depots are typically equipped with sufficient emergency medication to cover approximately three hours. Although the stock of emergency medication is limited, this timeframe is usually sufficient to stabilise the patient or to organise transport to the university hospital. The limited size of these stocks is primarily due to the fact that critically ill patients are often transported directly to the university hospital. Likewise, if a patient's condition deteriorates over time and becomes critical, it is generally more common to transfer the patient to a higher-level care facility—provided the patient is stable enough for transport—rather than transporting additional medication to the patient. Such cases typically require not only specific medications but also advanced medical expertise and infrastructure. Medication is therefore transported to the patient only when it is required immediately and the patient is too unstable to tolerate transport.

Another aspect highlighted during the interviews by the head of the University Hospital of Aachen pharmacy is the frequent occurrence of supply shortages, with approximately 700 delivery bottlenecks reported per year. Fortunately, these shortages rarely result in direct patient endangerment, as pharmacies across Germany maintain strong networks and routinely support one another. However, this often necessitates transporting medications over long distances within Germany, which is associated with significant financial costs, considerable time expenditure, and an increased environmental footprint. In many cases, the required medication may be available at a geographically closer hospital across the national border. Nevertheless, due to restrictive national regulations, high administrative burdens, and unresolved reimbursement issues, cross-border medication transport rarely takes place.

In life-threatening situations, patients are therefore transported to the location where the medication is available, rather than transporting the medication to the patient. This approach, however, entails inherent risks, as every transfer of critically ill patients carries the potential for adverse events[31,32,33,34,35]. Patient movement can lead to dislodgement of catheters or medical devices, increases the risk of injury, and may result in further clinical deterioration or hemodynamic instability during transport[36,37].

Across all three partner hospitals, urgent transports of medical goods occur with varying frequency depending on the department and are often difficult to plan due to their inherent unpredictability. Even when true emergency transports occur only rarely, they are highly time-critical. In such cases, transport commonly relies on taxi services—a solution that is costly, time-consuming and environmentally burdensome.

However, although all three hospitals transport a wide range of medical goods on a daily basis and urgent deliveries occur frequently, the experts interviewed at all three institutions reported a low number of international transports. In particular, the cross-border exchange of medical goods within the Meuse–Rhine region and the level of cooperation between geographically proximate hospitals across national borders appear to be limited. Establishing a cross-border hospital network in this region therefore holds considerable potential to enhance future cooperation and to strengthen healthcare system resilience as well as disaster and crisis preparedness. It can therefore be concluded that there is a clear medical need for fast, efficient, reliable, and predictable medical transport solutions. A cross-border drone transport network could meet all of these requirements, provided that the appropriate conditions are in place—both in terms of technical and operational feasibility and, above all, with regard to the legal and administrative framework.

2.4 The Status Quo: Pre-Clinical and Clinical Insights

Building on the assessment of transport frequency, urgency, and predictability presented in the preceding section, further qualitative insights into the current status quo of medical logistics are derived from structured focus group discussions with clinical and pre-clinical stakeholders. Two focus

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[31] https://www.anzca.edu.au/getContentAsset/a4542b62-9b7c-4e0d-91ed-03baa3b11d87/80feb437-d24d-46b8-a858-4a2a28b9b970/PG52-Guideline-for-transport-of-critically-ill-patients-2024-(PILOT).PDF?language=en&view=1

[32] Fanara B, Manzon C, Barbot O, et al. Recommendations for the intra-hospital transport of critically ill patients. Crit Care 2010. 14(3): vR87. https://doi:10.1186/cc9018

[33] Lahner D, Nikolic A, Marhofer P, et al. Incidence of complications in intrahospital transport of critically ill patients--experience in an Austrian university hospital. Wien Klin Wochenschr 2007. 119(13-14): 412-6. https://doi:10.1007/s00508-007-0813-4

[34] Papson JP, Russell KL, Taylor DM. Unexpected events during the intrahospital transport of critically ill patients. Acad Emerg Med 2007. 14(6): 574-7. https://doi:10.1197/j.aem.2007.02.034

[35] Beckmann U, Gillies DM, Berenholtz SM, et al. Incidents relating to the intra-hospital transfer of critically ill patients. An analysis of the reports submitted to the Australian Incident Monitoring Study in Intensive Care. Intensive Care Med 2004. 30(8): 1579-85. https://doi:10.1007/s00134-004-2177-9

[36] Knight PH, Maheshwari N, Hussain J, et al. Complications during intrahospital transport of critically ill patients: Focus on risk identification and prevention. Int J Crit Illn Inj Sci 2015. 5(4): 256-64. https://doi:10.4103/2229-5151.170840

[37] Doring BL, Kerr ME, Lovasik DA, et al. Factors that contribute to complications during intrahospital transport of the critically ill. J Neurosci Nurs 1999. 31(2):80-6. https://doi:10.1097/01376517-199904000-00004

groups were conducted, involving a total of 14 participants from Germany, the Netherlands, and Belgium, representing both hospital-based clinical care and pre-hospital emergency services.

The focus group discussions largely confirm and further contextualise the findings obtained through the interview-based analysis. Across all stakeholder groups, medical logistics are described as being characterised by high time pressure, limited predictability, and significant clinical consequences in the event of delays. Rather than identifying fundamentally new transport needs, the discussions reinforce the patterns already observed across the partner hospitals and highlight their relevance from a broader practitioner perspective covering different professional roles and healthcare systems.

In line with the interview findings, stakeholders emphasise that the medical necessity for fast and reliable transport solutions is not limited to exceptional crisis scenarios. While disasters, mass casualty events, and infrastructure disruptions are frequently referenced as illustrative situations, participants stress that routine emergency care already involves recurrent cases in which delayed access to medical goods directly affects clinical decision-making and patient outcomes. From both clinical and pre-clinical perspectives, drone-based medical transport is therefore perceived as a potential means to address existing logistical vulnerabilities rather than as a replacement for conventional transport systems.

The use cases discussed during the focus groups closely align with those identified in the interviews. Participants repeatedly refer to the transport of blood and blood products, organs and tissue samples, emergency and specialised medication including antidotes, as well as emergency medical equipment such as automated external defibrillators. These medical goods are described as being subject to strict time constraints, specific handling requirements, and high clinical relevance. Consequently, they are considered particularly suitable for aerial transport solutions, provided that operational reliability and regulatory clarity can be ensured.

At the same time, the focus group discussions allow for a more explicit articulation of persistent barriers to implementation. Regulatory and legal uncertainty is unanimously identified as the most critical cross-cutting challenge, particularly in relation to cross-border deployment. Participants describe complex authorisation procedures, unclear responsibilities, and limited practical experience with cross-border approvals as major obstacles to routine use. In this respect, the focus group findings further substantiate the conclusion that legal and administrative aspects represent the dominant bottleneck for the deployment of cross-border drone-based medical logistics.

Operational challenges are discussed in a similar manner. Stakeholders highlight the need to integrate drone operations safely into existing airspace structures, particularly with regard to coordination with helicopter-based emergency services and the avoidance of restricted or military airspace. Environmental influences such as adverse weather conditions, as well as technical limitations related to payload capacity and flight stability, are identified as factors that must be addressed to ensure dependable operation under real-world conditions.

In addition, participants emphasise several technical and infrastructural requirements that are critical from an end-user perspective and closely aligned with the operational realities described in the preceding section. These include the ability to maintain controlled temperature conditions for sensitive medical goods, the robustness and stability of drone systems under routine and adverse conditions, and the readiness of deployment and landing sites at hospitals and emergency locations. Stakeholders note that even minor inefficiencies at points of departure or arrival, such as non-standardised procedures or insufficient infrastructure, can undermine the potential time advantages gained through aerial transport.

Beyond the physical transport itself, the focus group discussions place particular emphasis on telemedical and system integration aspects. Participants highlight the need for a centralised platform that integrates drone operations with logistical coordination and medical information exchange. Secure handling of sensitive medical data, interoperability with existing clinical and pre-clinical information systems, and reliable connectivity, including in crisis situations, are identified as essential prerequisites. Furthermore, seamless integration into hospital infrastructure, for example through interfaces with internal transport systems and automated handover processes, is considered critical to avoid internal delays and fragmentation.

Taken together, the focus group insights validate and consolidate the findings derived from the interview-based analysis while adding depth to the understanding of practitioner priorities and constraints. They confirm that the medical need for faster, more reliable transport solutions is well established, while simultaneously highlighting that real-world implementation depends on clearly defined technical, operational, and legal conditions.

3 Technical and Operational Requirements

Medical goods show a high degree of variability (see Table 1), which leads to differing requirements for UAV-based air transport. This chapter will elaborate on these requirements and present the necessary adaptations and developments to drone systems, hospital infrastructure and digital platforms to enable a sustainable cross-border AAM-network for medical goods transport. It showcases the technical and operational feasibility but also the future potential of such solutions.

3.1 Weight and Dimension Constraints

The UAV must be capable of carrying loads of different weights while maintaining flight performance, including adequate speed, stability, and range. These aspects are particularly relevant for heavier medical goods such as AEDs or rescue buoys. Most other medical goods, such as laboratory samples and pharmaceuticals, are relatively light, typically within the double-digit gram range, whereas blood products and organ transplants can be significantly heavier (see Table 1).

In addition to weight, the physical dimensions of medical goods must be considered, as they affect transport feasibility. In most cases, medical goods fall within a small size range of approximately 10 × 10 × 10 cm, but ideally, transport capacities up to 30 × 30 × 20 cm or larger are necessary to safely accommodate bigger items such as organs or rescue equipment.

3.2 Environmental and Temperature Requirements

Depending on the type of medical goods being transported, specific preparation and storage requirements apply that directly influence transport conditions. For biological laboratory samples, triple packaging is mandatory — including tear-resistant bags and shockproof Styrofoam boxes — to ensure safety, particularly for blood or pathogen samples (biological material of "special" category). It must also be ensured that samples remain stable and upright during the entire transport process.

Additionally, maintaining a constant temperature within specified ranges is essential. Some samples must be transported frozen, while others require storage at room or body temperature. This can be achieved using cooling or heating packs to maintain the required conditions throughout the transport process. Continuous temperature monitoring and documentation according to regulatory standards are mandatory.

3.3 Strengths and Limitations of Different Drone Systems

When assessing the strengths and limitations of different drone configurations, it is essential to consider the intended use case to select the most suitable option. For medical applications, factors such as cargo volume, weight capacity, and operational range determine which concepts can be used. In the following paragraphs, different drone configurations and their advantages and disadvantages will be presented. These configurations can be categorised into three main types:

Multirotor systems

Multirotor systems are among the most common types of drones, widely used across various applications. They are capable of vertical takeoff and landing (VTOL) and do not require a dedicated runway for these operations. Compared to fixed-wing drones, multirotor systems typically operate at slower speeds and have a limited range since lift is generated solely by motor thrust. As a result, this type of drone is best suited for short-distance transport.

Fixed-wing systems

Fixed-wing systems require dedicated runways for takeoff and landing, making them less suitable for operations in constrained spaces. The lift during flight is provided by the aerodynamics of the wing, which is more efficient than the thrust-based flight of multirotor systems. This enables fixed-wing drones to fly faster and further; however, they cannot hover, which makes navigating in environments with limited space challenging. This type of drone is best suited for transport over longer distances between facilities equipped with runways.

Convertiplanes/hybrid aircraft

Convertiplanes—also referred to as hybrid aircraft—combine the capabilities of both multirotor and fixed-wing drones. Within this category, several configurations exist (e.g., tiltwing, tiltrotor, and lift-and-cruise)[38]. They are capable of VTOL flight during both the start and end phases as well as hovering when required. During cruise flight, they transition to fixed-wing mode, which enables them to fly further and faster than multirotor systems. However, combining the capabilities of fixed-wing drones with VTOL functionality leads to increased complexity and weight. This category is best suited for medium- to long-range missions where no dedicated runway is available.

Cargo container

Since the use of drones for medical transport is a rapidly developing sector, there are currently no standard containers certified for this use case that can be utilised across different drone types. To establish a cross-border drone network, a standard should be developed that defines both the size of the container for medical transport and the interfaces (hardware and software) used to attach it to the drone and communicate with the drone systems for monitoring the payload.

3.4 Automation and Ground Control Station

Regardless of the type of drone system employed, a high degree of automation is essential to ensure safe flight beyond the visual line of sight (BVLOS) between hospitals. The automation of drone systems should encompass several key components, including:

- Flight Control and Guidance Systems: These systems are necessary for maintaining stable flight and providing navigational assistance.
- Flight Path Planning: Automated planning tools can optimise routes based on real-time data, weather conditions, and air traffic.

[38] Guillaume J.J. Ducard, Mike Allenspach. Review of designs and flight control techniques of hybrid and convertible VTOL UAVs. Aerospace Science and Technology. Volume 118. 2021. 107035. ISSN 1270-9638. https://doi.org/10.1016/j.ast.2021.107035

Flights should be monitored from a Ground Control Station (GCS), where remote pilots can supervise multiple drones simultaneously. To enhance operational efficiency, the GCS software must alert remote pilots in cases of deviation from the nominal flight state, thereby reducing their workload.

Additionally, the Ground Control Station should be designed to manage flights of various drone types irrespective of the manufacturer. This capability allows remote pilots to operate within a unified environment, simplifying fleet management and enhancing operational flexibility.

3.5 Infrastructure Needs in Hospitals and Remote Areas

Integrating drones into the existing infrastructure of hospitals presents several challenges. Given the often-limited staff resources in the medical sector, drone operations should require minimal personnel involvement. Therefore, the operation of the drone system must be highly automated, encompassing processes such as loading and unloading.

To facilitate seamless integration with existing hospital logistics, the drone system should connect to current facilities. Additionally, to ensure easy integration, the ground systems required for drone operations should occupy as little space as possible. Drones equipped with VTOL capabilities are particularly advantageous due to their space efficiency.

Potential locations for ground systems include roof surfaces or other areas that provide a level surface while being cordoned off from public access during drone operations for safety reasons. Surrounding areas must also be free of obstacles to ensure safe flight paths.

Furthermore, the ground system should not be limited to a specific type of drone; it must be interoperable with various drone systems to adapt to future developments in this field.

For hospitals equipped with helipads, it is crucial to establish strategies that prevent conflicts between crewed and uncrewed air vehicles. This includes defining approach and departure patterns while ensuring that crewed air vehicles—such as emergency helicopters—are prioritised over uncrewed operations.

Additionally, reliable cellular coverage is essential for safe operations at and between hospitals, enabling effective communication between drones and remote operators supervising their activities.

Beyond technical considerations, successful integration also requires a clear institutional commitment on the part of hospitals. Implementing and maintaining drone-based transport solutions demands dedicated time, financial resources, and strategic attention. Hospitals need to actively prioritize this topic within their organisational agendas and ensure that responsibilities are clearly assigned. Ideally, this includes appointing a responsible contact person or establishing a dedicated working group that coordinates all aspects related to drone transport, including technical integration, operational procedures, regulatory compliance, and coordination with external partners.

3.6 Further Challenges

It is essential that the UAV’s transport container is equipped with a secure locking system to prevent unauthorised access. Safety requirements are of utmost importance to ensure the integrity and preservation of the transported medical goods. The UAV flight itself faces additional challenges: wind and weather conditions can significantly affect flight stability and the safety of the cargo. Vibrations, humidity or sudden temperature changes must not compromise the transport box or its contents, as this could render the medical goods unusable. Therefore, UAV systems must be designed to withstand such external influences to ensure the safety and quality of medical goods throughout the entire transport process.

Another key challenge lies in the seamless integration of landing platforms into the medical logistics chain to ensure smooth workflows. Landing sites should be located near medical facilities such as hospitals, laboratories or pharmacies — easily accessible yet protected from unauthorised access. Security measures like access control and video surveillance are essential.

To minimise delays, automated transfer systems — such as robotic arms or conveyor belts — can unload the drone and feed the goods directly into the facility's logistics system. A digital connection between the drone, the landing platform and the facility's logistics management system is necessary. Real-time tracking, automatic notifications, and the integration of order and delivery data improve efficiency and transparency.

Standardised interfaces for drones and landing platforms facilitate integration and enable interoperability between different providers and medical facilities. On-site personnel must receive appropriate training on the correct handling of medical goods and managing potential technical or safety-related incidents.

3.7 Telemedicine Platform

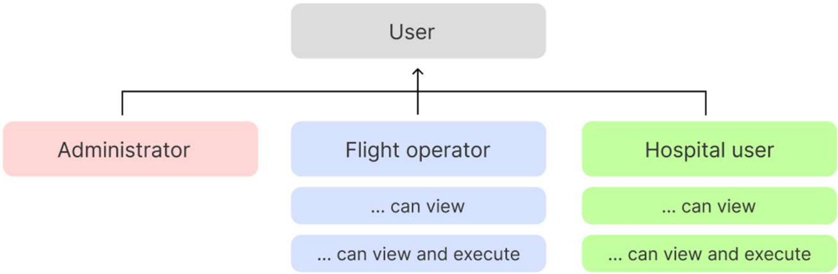
In order to connect all the different stakeholders that are involved in operating, maintaining and using such a complex system a telemedical platform is being developed as part of the EDEN-Medical project. This telemedicine platform constitutes the central technical infrastructure that integrates drone operations with hospital information systems and provides the primary user interface for all stakeholders involved in cross-border medical goods transport. It should be a secure, cloud-based system comprising application services, a user interface, and persistent data storage with real-time data exchange.

The platform shall provide a simple, robust, and multilingual user interface suitable for use in routine operations as well as in emergency and high-stress situations. The user interface (UI) shall:

- Use clear, unambiguous language and avoid medical or technical jargon where not strictly necessary.
- Support multiple languages relevant to the participating regions, with the ability to extend language support without architectural changes.
- Adhere to usability and accessibility guidelines by incorporating minimal interaction steps, clear status indicators, large actionable elements, and displaying only the interaction methods and information pertinent to the current workflow.
- Be usable on standard clinical workstations.

The platform shall implement **role-based access control** to reflect institutional responsibilities and legal constraints. At a minimum, the following roles shall be supported:

- Read-only users with access to transport status and documentation.
- Operational users who can create, modify, and cancel transport orders on behalf of an institution.
- Administrative users with rights to manage users, roles, and institutional affiliations. Roles and permissions shall be configurable per institution.



To ensure interoperability across borders and organisations, the platform shall be based on an **open and standardised data model**. In particular:

- Healthcare-related data (e.g. sender/receiver information, medical goods classification, handling requirements) shall be represented using established standards such as HL7 FHIR where applicable.
- Extensions to the data model shall follow open specifications and be documented to enable integration with hospital information systems, laboratory systems, and external registries.
- Vendor lock-in shall be avoided by using open interfaces and well-documented application programming interfaces (APIs).

Given the sensitivity of medical and operational data, the platform shall implement **end-to-end security mechanisms**. In particular:

- All data exchanges shall be protected using end-to-end encryption, ensuring confidentiality across institutional and national boundaries.
- Data at rest shall be encrypted using state-of-the-art cryptographic methods.
- Strong authentication mechanisms shall be enforced.

Altogether, it can be stated that technical and operational feasibility of medical goods transport via drone is already well established, while significant potential for further optimisation remains—particularly with regard to higher degrees of automation, more comprehensive design concepts aimed at unifying and harmonising transport solutions across different drone types and manufacturers, and integration into hospital systems.

4 Legal and Administrative Framework

Cross-border drone transport of medical goods raises many legal questions that must be addressed to make such operations possible. These legal aspects are also central to the EDEN-Medical project, in which Work Package 2 is specifically dedicated to analysing these questions and provide recommendations to overcome any legal obstacles. These findings will be further elaborated in the upcoming deliverables, in particular the legal analysis report to be finalised at the end of the project. This chapter discusses the preliminary findings and outlines the legal questions being researched.

Overall, cross-border drone operations both within and beyond the medical context remain relatively limited but represent a growing field. As part of a literature review, a mapping exercise was conducted to identify drone operations and projects implemented across Europe. In total, 43 projects and initiatives were identified and screened. At the European level, examples of projects are the Horizon Europe project AiRMOUR which explored the use of drones by emergency medical services in urban environments in several Member States, including Germany, Luxembourg and the Netherlands.[39] With regard to cross-border drone operations specifically, projects such as Emergency Drone[40], EULE[41], GrenzFlug[42] and SAFIR Med[43], also involving partners from the EDEN-Medical consortium, have examined the use of advanced air mobility for cross border emergency services, including search and rescue operations and disaster response. More recently, the BeNeDrone project[44] under Interreg Vlaanderen-Nederland and HawkEye[45] under Interreg Meuse-Rhine also explore cross border drone flights, focusing respectively on medical goods transport and live aerial support for fire services. At the national level, examples of medical drone operations can also be identified. In the Netherlands, the ANWB Medical Drone initiative has tested the transport of blood, diagnostic equipment and medicines.[46] In Belgium, initiatives include drone transport of blood samples between hospitals by Jan Yperman Hospital[47], as well as operations by CityMesh supporting fire services.[48] In Luxembourg, the GRIFFIN project focused on the transport of medical samples by drones.[49] These examples demonstrate a growing interest and application of drone-based solutions for emergency and medical logistics. At the same time, they show that the combination of *cross-border* operations and *medical* drone logistics remains relatively rare, is largely confined to national and project-based initiatives and has not yet been implemented on a structural basis.

Importantly, many projects have identified significant legal and regulatory challenges that complicate establishing cross-border cooperation in field of cross-border drone flights and the cross-border exchange of medical goods. Examples include obstacles arising from the complex legislative framework, large differences between countries on their approach of regulating airspace and differing medical regulations.[50] While the European Union actively promotes cross-border cooperation in healthcare, particularly in cross-border regions[51], numerous obstacles are known to persist in practice. In the context of the EDEN-Medical project, it is therefore necessary to identify and overcome these legal obstacles and to map the possibilities for enabling such cross-border cooperation. This includes a legal analysis of obtaining cross border flight authorisations, divergent legal requirements for transporting medical goods across borders, insurance and liability, as well as questions related to health data exchange and reimbursement.

4.1 Cross-border drone flights

The regulatory framework governing drone operations remains a relatively recent and still-evolving legislative field. On the EU-level, the rules on unmanned aircraft systems (UAS), in other words drones, have been harmonised in the EU pursuant to Regulation 2018/1139 and its implementing Regulations 2019/947 and 2019/945. Harmonisation implies that the same legal rules apply across all EU Member

[39] https://airmour.eu/
[40] https://deutschland-nederland.eu/nl/projects/emergency-drone/
[41] https://www.fsd.rwth-aachen.de/cms/fsd/forschung/projekte/~skuoz/eule-projekt/?lidx=1
[42] https://www.fsd.rwth-aachen.de/go/id/kdmvn/lidx/1
[43] https://www.fsd.rwth-aachen.de/go/id/mthto/lidx/1
[44] https://interregvlaned.eu/benedrone/over-ons
[45] https://www.interregmeuserhine.eu/nl/projecten/hawkeye/
[46] https://www.anwb.nl/maa/medical-drones
[47] https://yperman.net/nieuws/wereldprimeur-in-jyz-met-geautomatiseerd-transportsysteem-met-drones
[48] https://www.citymesh.com/nl/subsolution/emergency-services/
[49] https://droneradar.lu/luxembourg-griffin-drone-project/
[50] See, for instance, AirMour-project Deliverable 3.1 "Overview of legal environment EMS scenarios", 31.10.2023, accessed via: https://drive.google.com/file/d/1xmR7XbuylORDbL_GnWuFVIpaWU58K5pZ/view
[51] Art. 10 EU Directive 2011/24.

States, although the EU legislative framework may allow for national derogations. These Regulations lay down rules on the registration, operation of drones and flight authorisation requirements. The regulatory framework follows a risk-based approach, under which the applicable requirements are classified into different categories based on the level of risk: the open, specific, and certified categories. The category into which a drone operation falls depends on factors such the level of flight oversight (whether visual contact with the drone is maintained; VLOS vs BVLOS), the flight altitude, the weight of the drone, the area of operation, and the distance from uninvolved persons (for example, flights near people or settlements).[52]

In short, in the open category no prior flight authorisation is required (although national limitations may apply), meaning that a drone flight may take place without a prior approval of the competent national aviation authority.[53] The open category applies to operations where visual line of sight is maintained, the flight altitude is below 120 metres, and the drone weighs less than 25 kilograms. Within the open category, further subcategories (A1, A2, and A3) apply, each with different requirements regarding drone weight and operations over people or near settlements. For EDEN-Medical, the most likely applicable categories are the specific category[54] and, potentially, the certified category[55], primarily because the flights are planned to be conducted beyond visual line of sight. This implies that a flight authorisation must be obtained prior to the operation, based on an operational risk assessment that determines the measures required to ensure safety.[56] An operational authorisation may be issued as an approval of a single operation and/or a number of operations specified in time or locations. The certified category applies to the highest-risk drone operations, such as flights over crowds, the transport of people, or the transport of dangerous goods (which may be applicable if certain medical goods, such as infectious materials, are transported – see below). As the detailed rules for the certified category are still being developed by the European Union Aviation Safety Agency (EASA), it is not yet possible to apply for an authorisation under the certified category.

Regarding cross-border flights, as planned in the context of the EDEN-Medical project, the situation becomes more complex. The EU Regulations also provides rules for these cross-border operations and in fact, promotes this type of cross-border cooperation, and “efficient use of resources between authorities at Union and Member State level”.[57] As outlined above, the flights envisaged under the project are likely to require a prior authorisation. In the case of cross-border operations, authorisation must be obtained from all Member States in whose airspace the flight takes place. This procedure is set out in Article 13 of Regulation 2019/947. It provides that when an air operator holding an operating licence or declaration intends to carry out an operation in another EU Member State, the operator must inform the competent authorities of that Member State by submitting (i) a copy of the licence or declaration and (ii) information on the location of the operation, including the applicable risk-mitigation measures. The competent authority of the Member State where the operation is planned then assesses the documentation, whether local requirements are met and confirms whether the operation may proceed. This also means that authorisation must first be obtained in the Member State of registration, after which approval must be sought from the other Member State(s) whose airspace

[52] EU Commission Implementing Regulation 2019/947.
[53] *Ibid*, Art. 4.
[54] *Ibid,* Art 5
[55] *Ibid,* Art 6
[56] *Ibid,* Art. 11.
[57] Art. 4(1)(f) EU Regulation 2018/1139.

will be used. Depending on the use cases, for EDEN-Medical this entails that an approval must be obtained in two or even three countries.

Based on consultations with the project partners, several obstacles on obtaining these flight authorisations can be identified. First, although EU rules are harmonised, differences in national implementation and administrative practice remain between Member States. One example raised concerns the Netherlands, where, in the context of a cross-border flight carried out under the SAFIR-Med project, the authorities required that, for a BVLOS operation, the entire airspace be closed to other aviation traffic. This requirement significantly delayed the drone operation. Second, obtaining a flight authorisation, particularly for cross-border and BVLOS operations, was described as a lengthy and administratively burdensome process that requires substantial investment in time and expertise from the organisation submitting the application, which can be especially challenging for new or smaller companies. Finally, language was identified as an additional obstacle. Authorities were reported not always to communicate in English or other neighbouring languages, both during the application process and in the authorisation documents issued. Belgium, for example, was reported to issue authorisations only in French and Dutch. This can complicate matters for drone operators in the Meuse-Rhine region, for instance for German-speaking operators, which may have difficulty fully understanding the scope and conditions of the authorisation and the operations permitted. Same can be said when the parties involved are seeking information on applicable local regulations.

The most urgent obstacles concern the time required to obtain the necessary authorisations. The Regulation does not set specific deadlines for processing these applications. However, with regard to cross-border authorisations, it is stated that "the competent authority of the Member State of intended operation shall assess it without undue delay".[58] Project partners provided examples of highly variable processing times: in Germany ranging from six weeks to six months, and several months in both Belgium and the Netherlands. In addition, a backlog of applications was observed, further contributing to lengthy processing periods. This is particularly problematic in the context of EDEN-Medical, where drones are intended to be deployed rapidly in emergency situations. However, EU Regulations do not provide clear timelines for processing authorisation requests, nor do they foresee specific procedures for emergency operations. The situation becomes even more challenging in the case of cross-border operations, where approval must be obtained from multiple national authorities. Also, with regard to cross-border operations, it was also noted that cooperation between authorities is limited. The process largely runs through the applicant, rather than through direct exchanges between national authorities. In practice, the project partners noted that authorities do not share documentation with each other; instead, the applicant must submit separate applications. As a result, there is no single "cross-border authorisation" as such, but rather multiple national authorisations that each stop at the respective national border, which results in administrative burden for the drone operators.

Another obstacle concerns the planning of flight routes in a "cross-border air space". As set out in Article 15 of EU Regulation 2019/947, Member States may designate geographical zones in which drone operations are allowed only under specific conditions or completely prohibited. A first issue in this respect concerns the area in which EDEN-Medical aims to operate. The Meuse-Rhine region is characterised by heavily regulated airspace, for example due to the presence of multiple military bases

[58] Article. 13(2) EU Commission Implementing Regulation 2019/947.

and airports. For EDEN-Medical, this may require flight routes to be planned in a "zigzag" manner avoiding the restricted zones, resulting in less time-efficient flight routes. In addition, this introduces another regulatory layer next to obtaining the flight authorisation, if/when the drone operator must obtain permission for each restricted airspace. This can, in turn, further delay the envisaged drone operations. A further obstacle is the absence of common, legally binding geo-zone maps across the EU or the Euregion. As noted, each Member State defines its own zones, and differences in national approaches and "philosophies" can be observed, for example in their approach of measuring population density data. Importantly, geo-zone maps stop at national borders. This makes it burdensome for cross-border operators to combine multiple maps and plan coherent flight routes. This also results in administrative burden for the operator, as their application must be separately submitted for each national territory involved. Additional challenges arise in the context of ad hoc flights. While routes between fixed locations, such as hospital-to-hospital flights, can be planned in advance, operations requiring drones to reach an (priorly unknown) emergency scene pose further difficulties under the current framework.

Finally, it should be noted that, in addition to the EU rules described above, national legislative frameworks may provide for different regimes in the case of drone operations carried out by state operators. The EU Regulation 2018/1139 explicitly provides that the Regulation does not apply to "aircraft, and related equipment, when carrying out military, customs, police, search and rescue, firefighting, border control, coastguard, or similar activities under the control and responsibility of a Member State and undertaken in the public interest by, or on behalf of, a body vested with public authority powers."[59] With regard to this exemption, Member States are nevertheless required to ensure that such activities and services are carried out with due regard to the safety objectives of the EU Regulations. This is a relevant aspect to consider in relation to the long-term implementation of the EDEN-Medical project objectives. In the current project, drone flights are carried out by hospitals in cooperation with private drone operators. However, in the longer term, it may be worth examining whether such drone operations could be integrated into state emergency systems, in line with existing forms of cross-border cooperation, such as in ambulance care coordinated in the Meuse-Rhine region by EMRIC. It is therefore also important to assess whether the regulatory framework applicable to state operations could offer greater flexibility in urgent emergency healthcare situations, which the EDEN-Medical project aims to address. However, legal obstacles are also identified in this area, notably with regard to the definition and interpretation of what constitutes state aviation versus civil aviation. In addition, unlike civil aviation, there is no harmonisation at EU level for state aviation, meaning that national regulations governing drone operations carried out as state aviation differ between Member States.[60] It is therefore necessary to examine and compare these requirements, and their potential differences, across the Meuse-Rhine region.

4.2 Cross-Border Medical Goods Transport

Another key objective of the EDEN-Medical project is to transport medical goods across borders, which the project partners have identified as a major legal obstacle. Despite one of the core freedoms of the EU internal market laid down in Article 114 of the Treaty on the Functioning of the European Union (TFEU), the free movement of goods, significant restrictions continue to hinder the cross-border

[59] Article 2(3)(a) EU Regulation 2018/1139.

[60] Results of Interreg Euregio Meuse-Rhine project IKIC Public Safety, see more at http://www.ikic-publicsafety.eu/.

transport of medical goods. This applies not only to drone-based medical logistics, but also to traditional transport methods, such as transport by car. All hospitals involved in the consortium indicated that cross-border transfers of medical goods occur only very infrequently, also due to these legal challenges, with only a limited number of individual cases identified, for example during the COVID-19 crisis.

Within the framework of Work Package 1, several use cases have been identified specifying which medical goods are intended to be exchanged within the scope of the EDEN-medical project. These use cases are further elaborated in Deliverable D1.1, "Report on Schedule of Requirements and Demonstration Flight Planning Framework", which identified specialised catheters, dantrolene/specialised antidotes, blood and blood platelets, human tissue for frozen section examination, and corneal tissue as possible use cases. This necessitates an examination of the legal requirements governing the import and export of different types of medical goods (see table below). Based on the preliminary list of medical items to be exchanged, these goods can be legally categorised as human tissues, blood, medicinal products, and medical devices. This chapter focuses specifically on the EU legal framework and on identifying the key legal questions arising in this context.

Category of medical goods	**EU legislation**	**National legislation**
Blood, blood platelets	Directive 2002/98 Directive 2004/33 Directive 2005/61 From 7.8.2027: Regulation 2024/1938 on substances of human origin	NL: *Wet inzake bloedvoorziening*[61] BE: *Koninklijk besluit betreffende de afneming, de bereiding, de bewaring en de terhandstelling van bloed en bloedderivaten van menselijke oorsprong*[62], *Wet betreffende bloed en bloedderivaten van menselijke oorsprong*[63] DE: *Transfusionsgesetz*[64]
Human tissue and cells	Directive 2004/23 Commission Directive 2006/17 Commission Directive 2006/86 From 7.8.2027: Regulation 2024/1938 onsubstances of human origin	NL: *Wet veiligheid en kwaliteit lichaamsmateriaal*[65] BE: *Koninklijk besluit betreffende de biobanken*[66], *Koninklijk besluit tot vaststelling van de kwaliteits- en veiligheidsnormen voor het doneren, wegnemen, verkrijgen, testen, bewerken, bewaren en distribueren van menselijk lichaamsmateriaal, waaraan de banken voor menselijk lichaamsmateriaal, de intermediaire structuren voor menselijk*

[61] https://wetten.overheid.nl/jci1.3:c:BWBR0009079&z=2023-10-05&g=2023-10-05
[62]https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1996040445&table_name=wet
[63]https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1994070545&table_name=wet
[64] https://www.gesetze-im-internet.de/tfg/BJNR175200998.html#BJNR175200998BJNG003401310
[65] https://wetten.overheid.nl/BWBR0014682/2022-01-01
[66] https://www.afmps.be/sites/default/files/content/mb_2018-02-05.pdf

		lichaamsmateriaal en de productie-instellingen moeten voldoen[67], *Wet inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek*[68], *Koninklijk besluit betreffende de afneming, de bereiding, de bewaring en de terhandstelling van bloed en bloedderivaten van menselijke oorsprong*[69] DE: *Gewebegesetz*[70], *Transplantationsgesetz*[71], *Transplantationsgesetz-Gewebeverordnung*[72]
Organs	Directive 2010/53/EU Commission Directive 2012/25	NL: *Wet op de orgaandonatie*[73] BE: *Wet van 13 juni 1986 betreffende het wegnemen en transplanteren van organen*[74] DE: *Transplantationsgesetz*[75], *Transplantationsgesetz-Gewebeverordnung*[76]
Medical devices	Regulation 2017/745	NL: *Wet medische hulpmiddelen*[77], *Besluit medische hulpmiddelen*[78] BE: *Wet betreffende medische hulpmiddelen*[79] DE: *Medizinprodukterecht-Durchführungsgesetz*[80]
Medications	Directive 2001/83	NL: *Geneesmiddelenwet*[81], *Besluit Geneesmiddelenwet*[82]

[67] https://www.ejustice.just.fgov.be/cgi_loi/article.pl?language=nl&lg_txt=n&type=&sort=&numac_search=&cn_search=2009092808&caller=SUM&&view_numac=2009092808f

[68] https://www.ejustice.just.fgov.be/cgi_loi/article.pl?language=nl&lg_txt=n&type=&sort=&numac_search=&cn_search=2008121944&caller=SUM&&view_numac=2008121944f

[69] https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1996040445&table_name=wet

[70] https://www.gesetze-im-internet.de/gewebeg/BJNR157400007.html

[71] https://www.gesetze-im-internet.de/tpg/index.html

[72] https://www.gesetze-im-internet.de/tpg-gewv/index.html

[73] https://wetten.overheid.nl/BWBR0008066/2022-01-01

[74] https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&table_name=wet&cn=1986061337

[75] https://www.gesetze-im-internet.de/tpg/index.html

[76] https://www.gesetze-im-internet.de/tpg-gewv/index.html

[77] https://wetten.overheid.nl/BWBR0042755/2025-07-05

[78] https://wetten.overheid.nl/BWBR0043470/2022-05-26

[79] https://www.ejustice.just.fgov.be/eli/wet/2020/12/22/2021030071/justel

[80] https://www.gesetze-im-internet.de/mpdg/

[81] https://wetten.overheid.nl/BWBR0021505/2025-09-09

[82] https://wetten.overheid.nl/BWBR0021672/2018-08-01

		BE: *Wet op de geneesmiddelen [voor menselijk gebruik]*[83] DE: *Gesetz über den Verkehr mit Arzneimitteln*[84]

Blood, blood products, human tissues and cells

EU Directive 2002/98 currently regulates the safety, quality and distribution of blood and blood platelets, while human tissues and cells fall within the scope of EU Directive 2004/23. It should be noted that the existence of common EU minimum standards on safety, quality, labelling, documentation, donation and packaging, as laid down in these EU Directives, is a positive regulatory foundation for the cross-border exchange of these medical items. These standards support the harmonisation of safety and quality requirements across Member States and, in principle, should reduce obstacles to the movement of these materials across internal EU borders. However, the Directives establish only minimum standards in areas such as safety and do not prevent Member States from maintaining or introducing more stringent protective measures. As a result, it remains essential to assess the relevant national legislative frameworks. Indeed, although the Directives have achieved a certain degree of harmonisation in the field of quality and safety of blood, tissues, and cells, they leave considerable discretion to Member States in how the rules are implemented. This has led to divergences between national regimes, which can create barriers to the cross-border exchange of such items. As a result of this regulatory fragmentation, EU has recently decided to revise the legislative framework. The objective is to establish a robust, transparent, up-to-date regulatory system that ensures high levels of quality and safety, enhances legal certainty for patients and stakeholders, including the cross-border exchange of these substances.[85] The legal revision is also noted to be important for the exchanges between Member States, in order to ensure optimal patient access, particularly in cases of local crises and shortages.[86]

Following this legislative change, the regulatory framework set out in EU Directives 2002/98 and 2004/23 is replaced by a single instrument, EU Regulation 2024/1938, which will apply from 7 August 2027 onwards.[87] The new Regulation further harmonises the regulation surrounding donation, collection, testing, processing, storage, distribution, and application of 'substance of human origin' (SoHO). These activities may only be carried out pursuant to an authorisation, obtained by recognised and registered SoHO entities in each Member State.[88] As defined in Article 3(1) of the Regulation, a SoHO refers to "any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance." Accordingly, Recital 7 indicates that blood products, blood platelets, tissues and cells fall under the scope of the Regulation. The Regulations also imposes rules on the export and import of these substances, however these apply to third countries and not cross-border exchange between the Member States. Consequently, in principle, no additional authorisation is required solely because SoHO are transported across internal EU borders, although Member States may introduce additional

[83] https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1964032530&table_name=wet
[84] https://www.gesetze-im-internet.de/amg_1976/
[85] EU Regulation 2024/1938.
[86] *Ibid,* Recital 69.
[87] *Ibid,* Art. 85, see other transitional provisions in Arts. 81-84.
[88] *Ibid,* Art 16

requirements.[89] Thus, while cross-border exchange is facilitated by EU legislation, recognition and requirements of authorisations may still depend on national rules and practices. Accordingly, while the harmonisation achieved through the adoption of the Regulation constitutes a welcome development in clarifying and facilitating the cross-border transport of medical goods, including within the context of the EDEN-Medical project, it remains necessary to examine the relevant national implementing legislation. Such an analysis is required in order to determine whether legal barriers persist with respect to the cross-border exchange of blood products and human tissues.

Organs

Generally, organ (donation) falls under a separate legislative framework on the EU level, namely under EU Directive 2010/53 on standards of quality and safety of human organs intended for transplantation. The above-mentioned Directive 2004/23 on human tissue notes that it is not applicable to "organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body." Furthermore, the Directive distinguishes between organs and human tissues, defining "'organ" as "differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;" whereas 'tissue' means "all constituent parts of the human body formed by cells."[90] This distinction is also reflected in EU Regulation 2024/1938, as illustrated by the definitions within the respective legislative framework set out in the table below. One of the identified case uses for the EDEN-Medical is corneas, a transparent part of the eye that covers the iris and the pupil.[91] Corneal tissue transports are required both for elective surgeries (e.g. planned keratoplasties) and for emergency procedures following severe eye injuries or acute graft failures.[92] Therefore, it has to be examined whether in the use case of EDEN-Medical, the corneas fall under the rules of human tissue distribution or organ transplantation for accurate analysis of legal rules applicable under both EU and national law. As is the case for blood and human tissues, it is necessary to analyse the relevant national legal frameworks. This is particularly important for organ donation, as the EU framework provides only minimum requirements relating to the safety, information exchange and traceability of organs within the EU[93], while more detailed and substantive rules are laid down in national law.

Definitions of 'human tissue' and 'organs' across the EU legal framework		
Legal source	Human tissue	Organ
Directive 2004/23	"all constituent parts of the human body formed by cells"	"organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body" "differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;"

[89] *Ibid,* Art. 18(4), Art. 24(5).
[90] Art. 3 EU Directive 2010/53.
[91] Definition of National Cancer Institute of US, see https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cornea.
[92] EDEN-Medical Deliverable D1.1, "Report on Schedule of Requirements and Demonstration Flight Planning Framework."
[93] EU Commission Directive 2012/25.

Regulation 2024/1938	"This Regulation should apply to blood and blood components, as regulated by Directive 2002/98/EC, as well as to tissues and cells, including haematopoietic stem cells from peripheral blood, from umbilical-cord blood or from bone marrow, reproductive cells and tissues, embryos, foetal tissues and cells and adult and embryonic stem cells" "Nonetheless, when organs are removed from a SoHO donor for the purpose of separating tissues or cells for human application, for example heart valves from a heart or pancreatic islets from a pancreas, this Regulation should apply."	
Directive 2010/53		"'organ' means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation"

Medical devices

Medical devices within the EU are regulated by Regulation 2017/745. Catheters, one of the identified case uses of EDEN-Medical, also falls under this Regulation as it applies to any instruments that are used for diagnosing, preventing, monitoring, predicting, investigating, and treatment "of the anatomy or of a physiological or pathological process".[94] Any such device may be placed on the European market when it meets the general safety and performance requirements set out in the Regulation. This also means that in general within the EU, medical catheters may be transported freely across internal borders provided they comply with the Regulations. However, although the legal exchange of medical equipment such as catheters should in principle be straightforward, obstacles may still arise where equipment is not interoperable, for example, if hospitals use different types of machines or systems. This was also identified as a barrier in the context of cross-border procurement and the exchange of medical goods during shortages experienced in the COVID-19 crisis.[95]

Medications

Regarding human medicines, EU Regulation 726/2004 and EU Directive 2001/83 set out rules on market authorisation, manufacturing and distribution of medicines in the EU, overseen by European Medicines Agency. Also relevant is EU Regulation 2022/123 which, following the COVID-19 pandemic,

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[94] Art. 2(1) EU Regulation 2017/745.

[95] Schoenmaekers, S., Sivonen, S., & Kortese, L. (2021). *The Limitations and Opportunities of Cross-border Procurement during the COVID-19 Crisis and Recommendations for the Future*. ITEM, accessed via: https://crossborderitem.eu/en/projects/pandemric-euroregional-cooperation-at-the-time-of-a-pandemic/

was adopted to strengthen EU-wide crisis preparedness for medicinal products and medical devices, in response to supply uncertainties and the risk of shortages that prompted national export restrictions and protective measures. Marketing authorisations for medicinal products are not automatically valid across all Member States. Their territorial scope depends on whether the product has been authorised through the centralised procedure (valid EU-wide), the decentralised or mutual recognition procedures (valid in multiple Member States), or a purely national procedure (valid only in one Member State). Although a medicinal product authorised in one Member State may, in principle, be submitted for recognition in another Member State through the mutual recognition procedure, this does not guarantee uniform availability across the EU. As a result, differences persist between Member States as to which medicinal products are placed on the market and are available. This necessitates a more detailed analysis of the legal status of specific medicines, such as dantrolene or other antidotes (identified use cases for EDEN-Medical). Furthermore, Member States may introduce stricter national rules for certain categories of medicinal products within their territory.[96] This applies in particular to narcotic and psychotropic substances, medicinal products derived from blood, immunological medicinal products, and radiopharmaceuticals. This divergence is reflected in national legislation regarding opiates and has already been identified as an obstacle in existing cross-border ambulance cooperation between the three countries.[97] Additional obstacles may also arise in relation to reimbursement. Member States remain competent to determine the pricing of medicinal products, as well as which medicines are included in and reimbursed under their national health insurance schemes.[98] These differences in reimbursement frameworks have likewise been identified by the project partners as a practical barrier to cross-border cooperation.

Infectious materials

The cross-border transport of infectious materials, such as laboratory samples of untested blood and urine, has another legal dimension to it next to the rules on cross-border transport. As noted under the section on drone flight operations, dangerous goods can be only transported by a drone pursuant to operational authorisation in the certified category. Dangerous goods are considered goods which may result in high risk for third parties in case of accident.[99] Dangerous goods are further defined as "articles or substances, which are capable of posing a hazard to health, safety, property or the environment in the case of an incident or accident, that the unmanned aircraft is carrying as its payload", including items such as explosives, flammable materials, corrosives and radioactive substances.[100] Of particular relevance for EDEN-Medical is the fact that the definition also includes infectious substances. The EASA technical instructions further specify that *"blood that contains or potentially contains infectious substances should be transported in the 'specific' or 'certified' categories. If such transport results in a high risk for third parties in case of an accident, the UAS operation falls under the 'certified' category. If the blood contains or potentially contains infectious substances and is enclosed in such a container such that the blood will not be spilled in case of an accident, the UAS operation may fall under the 'specific' category if there are no other causes of high risk for third parties."*[101] This may introduce

[96] Art. 83 EU Directive 2001/83.
[97] Sivonen, S., & Kortese, L. (2021). Cross-border Cooperation on Ambulance and Intensive Care Transport: Examining Opportunities to Strengthen Cooperation. ITEM, accessed via: https://crossborderitem.eu/en/projects/pandemric-euroregional-cooperation-at-the-time-of-a-pandemic/
[98] Art. 4(3) EU Directive 2001/83.
[99] Art. 6(1)(b)(iii) EU Regulation 2019/947.
[100] *Ibid,* Art. 2(11).
[101] Accessed via: https://www.easa.europa.eu/en/document-library/easy-access-rules/online-publications/easy-access-rules-unmanned-aircraft-systems?page=4

additional limitations for the envisaged cross-border operations in the EDEN-Medical project. It should therefore be assessed by the project partners, in close cooperation with the national competent aviation authorities, whether it is feasible to transport these items in sealed containers in order to limit risks and to allow authorisation under the specific category, as is the case for other envisaged drone operations. This assessment is particularly relevant given that authorisation under the certified category is not yet possible due to the ongoing development of the regulatory framework. Furthermore, it should be noted that, although the Regulation provides a common definition of dangerous goods, the AiRMOUR project reports differences between countries in how this definition is interpreted. It is reported that some countries classify all blood samples as dangerous goods, whereas others do so only when blood samples are suspected or confirmed to be infected with a contagious disease.[102] These potential differences within the Meuse-Rhine region should therefore also be mapped.

4.3 Other Legal Aspects: Insurance, Liability, Data Exchange and Reimbursement

In addition to the legal questions surrounding the obtaining of flight authorisations in cross-border contexts and the exchange of medical goods across borders, several other elements are relevant and require consideration. First, it must be ensured that insurance and liability arrangements are adequately in place, as these aspects must also be addressed in the flight authorisation application. Indeed, operational authorisation is granted only where the operator has "provided a statement confirming that the intended operation complies with any applicable Union and national rules relating to it, in particular with regard to privacy, data protection, liability, insurance, security and environmental protection."[103] The project partners indicated that liability insurance covering damage to third parties is usually obtained in the country of operation and, depending on the insurance conditions, may also be valid in other EU Member States. However, additional legal questions may arise in relation to liability and the automated nature of the flights, as well as with regard to insurance coverage for the transported contents, namely the medical goods themselves.

Another relevant aspect concerns the exchange of medical data and related privacy considerations. Within the EU, the collection and processing of personal data are governed by the General Data Protection Regulation 2016/679 (the GDPR). In general, the GDPR permits the processing of personal data in case a consent of the patient is obtained or when it is necessary in order to protect the vital interests (such as health) of the data subject.[104] Although the GDPR provides for harmonisation of data protection rules, other projects have shown that national differences in implementation and interpretation continue to complicate the cross-border sharing of health data.[105] As the objective of the EDEN-Medical project is to enable the exchange of medical goods for patient treatment, it is necessary to determine which patient information must be shared and whether this can be limited through the use of anonymised or pseudonymised identifier codes linking the delivered medical goods to the patient at the receiving hospital. These considerations are also relevant for the development of the telemedical platform envisaged within the project, which would enable hospitals to order medical

[102] AiRMOUR D3.6: The impact of EMS scenarios on aviation and future regulations, 31.8.2023, p. 12, accessed via: https://drive.google.com/file/d/1YnbtSWv5DrVt1ihG02r55u5CZR14lasP/view

[103] AMC1 Article 13(1) Cross-Border Operations or Operations Outside the State of Registration, Application Form for a Cross-Border UAS Operation.

[104] Art. 6 EU Regulation 2016/679.

[105] Mertens, P., Unfried, M., & Schneider, H. (2021). Applying the GDPR and national legislation in cross-border public health cooperation. European Commission. https://www.aebr.eu/wp-content/uploads/2021/11/Report_16.pdf

goods cross-border via drone logistics. In this context, it is furthermore relevant to assess the extent to which hospitals already process patient data electronically, as opposed to relying on paper-based systems, as practices differ significantly between hospitals. Recently, the EU Regulation 2025/327 establishing the "European Health Data Space" entered into force, with the aim of establishing interoperable data standards and infrastructures that enable patients and healthcare professionals to access health data across Member States.[106] This framework functions as a *lex specialis* to the GDPR for health data and may provide both a legal and technical basis for more efficient electronic data exchange in the coming years. This is particularly relevant and a positive legal development in light of the current fragmentation, not only in the level of digitisation but also in the underlying technical systems, which are often not fully interoperable: an obstacle that arises not only in a cross-border context, but also at the national level.[107]

A final remark concerns the reimbursement of costs. This is a relevant issue for hospitals, particularly in relation to who bears the costs of the drone operations, the medical goods themselves, and their cross-border transfer – but also relevant for the patient receiving the medical goods. At EU level, the legal framework for cross-border healthcare, notably EU Regulation 883/2004 on the coordination of social security systems and EU Directive 2011/24 on patients' rights in cross-border healthcare, establishes the conditions under which healthcare costs incurred in another Member State may be reimbursed. In certain cases, prior authorisation of the health insurer is required, which may also affect the level of reimbursement. Despite the existence of this EU framework, practical difficulties may still arise, particularly where the medical goods concerned are not included in the national health insurance coverage of the Member State of affiliation. As noted above, this is for instance the case for medications, where availability and reimbursement differ between Member States.[108] In light of these uncertainties, it is advisable for the hospitals involved to address these issues proactively and to reach clear agreements among themselves on cost allocation and reimbursement. Inspiration may be drawn from existing agreements on cross-border healthcare reimbursement, such as those established for ambulance cooperation under EMRIC and the Benelux Union, as well as from hospital cooperation frameworks within the Meuse-Rhine region, including agreements relating to NICU and PICU intensive care services.[109]

5 Stakeholder Engagement and Institutional Cooperation

Identifying hurdles and obstacles of any nature is only a first step. The next step is to translate these findings into impact by defining how relevant stakeholders can be reached and engaged, which stakeholder groups must be involved, and which measures are required to enable institutional cooperation and practical follow-up.

5.1 Stakeholder Landscape and Rationale for Engagement

The analysis in the preceding chapters shows that the technical feasibility and medical necessity of drone-based transport of medical goods are well established or on its way to be established, while

[106] EU Regulation 2025/327.
[107] Sivonen, S., & Clemens, T. (2022). ITEM Cross-Border Impact Assessment 2022: Dossier 1: European Health Data Space: Ex-ante analysis of the cross-border effects on the Euregio Meuse-Rhine. ITEM. https://crossborderitem.eu/en/european-health-data-space-ex-ante-analysis-of-the-cross-border-effects-for-the-euregio-meuse-rhine/
[108] Sivonen, S., & Büttgen, N. (2021). Is the EU Patient's Rights Directive fit for providing well-functioning healthcare in cross-border regions? An ex-post assessment. ITEM, accessed via: https://crossborderitem.eu/en/publications/cross-border-assessment-2021-dossier-4-is-the-eu-patients-rights-directive-fit-for-providing-well-functioning-healthcare-in-cross-border-regions-an-ex-post-assessment/
[109] See list of regulations at https://www.emric.info/wat-emric/verdragen.

major obstacles persist in legal and administrative practice, particularly in cross-border settings. Against this background, stakeholder engagement is a central element of this concept paper and the EDEN-Medical project. It is required to align clinical needs, operational feasibility, and regulatory expectations, and to support the development of a pragmatic and scalable framework for cross-border medical AAM.

Relevant stakeholder groups can be structured into four main categories:

- First, end users include in-hospital clinicians and other healthcare staff, as well as pre-hospital emergency medical personnel. Their perspectives are essential to ensure medical relevance, usability, and acceptance in routine and emergency settings.
- Second, operational actors include logistics providers, drone operators, and infrastructure providers responsible for flight operations, ground handling, and integration into existing logistics chains. Their input is necessary to assess feasibility, safety, and scalability, and to translate requirements into operational concepts.
- Third, regulatory and policy stakeholders at regional, national, and European level are critical to address the dominant legal and administrative barriers identified in Chapter 4. This includes aviation authorities and airspace-related actors, as well as authorities responsible for medical goods regulation (see table below), data governance, reimbursement, and cross-border healthcare arrangements.
- Fourth, industry actors and comparable initiatives in the medical transport, logistics, and drone sectors provide valuable reference points and implementation experience. They support benchmarking, knowledge exchange, and the identification of viable pathways towards sustainable deployment beyond project-based pilots.

The overall rationale of engaging these stakeholder groups is to ensure that technical feasibility, medical necessity, and regulatory viability are addressed in an integrated manner. Structured stakeholder engagement is recognised as a key factor in European research and innovation policy, contributing to the co-creation of knowledge and the alignment of innovation outcomes with policy objectives[110]. This integrated approach is required to generate impact beyond isolated demonstrations and to support a cross-border implementation perspective that is suitable for the Meuse–Rhine region and that can be translated to other cross-border regions. Given the extensive role of national authorities and legislators in these matters, it is both important and planned that these stakeholders will be consulted as part of the legal analysis.

Competent authorities		
Country	**Medical goods**	**Drone flight operations**
Netherlands	Ministry of Health (Ministerie van Volksgezondheid, Welzijn en Sport), Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd, IGJ)	Human Environment and Transport Inspectorate, (Inspectie Leefomgeving en Transport Ministerie van Infrastructuur en Waterstaat, ILT)

[110] Gudek L, Rao M, Broerse J. Stakeholder engagement in European research and innovation: An investigation into how and why EU R&I projects develop engagement tools [version 2; peer review: 3 approved]. Open Res Europe 2025. 5:107. https://doi.org/10.12688/openreseurope.19907.2

Germany (North Rhine-Westphalia)	Federal level: Federal Ministry of Health (Bundesministerium für Gesundheit), Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), Paul-Ehrlich-Institut (PEI), State-level: Bezirksregierung	State aviation authorities of the corresponding federal states. However, some states including NRW have transferred responsibility to the Federal Aviation Office (Luftfahrt-Bundesamt)
Belgium	Federal Public Service Health, Food Chain Safety and Environment (FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu), Federal Agency for Medicines and Health Products (Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten)	Federal Public Service Mobility and Transport (Federale Overheidsdienst Mobiliteit en Vervoer), Belgian Civil Aviation Authority (Directoraat-generaal Luchtvaart)

5.2 Early End-User Involvement

Early involvement of end users is applied in EDEN-Medical to ensure that project assumptions and solution concepts reflect real-world practice. In this context, structured interviews and two focus group discussions were conducted with external and internal, clinical and pre-clinical stakeholders representing key end-user groups across the border-region of the Meuse-Rhine area from Germany, the Netherlands, and Belgium.

The purpose of these activities is to capture practitioner perspectives on cross-border drone-based medical transport, with a focus on operational realities, acceptance conditions, and practical constraints. The discussions involved multidisciplinary groups of participants, including clinicians, anaesthesiologists, logistics specialists, representatives of cornea banks, hospital innovation management and pharmacy leadership, as well as emergency physicians, telemedicine experts, emergency medical service volunteers, field instructors, and paramedics. The insights generated through this early end-user involvement form an important empirical basis for the analysis of medical necessity presented in Chapter 2 and for the definition and prioritisation of technical and operational requirements addressed in Chapter 3.

At the same time, these activities serve a strategic role within the overall stakeholder engagement approach. They function as an early co-creation instrument to ensure that subsequent engagement formats and implementation concepts address the priorities of practitioners and operational stakeholders[111]. Detailed findings from the interviews and focus groups are presented in Chapter 2 and are therefore not repeated in this chapter.

[111] Petkovic J, Magwood O, Lytvyn L, et al. Key issues for stakeholder engagement in the development of health and healthcare guidelines. Res Involv Engagem 2023. 9(1):27. https://doi:10.1186/s40900-023-00433-6

5.3 Planned Stakeholder Workshops and Engagement Formats

Future stakeholder engagement in the context of cross-border medical AAM requires structured and differentiated formats that address the needs of both implementation-oriented actors and policy-level decision-makers. To this end, two complementary engagement formats are envisioned.

First, an exchange-oriented workshop format focusing on peer initiatives and market actors serves to facilitate dialogue with comparable research and innovation projects as well as companies active in medical transport, logistics, and drone-based delivery systems. Such a format enables the systematic mapping of relevant stakeholders across the medical AAM ecosystem and supports the identification of scalable and transferable approaches beyond individual pilot contexts. In addition, it provides insights into market-driven and implementation-oriented pathways, including operational models, governance structures, and emerging standardisation practices relevant for the future regulation of medical AAM in this cross-border region. Such dialogue is also important in identifying common legal and administrative obstacles, which can be used to define common policy-level recommendations.

Secondly, a policy- and administration-focused engagement format is required to ensure alignment with regulatory realities and legislative processes. Engagement with policymakers, ministries, and competent regulatory and administrative authorities enables the discussion of regulatory options and potential pathways for legal adaptation in the field of cross-border medical AAM. This format supports the validation of project findings from a policy perspective and provides a structured setting for consolidating evidence into legislative and administrative considerations. It contributes to the development of a regional and potentially supra-regional position paper addressing cross-border medical AAM, with a focus on harmonisation needs, process simplification, and the clarification of roles and responsibilities, in line with the legal and administrative barriers identified in Chapter 4.

Moreover, future engagement of a diverse and representative set of stakeholders is expected to strengthen policy dialogue and increase the likelihood that conceptual insights lead to tangible regulatory and institutional change within the legislation of the Meuse-Rhine region and Europe-wide.

5.4 From Engagement to Impact: Towards a Position Paper

To make such change tangible, the stakeholder engagement approach follows a coherent progression from practice-based insights to ecosystem-level reflection and policy consolidation. Inputs derived from interviews and focus group discussions provide grounded perspectives from end users and practitioners and support the identification and prioritisation of key requirements and bottlenecks. Building on this foundation, engagement with peer initiatives and market actors enables the mapping of relevant stakeholders and the identification of viable implementation options and transferable approaches. Subsequent dialogue with policymakers and competent authorities provides a setting for policy-level consolidation and prioritisation, with the objective of translating empirical findings into actionable regulatory and administrative considerations.

The intended outcome of this engagement pathway is an evidence-based position paper with strong regional anchoring in the Meuse-Rhine region. At the same time, the position paper is designed to consider transferability to other cross-border regions facing comparable challenges in cross-border drone operations and medical goods transport. As such, these engagement activities provide a concrete basis for defining strategic concepts and future frameworks.

6. Conclusions and Policy Recommendations

6.1 Summary of Key Findings and Core Barriers

Medical Requirements and Necessity

Medical logistics play a critical role in ensuring timely healthcare delivery, particularly in crisis and emergency situations. Patients who urgently require specific medications or blood products, as well as hospitals that depend on the rapid availability of specialised medical equipment to maintain an adequate level of care, rely on transport solutions that are reliable and fast. There is a clear medical necessity for transport systems that are efficient in terms of time and personnel, predictable in their performance, and ideally also environmentally sustainable.

At present, the transport of medical goods remains largely dependent on conventional road-based infrastructure, which is vulnerable to congestion, disruption, or damage. This dependency poses significant risks for time-critical deliveries of essential medical supplies, laboratory samples, blood products, tissues, medications, and transplant-related materials. Findings from the EDEN-Medical project show that across all three partner hospitals, medical goods are transported on a daily basis, often under considerable time pressure. While routine transports are frequent and largely predictable, emergency transports occur less often but are highly time-critical, difficult to plan, and frequently rely on taxi services, which are costly and inefficient. Despite the close geographical proximity of hospitals across national borders in the Meuse–Rhine region, cross-border transport of medical goods currently takes place only to a very limited extent. This points to a substantial and largely untapped potential for cross-border cooperation and shared use of resources.

Technical and Operational Considerations

Although the technical and operational feasibility of transporting medical goods by drone has already been demonstrated in multiple studies, further developments and adaptations are required to fully realise the potential of these systems. Medical goods differ significantly in size and weight, which directly influences the suitability of different drone systems. In addition, they impose varying requirements with regard to temperature control, positioning within the drone, vibration sensitivity, and packaging. All of these factors must be considered when selecting an appropriate drone system for a given transport task. Beyond the characteristics of the medical goods themselves, operational aspects such as transport distance and the availability of suitable landing sites also play a crucial role. While some drone systems require runways for takeoff and landing, others are capable of vertical takeoff and landing and only need a dedicated and secure area. As a result, different drone systems exhibit distinct strengths and limitations, and no single system is suitable for all use cases.

For this reason, a functional cross-border medical drone logistics network should be manufacturer-independent and capable of operating different types of drone systems. In addition, standardised cargo containers that can be used across systems and accommodate various types of medical goods would be highly beneficial. A high degree of automation is another key requirement to ensure efficiency and scalability. Equally important is the integration of drone logistics into existing hospital systems, both in terms of logistical workflows and interoperability with hospital IT infrastructure. Such integration is essential to enable smooth operational processes, increase user acceptance, and ensure the long-term sustainability, adaptability, and resilience of a drone-based logistics network.

Identified Legal and Administrative Barriers

The most significant barriers to establishing a cross-border drone transport network for medical goods are therefore not of a clinical, technical, or operational nature, but rather lie in legal and regulatory constraints and in lengthy and complex administrative procedures.

The preliminary analysis shows that, while the European Union promotes cross-border healthcare cooperation and has established a harmonised legal framework for both drone operations and the regulation of medical goods, legal fragmentation persists at national level. In particular, differences in implementation, administrative practice, interpretation, and complementary national rules continue to create legal and practical obstacles. These obstacles are amplified in cross-border regions such as the Meuse-Rhine region, where drone operators and hospitals must navigate multiple regulatory systems.

With regard to drone operations, the EU framework under Regulations 2018/1139 and 2019/947 provides a common legal basis, including specific provisions for cross-border flights. Nevertheless, the requirement to obtain separate national authorisations and divergent approaches to airspace management and geo-zones significantly undermine the feasibility of cross-border emergency drone operations. The long processing times of applications, lack of expedited procedures for emergency operations and the absence of a single “cross-border authorisation” remain key structural bottlenecks. Regarding flight authorisation, it is important to assess whether cross-border cooperation between national aviation authorities can be facilitated, whether cross-border authorisations could be simplified - with a view to a more effective single authorisation in a cross-border region - and whether geozone areas and maps can be better aligned across Europe or speficially in the Meuse–Rhine region. In relation to medical goods transport, the analysis shows that despite the principle of free movement of goods, the applicable legal regime permitting cross-border transfers differs substantially depending on the category of goods involved. Blood, tissues, cells, organs, medical devices, medicinal products, and infectious materials are each subject to distinct EU and national rules. This legal complexity and absence of clear guidelines on the cross-border transport of medical goods hinders cross-border initiatives such as EDEN-Medical. The forthcoming application of EU Regulation 2024/1938 on substances of human origin represents an important step towards greater harmonisation, yet national implementing measures and remaining discretion will continue to require careful legal assessment. The EU regulatory system is largely based on a risk-based approach, which is also reflected in the regulation of different categories of medical goods. In general, medical equipment such as catheters is subject to fewer legal constraints when transported across borders, while substances of human origin (such as blood and tissues) are subject to stricter rules, organs and medications to even more stringent requirements and national rules. Consequently, the cross-border transport of medical goods requires an in-depth analysis of the applicable national legislation for each specific category. It is also essential to consult the hospitals involved, as, in addition to EU and national legislation, hospitals may impose their own internal rules and limitations on the cross-border procurement of medical goods.

Finally, cross-cutting legal issues, such as liability, insurance coverage, health data exchange, interoperability of digital systems, and reimbursement, remain critical determinants for the operational viability and sustainability of cross-border drone-based medical logistics.

Against this background, the EDEN-Medical project plays a crucial role in identifying, analysing, and addressing these legal obstacles. The preliminary findings set out in this concept paper form the basis for further in-depth legal analysis and targeted recommendations, which will be elaborated in the forthcoming project deliverables, in particular the final legal analysis report.

6.2 Policy and Legislative Recommendations

Based on the findings from the structured interviews and focus group discussion with clinical stakeholders as well as the preliminary legal and regulatory analysis conducted within the EDEN-

Medical project, several key policy and legislative recommendations can be derived. These recommendations aim to address existing regulatory fragmentation and administrative barriers that currently limit the scalability and operational viability of cross-border drone-based medical transport.

Harmonisation of EU and National Legal Frameworks

Although the European Union has established a common regulatory framework for unmanned civil aviation, significant fragmentation persists at the national level. Divergent interpretations, implementation practices, and supplementary national rules create uncertainty and complexity, particularly for cross-border operations. Future policy efforts should therefore focus on strengthening harmonisation between EU-level regulations and national legislation, with the aim of reducing legal inconsistencies and improving legal certainty for operators involved in cross-border medical drone transport.

Unified Approaches to Airspace Management and Geo-Zones

Differences in airspace management and the designation of geo-zones represent an additional barrier to cross-border flight planning. The absence of a common, legally binding approach to geo-zone definition complicates route planning and increases operational uncertainty. Policymakers should work towards more unified and interoperable approaches to airspace management, including harmonised geo-zone classifications and up-to-date digital maps accessible across borders.

Establishing a Single Cross-Border Flight Authorisation Process

One of the most significant obstacles identified is the requirement to obtain separate flight authorisations in each country involved in a cross-border operation. These procedures are often lengthy, administratively burdensome, and subject to differing national requirements. To streamline this process, a Single Cross-Border Flight Authorisation should be established. From the drone operator's perspective, this would function as a "one-stop shop" through which the application could be submitted. This would contrast with the current process, under which authorisation must first be obtained from one country, followed by separate approvals from other countries. A single procedure would therefore substantially reduce the administrative burden for cross-border drone operators, especially those operating in a cross-border region of three countries. As an initial step, such a one-stop-shop system could be established between neighbouring countries with significant cross-border activity, for example within the Benelux or at a cross-border regional level (e.g. the Meuse-Rhine region).

Expediting Authorisation Processing Times

Currently, aviation authorities are under significant pressure due to a high volume of applications and insufficient human resources. This has resulted in application backlogs and lengthy processing times, ranging from several weeks to several months. Member States should therefore invest and allocate adequate financial resources to increase administrative capacity. Moreover, as no dedicated high-urgency (emergency) authorisation procedure currently exists, the system makes it difficult to implement initiatives in response to healthcare emergencies or other public emergencies, such as fire response. This challenge is particularly acute for cross-border and ad hoc operations, where a general operational authorisation cannot be requested well in advance due to urgent needs, or where flights fall outside the scope of an existing authorisation (for example, deviations from predefined routes, such as flights to or from emergency locations rather than between pre-approved hospitals).

Strengthening Cross-Border Cooperation Between Aviation Authorities

Improving cooperation between national aviation authorities includes closer alignment of approval procedures, shared understanding of operational requirements and regulation on airspace, and improved communication channels such as joint working groups or formal coordination mechanisms.

Currently, such cooperation largely exists under the EU umbrella, notably through EASA. However, some our project policy recommendations such as the introduction of a single authorisation procedure could be more effectively promoted through more intensive cooperation between neighbouring countries (Belgium, the Netherlands and Germany) and cross-border regions (e.g. the Meuse-Rhine region).

Creating Clear Guidelines on Cross-Border Transport of Medical Goods

Understanding which rules apply to the cross-border transport of medical goods (whether for aviation-based drone logistics or road transport) is highly complex. The relevant legislation is fragmented at the national level and largely depends on the category of medical goods being transported. To support both emerging medical initiatives and existing forms of cooperation, such as ambulance services, hospitals, and other healthcare organisations, there would be significant value in developing clear and harmonised guidelines. For example, guidelines established jointly between the Netherlands, Belgium, and Germany could help stakeholders understand which rules they must comply with when transporting medical goods across borders.

6.3 Outlook and Roadmap for Further Implementation

Establishing a cross-border medical goods transport network using drone technology would strengthen the healthcare systems in the Meuse-Rhine region. The population in the region would benefit from the improved cooperation between hospitals and clinicians, sharing not only medical goods but also knowledge and experience. The healthcare resilience and disaster preparedness of the entire region could be increased. To enable this vision of a more connected border region regarding medical goods transport the EDEN-Medical project proposes certain steps to be taken concerning technical and operational considerations such as automation, interoperability of systems and integration into logistical concepts, as well as legislative adaptations to harmonise the regulatory framework, streamlining cross-border authorisation processes and fostering cross-border coordination between authorities.

But, additionally to these proposed steps, the project EDEN-Medical should be viewed within the context of broader European developments, particularly strategies on AAM, disaster resilience goals outlined by the EU and initiatives promoting digital health and telemedical implementation. In this context, medical drone transport should not be regarded as a niche application, but rather as a potentially system-relevant component of future healthcare logistics. Beyond immediate transport use cases, AAM systems could support centralised stocking of selected high-value or time-critical medical goods, optimise regional resource utilisation, and be integrated into national and cross-border emergency response systems, similar to existing ambulance service cooperation. The integration of artificial intelligence (AI) and AI-driven predictive models may further enhance preparedness and operational efficiency.

Looking ahead, several technological, regulatory, and institutional developments can be anticipated. From a technological perspective, increasing maturity is expected in areas such as beyond visual line of sight operations, the introduction of certified categories for higher-risk drone missions, and the integration of drone traffic into U-space and conventional air traffic management systems. In parallel, regulatory frameworks are likely to evolve, including further development of the EASA certified framework and increased harmonisation of rules governing the transport of medical goods, for example through upcoming regulatory changes expected from 2027 onwards. At an institutional level, authorities are expected to gain growing experience with cross-border AAM operations, leading to learning effects and more streamlined administrative processes over time.

In the long term, the vision is to establish a permanent, cross-border medical AAM network that moves beyond pilot projects and isolated demonstrations toward sustained routine operations. Such a network should be fully integrated into existing state crisis and disaster response systems as well as into regular hospital logistics.

Two aspects that could not be fully addressed in this concept paper due to a different focus (namely on legislative barriers), but which are nevertheless highly relevant and must be examined in greater detail when it comes to long-term implementation, are economic viability and environmental considerations (sustainability).

From an economic perspective, the full utilisation of such a cross-border drone transport network is crucial, as optimal profitability can only be achieved when the system is used to its full capacity. The network should therefore be available both for urgent and emergency transports as well as for routine operations and regular transport tasks. If, as considered in the use case of the EDEN-Medical project, the primary focus is on emergency and time-critical transports, it must be taken into account that these occur relatively infrequently compared to regular transport operations. This raises the question of how a high level of system utilisation can be ensured, for example by avoiding empty flights and by enabling flights during night-time hours as well (and possibly even especially at night).

In addition, regular use of the system ensures that all stakeholders (clinical users, drone operators, etc.) remain trained and experienced in handling the system - both the drone itself and the associated telemedicine platform, the loading and unloading processes, logistical interfaces with hospitals, flight planning, and related procedures. This regular practice ensures that, in emergency situations where time is critical, the entire process chain functions smoothly, quickly, and reliably. Regular maintenance is also essential to ensure safe and reliable operation.

Consequently, prior to implementation, a comprehensive economic assessment as well as a sustainability analysis in line with the principles of the circular economy will be necessary. This should include considerations of product longevity, social, ecological and economic dimensions, circularity, and the 9R strategy[112].

To move from conceptual exploration to sustainable implementation, a phased and structured roadmap is required.

Short-term: Preparation and Enabling Conditions (0-2 years)

In the short term, the focus should be on creating the necessary enabling conditions for cross-border medical drone operations. This includes the implementation of clearly defined pilot projects, such as EDEN-Medical, with a limited number of participating hospitals and well-defined medical use cases.

At the institutional level, stable cooperation structures between hospitals, aviation authorities, health authorities, and emergency services should be established. Particular attention should be given to streamlining authorisation processes, developing pragmatic procedures for time-critical operations, and improving coordination between national authorities in cross-border settings. In parallel, technical foundations such as standardised cargo containers, interoperable ground infrastructure, and interfaces to hospital information systems should be further developed and tested.

[112] https://circulareconomy.europa.eu/platform/sites/default/files/categorisation_system_for_the_ce.pdf

Where possible, medical drone logistics should also be integrated into existing cross-border cooperation structures rather than creating new parallel frameworks, for example by embedding coordination mechanisms within established platforms such as EMRIC. Leveraging such structures can facilitate implementation, as trusted governance and communication channels are already in place.

Data collection during this phase is essential to generate evidence on safety, reliability, cost efficiency, and environmental performance, thereby providing a robust basis for future regulatory and policy decisions.

Mid-term: Harmonisation and Scaling (2-5 years)

In the mid-term, successful pilot activities should be gradually expanded in scope and scale. This includes the integration of additional hospitals, an increased range of transported medical goods, and the extension of operational areas across borders. Regulatory efforts should focus on reducing fragmentation through mutual recognition of operational approvals, harmonised approaches to airspace management, and the development of standardised procedures for emergency medical drone operations.

During this phase, cross-border medical drone transport should increasingly be embedded into regional emergency and disaster response frameworks, analogous to existing cross-border cooperation in ambulance services. Telemedicine platforms can evolve into a central operational backbone, linking drone operations with clinical workflows, logistics systems, and health information exchange.

Long-term: System Integration and Routine Operation (5+ years)

In the long term, the objective is to transition from project-based operations to a stable and sustainable system that is fully integrated into routine healthcare delivery as well as crisis and emergency response mechanisms. This includes the establishment of EU-wide interoperable standards for medical AAM operations, data exchange, and safety management, as well as the alignment of reimbursement and liability frameworks.

Advanced applications, such as centralised or shared cross-border stocking of high-value or time-critical medical goods, and the integration of AI-based predictive models for demand forecasting and logistics optimisation, may further enhance efficiency and resilience. Ultimately, cross-border medical drone transport can become an integral component of a digitally connected, resilient European healthcare ecosystem, strengthening both everyday medical logistics and preparedness for future crises.

In conclusion, EDEN-Medical demonstrates that cross-border medical drone logistics are both technically feasible and strategically valuable, but require coordinated legislative adaptation, administrative harmonisation, and close collaboration between healthcare providers, authorities, and policymakers. By addressing these challenges, AAM can become a key enabler of resilient, efficient, and future-proof healthcare systems in the Meuse–Rhine region and beyond.

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