Journal of Intelligent & Robotic Systems (2022) 106: 12
https://doi.org/10.1007/s10846-022-01681-6

REGULAR PAPER

U-Space and UTM Deployment as an Opportunity for More Complex UAV Operations Including UAV Medical Transport

Mateusz Kotlinski[1] · **Justyna Krol Calkowska**[2]

Received: 13 May 2021 / Accepted: 28 June 2022 / Published online: 24 August 2022

Abstract

Unmanned Aerial Vehicles (UAVs) or Unmanned Aircraft Systems (UASs) commonly called drones are relatively new entrants to the airspace. The regulatory agencies, numerous States and entities are involved in creation of the safe integration with manned aviation. The so-called U-space concept announced by the European Commission is one of the approaches to achieve that goal. There is also known concept of Unmanned Traffic Management (UTM) – a tool which would enable the services needed for safe conduct of UAV flights in generally accessible airspace. There are quite a few European projects which focuses on testing UTM capabilities in order to find a solution which could enable the market and ensure safe UAV operations. One of those systems is PansaUTM – which was developed in order to coordinate drone flights in different types of airspace in Poland. The first part of the paper will present an example of the implementation of this system as a foundation for new possible applications of drones and increasing number of operations. The conclusion of the first part of the article is that, in line rapid growth of UAS flights and different applications of drone services, the European drone ecosystem should evolve even further to deploy very complex drone operations in scalable manner. In order to accommodate unmanned air taxi operations, cargo flights, medical cargo flights, automatic surveillance flights, etc. Europe is preparing towards deployment of Advanced Air Mobility (AAM).

The second part of the text indicate the possibility of extensive use of drones in medical logistics as well as minimizing the epidemiological risk as a result of the use of this mean of transport. At the same time, it should be stressed out that the medical transport using drones can be used in urgent situations, where the main variable that has an impact on the success of life and health saving is the breaking of barriers to reaching difficult-to-reach places. In addition, the development of transport using drones can have a lasting impact on improving the quality of life of chronically ill patients who experience severe disease recurrence and thus on the need to implement emergency prevention or treatment measures.

The second part of the article focuses as well on the U-space concept as an opportunity for UAVs to be widely used in the field of day-to-day supplies as well as health-related supplies. In the context of the spread of SARS-CoV-2 virus, drones may be used to provide diagnostic screening tests, medicinal products and septic materials, transport of samples of biological material, as well as an information campaign on how to deal with an epidemic, quarantine or isolation at home. The use of UAV for medical supplies is economically and legally justified. The U-space environment from the operational and regulatory side is a multidisciplinary approach that requires the interaction of aviation, law, medicine, robotics, mechatronics and engineering experts. The legal framework for the development of U-space should be taken into account, as well as sector-specific regulations taking into account the principles of the use of drones in strictly defined areas, including in the process of medical supply, and liability for damage caused by UAV medical supply or AI-controlled intelligent machines.

Keywords UAV · UAS · Drones · U-space · UTM · Regulations · Medical transport · COVID-19

1 Introduction

The boom of the drone market is visible around the world. The drones flights are no longer incidental because drones started to be accessible to almost anyone, even the private users due to the drone manufacturers which provide easy to

✉ Mateusz Kotlinski
mateusz.kotlinski@pansa.pl

Extended author information available on the last page of the article

use consumer and semi-professional drones. From the one side the new developing aviation market is a chance for the economy and new applications supporting many aspects of life, however drones could simultaneously be a threat for the legacy aviation. Due to this very reason, all aviation stakeholders became vigilant on this matter and started to create concepts which might arrange the drone traffic without compromising existing level of safety. One of the concepts is LAANC (Low Altitude Authorization and Notification Capability)[1] which is endorsed by the Federal Aviation Administration (FAA). The different American concept worth mentioning is the National Aeronautics and Space Administration (NASA) UTM concept.[2] In Europe the need for solutions related to drones and their integration with manned aviation was quickly identified. The concept was named U-space and announced by the European Commission (EC) at the European Union Aviation Safety Agency (EASA) High Level Conference on Drones in 2016 in Warsaw, Poland.[3] Back then the market was at its preliminary stage and due to ambitious task and urgent call from the EC to develop solutions and U-space services, many entities started to do so. National Aviation Authorities (NAAs) and Air Navigation Services Providers (ANSPs) began to look for the realizing the U-space concept. The SESAR U-space Blueprint[4] assumed that U-space implementation will be conducted in phases – starting with U1 foundation services, U2 initial services, U3 advanced services, U4 full services.

Blueprint document did not provide the exact dates of rolling out of certain level of services. The general timeframe can be find in Drone Roadmap document.[5] The U1 services were scheduled to be deployed in 2019, U2 level in 2022, U3 level in 2027 and the U4 level in 2035.

The authors' contribution to the writing of this work are as follows: The works related to the collection of material and its preparation in part one were carried out by the first author of this manuscript. The second part, both for the collection and analysis of the material, is the participation of the second author.

2 Materials and Method

The material used in the article is the applicable law and data relating to the use of UAV. The study uses the method of analyzing the collected material and the method of statistical data analysis. The article also analyzes the implementation of PansaUTM system as an fundament for new possible applications of drones. The authors' analysis based on review of the current literature included the scope of using drones for medical transport, minimizing health risks and improving the quality of health services.

The article presented consists of two parts. The first part of the paper will present an example of the implementation of this system as a foundation for new possible applications of drones. It also stresses out the importance of the regulations that support the development of the new branch of the economy and aviation without putting too many constraints on it, while still keeping the safety aspect as a priority.

The first part is a systematic review of the principles of UAV in airspace as well as of the development of PansaUTM system. Part one also contains the elements of meta-analysis of UAV usage and development data.

The second part of the article is devoted to the analysis of the possibilities offered by the use of UAV in the wider protection of health, as well as to the prevention and fight against COVID-19. It also presents a systematic review of the use of UAV at the medical transport level, the reduction of greenhouse gas emissions through the use of UAV as an alternative to road transport, as well as liability for damage caused in connection with the transport of infectious materials using UAV.

3 Legal Fundaments of UAS Operations

Despite the well distributed milestones, some pioneer States manage to develop and deploy some of the elements of the described level of services before the deadlines. It was triggered by the number of drone flights which was no longer possible to manage in the traditional way. The development of digital tools and services was also more probable and justified when the regulatory framework was there. The drone operations in recent years were not unified on the European level – it was a duty of the each National Member State to develop their own regulations and procedures or wait until the European Regulations are adopted. [6] In example the first Polish regulations were published in 2013. The European regulations were scheduled to come into force on 1 July 2020.[7] However the coronavirus pandemic resulted in postponing the implementing and delegated regulations, which eventually went into force on 31 December 2020.[8] This paper will present the example of Poland as a one of the States which started to develop their regulations early and how this regulation was used in order to implement the Unmanned Traffic Management (UTM) system in Poland called PansaUTM by Polish Air Navigation Services Agency – Air Navigation Services Provider in Poland before the implementation of the European Regulations.

3.1 Aviation Law Act

Polish aviation law has a long history and reaches the beginning of aviation itself. The first Decree of President of Poland publishing the first Aviation Law Act set the starting point for this branch of law. This act was replaced by

Aviation Act of 1962 and after that by the Aviation Law of 2002 which after few changes is still in force.[9] The art. 126 paragraph 2 of this Act states that an unmanned aerial vehicle must be equipped with the same flight, navigation and communication facilities as a manned aircraft performing a flight in line with visual flight rules (VFR) or instrument flight rules (IFR) within a defined class of airspace. The derogations applicable to manned aircraft in this respect apply uniformly to UAVs. According to para. 3, flights of unmanned aerial vehicles equipped in accordance with para. 2 may be carried out on the basis of a filed flight plan, in a manner and in accordance with the conditions referred to in para. 5, subject to art. 149. In art. 126, a fundamental obligation is established that unmanned aerial vehicle flights are permitted in the Polish airspace without individual approval and the requirements for conducting these logs are determined (paragraphs 2–4).

Determination of the way of proceeding of UAS pilots with air navigation services providers should be a subject of regulation issued in accordance with paragraph 5 of the above mentioned article.

Unfortunately, to this date the regulation has not yet been published..[10] One of the possible reasons for such situation was the unpreceded increase of the smaller UAS flights which were by the definition not able to meet this rigorous equipment requirements.

3.2 Regulation of the Visual Line of Sight (VLOS) and beyond Visual Line of Sight (BVLOS) Flight Requirements

In order to fulfill this gap and demand from the market, an article 33 paragraph 2. of Aviation Law Act helped to exclude the application of some provisions of the Aviation Law Act to certain types of aircraft, including specific type of UAS. The Regulation of the Minister of Transport, Construction and Maritime Economy of 26 March 2013 on the exclusion of certain provisions of the Aviation Law Act as non-applicable to certain types of aircraft and defining conditions and requirements for the use of these aircraft (hereinafter: *Regulation on the exclusion*) were focused to set a conditions for drone flights in Poland and was one of the first in Europe of regulations of that kind. The regulation applied since 2013 to the end of 2020 with few adjustments in 2016 and 2019.

Appendixes 6 and 6a regulated among others the flight rules concerning the VLOS and First Person View (FPV) operations of unmanned aircraft and model aircraft.

Appendix 6 set requirements for Unmanned Aerial Vehicles with take-off mass not more than 150 kg used in visual line of sight and for Unmanned Aerial Vehicles with take-off mass not more than 2 kg used in FPV operations in recreational or sport purposes. For purposes of this Appendix the UAVs used for recreational purposes are referred to as “model aircraft”.

The Appendix 6a set requirements for Unmanned Aerial Vehicles with take of mass not more than 150 kg used in visual line of sight and for Unmanned Aerial Vehicles with take of mass not more than 2 kg used in FPV operations in non – recreational or sport purposes. The flight rules differ than those for recreational purposes.

Appendix 6b included requirements for UAVs with take-off mass not more than 25 kg used in beyond visual line of sight excluding the UAVs with take of mass not more than 2 kg used in FPV operations.

The last novelization of the regulation helped to adapt to changing demand for short BVLOS flights. It simplified the acceptance of the BVLOS missions and allowed them in unsegregated airspace on certain conditions.

3.3 Operator’s responsibility

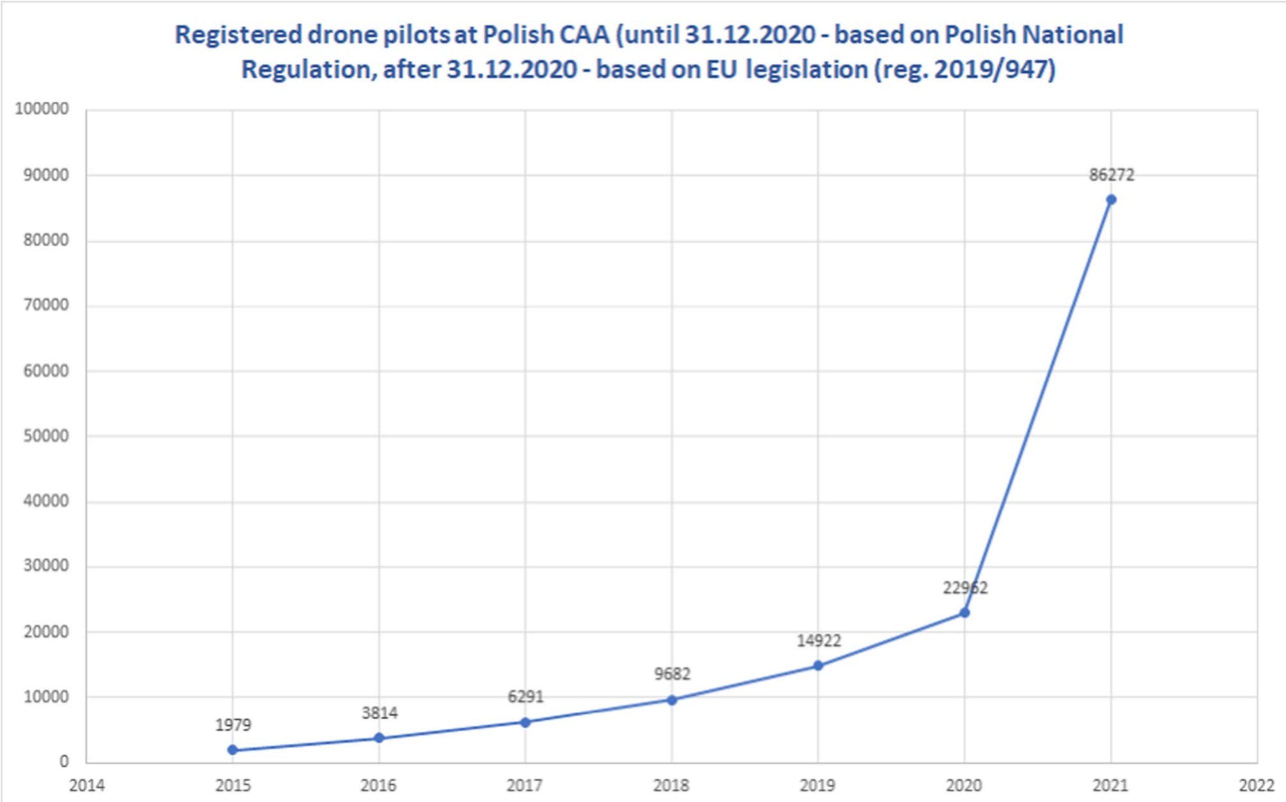
The Regulation on exclusion lays out detailed requirements concerning the UAV operator’s responsibility.

The operator of the UAV must:

1) exercise due caution, avoid any act or omission that could:

a) create a safety risk, including the threat to air traffic safety,
b) obstruct air traffic,
c) disrupt peace or public order, and
d) expose anyone to damage.

2) control the UAV so that it avoids collision with other aircraft;
3) ensure that the UAV he operates gives priority to manned aircraft;
4) be responsible for the decision to perform the flight and its correctness, and the appointment and participation of the observer in the performance of flights does not release him from the responsibility for the safety of performed operations[11];
5) use the flying model and control devices in accordance with the manufacturer’s recommendations and restrictions, if published;
6) check the technical condition of the model aircraft before the flight;
7) perform flights only with a model aircraft that is technically efficient.



Graph 1 Number of certified/ registered UAVO pilots in Poland. *Source: CAA of Poland*

3.4 Role of Air Navigation Service Provider in Poland – Polish Air Navigation Services Agency (PANSA)

The main requirement in every appendix to the regulation on exclusion was the role of the manager of the control zones which decides on the conditions on basis which the drone operations are conducted. The solely air navigation service provider in Poland according to article 127 of Aviation Law Act is the Polish Air Navigation Services Agency. The obligation to coordinate the flight with PANSA before the flight was strictly mentioned in the specific appendixes to the regulation. The obligation to pre-tactically coordinate the flight did not covers the cases:

- Flying more than 6 km from the fence of the airport in Control Zone (CTR) zone using UAS weighing less than 25 kg up to 100 m above ground
- Flying more than 1 km from the fence of the airport in Control Zone (CTR) zone using UAS weighing less than 600 g up to 30 m above ground.

Generally – other cases were subject to the pre-tactical coordination.

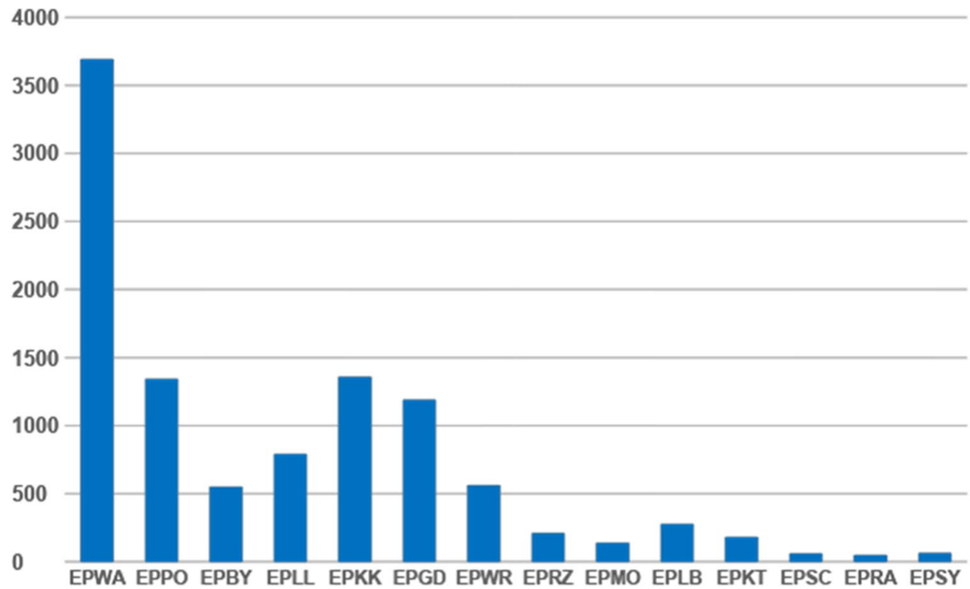
All the flights despite the weight of UAS or the height of the flights were subject to inform PANSA within the digital system (since 2.03.2020 it was realized by the PansaUTM).

3.5 Licensing of the UAV Operators

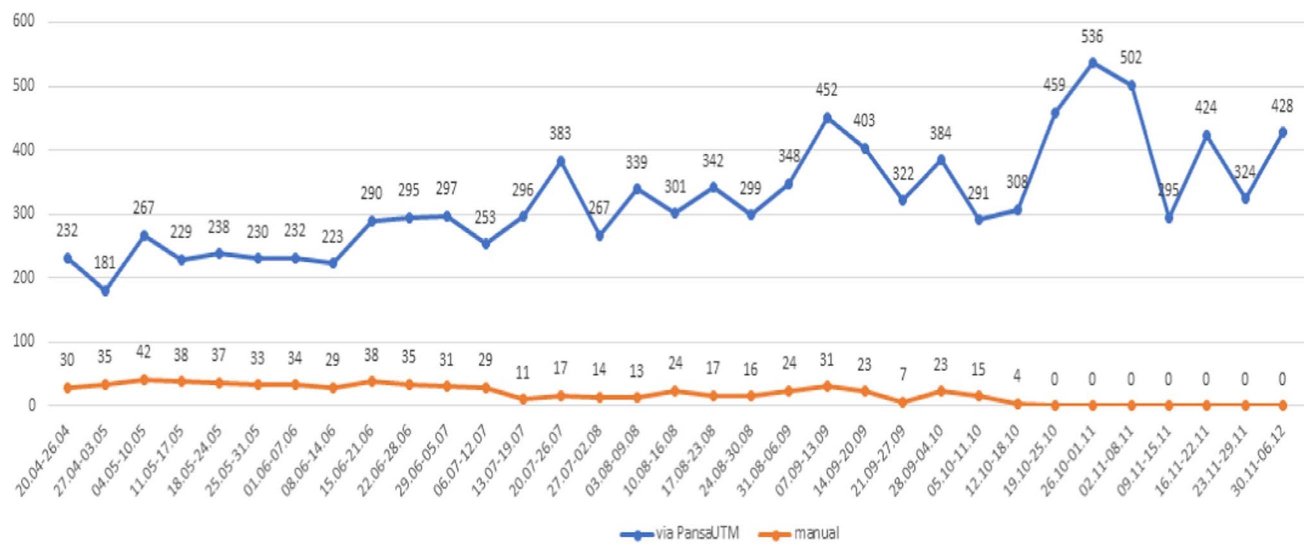
In Poland until 30 December 2020 there was an obligation to hold a certificate of competence in accordance with Article 95 paragraph 2 point 5a of the Aviation Law Act of 3 July 2002 imposed on persons being operators of unmanned aircraft used for non-recreational or sport purposes.

The possibility to have the UAVO certificate issued by the Civil Aviation Authority of Poland (CAA of Poland) on basis of the training and dedicated exam resulted in increasing number of operators who were allowed to fly drones commercially. The overall number of Unmanned Aerial Vehicles Operators certificate holders are greater than glider pilot and private pilot licenses combined. The registration of the drone pilots since 31 December 2020 are regulated by the Regulation 2019/947 (Graphs 1, 2, 3, 4, 5, 6 and 7).

The statistics showed that theoretical number of operators who would use the airspace (including controlled airspace) were increasing throughout the years. The trend was confirmed in the statistics of the Polish Air Navigation Services Agency. In 2018 alone the number of pre-coordinated drone



Graph 2 Number of UAV operations conducted in CTRs in 2018 in Poland. *Source: PANSA*



Graph 3 Number of VLOS mission planned via operational PansaUTM in 2020. *Source: PANSA*

flights in controlled zones (near the international airports in Poland) exceeded 10,000.

The equivalent of the operations conducted in CTRs after deployment of the UTM system in Poland is number of the missions pre-tactically coordinated via the system in order to have pre-authorised acceptance of the flight.

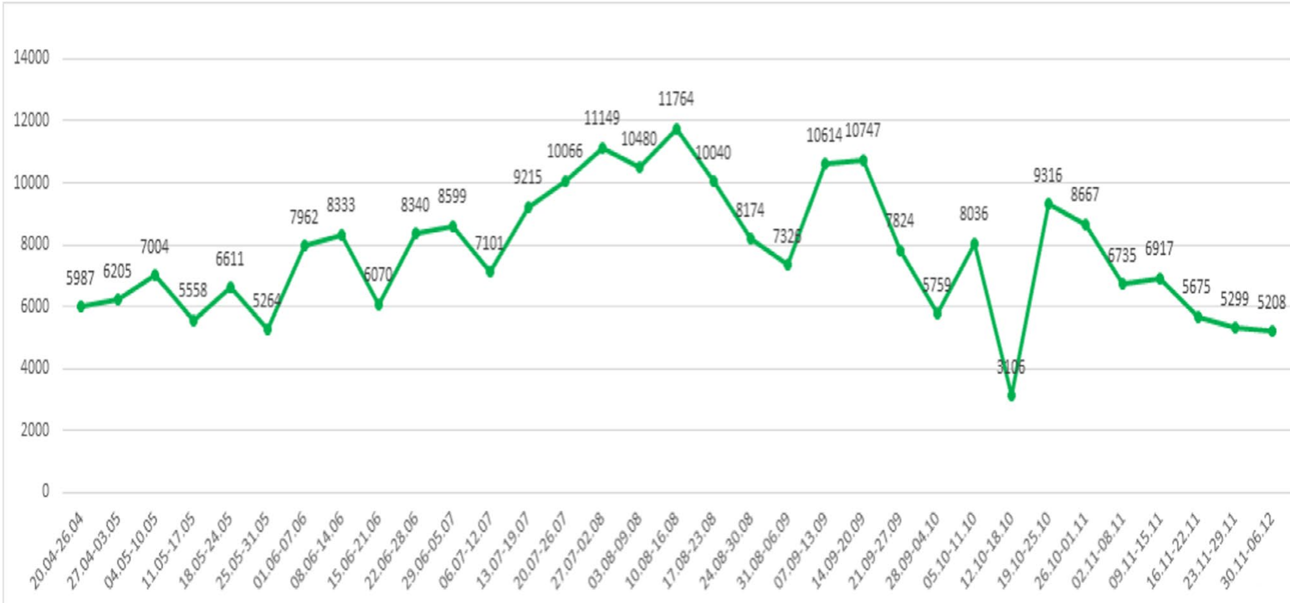
The VLOS and BVLOS pre-tactical coordination in the UTM also started increasing as the system was introduced on more and more TWRs through all 2020 reaching almost 11,000.

This number in 2021 only from January to September reached almost 15,000 operations.

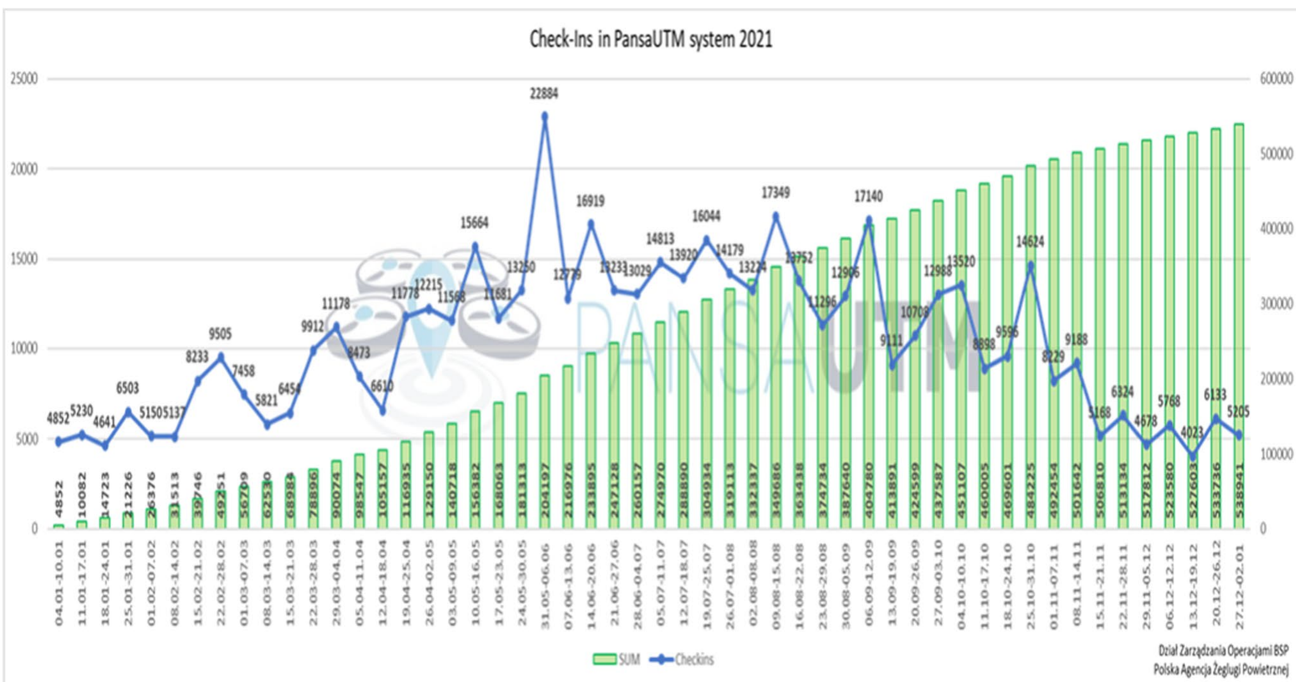
In the same time the overall number of UAV operations across Poland (those which require pre-tactical coordination and those which do not require such coordination) were increasing significantly.

According to the statistics The number of all operations in 2020 reached almost 300,000 UAV flights submitted to the PansaUTM. PANSA recorded in 2020 more than 260,000 manned aircraft operations in uncontrolled airspace in 2020. It shows clearly that the unmanned aviation remarkable potential and an "immunity" of unmanned aviation to the crisis situation which had been created in aviation sector by pandemic of COVID-19.

The reported number of UAV operations via PansaUTM system in 2020 exceeded 300,000 submissions. In 2021 from January to September number of flights already surpassed 400,000. The number reach almost 600,000 operations in



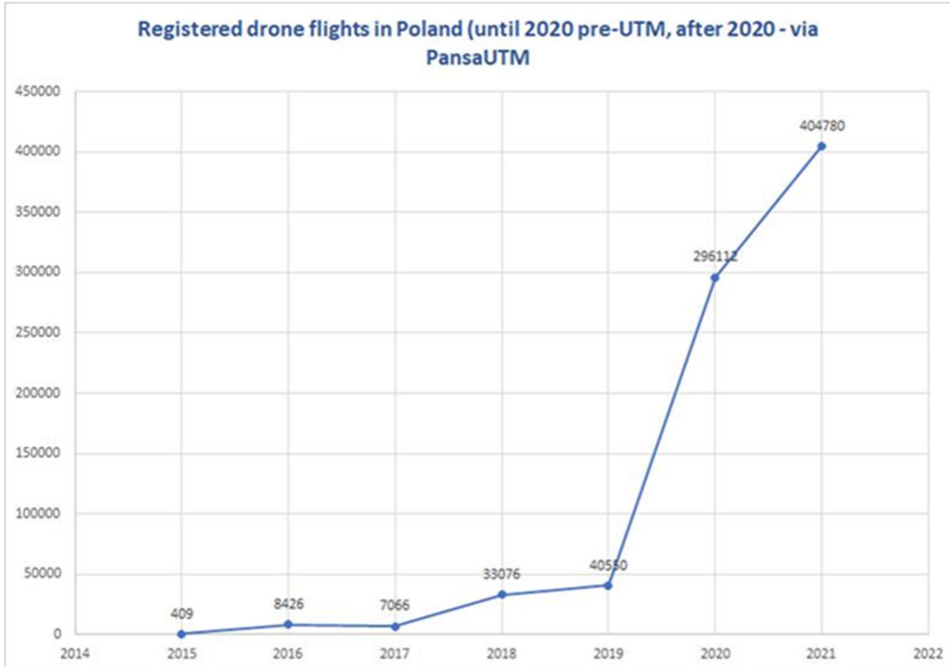
Graph 4 Number of UAV operations (check-ins) submitted to the PansaUTM via DroneRadar app in 2020. *Source: PANSA/ DroneRadar*



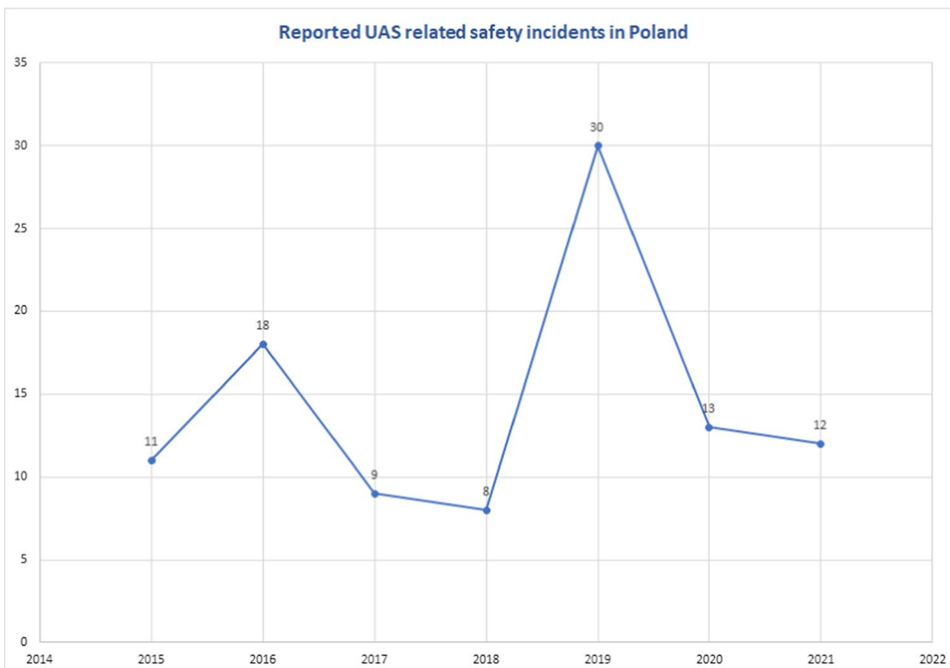
Graph 5 Number of UAV operations (check-ins) submitted to the PansaUTM via DroneRadar app in 2021. *Source: PANSA/ DroneRadar*

2021, which doubled the number registered in 2020. In 2020 this number is expected to exceed 1 mln submitted operations.

One of the concerns when the number of operations raise in the manner it did in Poland is how it impacts the safety of aviation. According to the statistics of incidents in Polish Airpsace regarding drones, introduction of the UTM system in Poland not only supported the unprecedented growth of drone flights and simultaneously influenced the decrease of numbers of incidents. In 2019 – year before introduction of the UTM system, the number of reported incidents reached 30. After operational deployment of the PansaUTM system



Graph 6 Number of reported UAV operations in Poland (2015–2021). *Source: PANSA/ DroneRadar*



Graph 7 Number of reported UAV incidents in Poland *Source: PANSA/ CAA*

the of incidents dropped to respectively to 13 in 2020 and 12 in 2021 (from January to September). The ratio between the number of incidents and the number of operations has decreased.

3.6 Transition Period in Polish National Regulations

Due to the entering into the force of the Commission Implementing Regulation (EU) 2019/947 of 24 May 2019 on the rules and procedures for the operation of unmanned aircraft, Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems, the National regulations mentioned above (regulation on exclusion) stopped to be applicable. Taking into account that the scope of the European regulation differ slightly from those used in the Polish regulations, not covering in details the principles of UAS flight conducts, Civil Aviation Authority of Poland issued the Guidelines of the President of the CAA which supplements the European regulations. Due to introduction of so-called “geographical zones” - the Aviation Law act and other regulations are currently in the novelization process in order to introduce new principles which will together with the European regulations create new regulatory framework in Poland. At the moment majority of the principles from the regulation on exclusion were transferred on the level of the geographical zones which since 31 December 2020 are published by the Member States on basis of art. 15 of the Regulation 2019/947. What is important, all geographical zones will be subject to publication by Member States in the unique digital format. The format proposed by the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) to the Regulation 2019/947 were subject to public consultations until 30 September 2020. In the draft it refers to the Eurocae ED-269 Chapter 8 which describes the unique format of data to be published since 1 January 2021. Until the formal publication of the AMC/GMs after consultation process, the unique format is not yet officially decided. However this process is crucial for interoperability of the geographical zones data between Member States and between different UTMs and U-space Service Providers (USSPs).

4 PansaUTM

The necessity of creating the digitized solution to coordinate drone flights in Poland became visible when the number of flights started to surpass the capabilities of existing manual procedures.

In 2017 there were conducted test of primary system which showed that there is need for tools helping the operators to conduct operations in line with the existing regulations and principles.[12] DroneRadar was one of the first mobile applications which were aimed to provide users with such information.[13]

The tool was used on non-mandatory basis and provided the information on airspace elements along with simple green, yellow, red lights which represented were the flight is possible, restricted or banned.

In 2018 Polish Air Navigation Services Agency made an agreement with technology providers - HAWK-E and Droneradar in order to deploy the system and combine it with PANSA procedures. The backbone of the system was to build communication layer – between Air Traffic Control (ATC) and drone pilots. According to the Drone Roadmap[14] the aim of the implementation was the creation of procedural and collaborative interface with Air Traffic Management system (ATM).

PansaUTM was created by the Polish Air Navigation Services Agency and technological partners. It combines and reflects needs of UAV operators, ANSP and Air Traffic Controllers. This approach allowed PANSA to prepare a convenient and functional tool that provides greater situational awareness and safety in the air, also simplifies and digitalizes UAVs flight coordination processes. The system at the moment is integrated with DroneRadar mobile app.

The official announcement of the PansaUTM system took place at the 2019 World ATM Congress and the 2019 JARUS (Joint Authorities for Rulemaking on Unmanned Systems) Plenary Session in Katowice.(https://www.pansa.pl/o-pansautm-na-sesji-plenarnej-jarus-w-katowicach/) After one year of certification process with the Civil Aviation Authority of Poland obtained a positive decision for operational use in the Polish Towers (TWRs) and Flight Information Services (FIS) Sectors. *The system was launched on* March 2nd, 2020 in Poland, PansaUTM is the first one in Europe and *one of world’s first national operational UAS traffic management/ air traffic management (UTM/ATM) systems* used by ATC operational personnel on daily basis. Currently the implementation is completed on all 15 civil active TWRs and all 5 FIS Sectors. It means that all drone operators in Poland can conduct the digital coordination of UAV flights with PANSA. In February 2021 the new version (1.2) of the system has been introduced allowing more automatic approvals.

The PansaUTM system is a single source of aeronautical data for drone pilots and supports flight coordination process. It also provides fast, digital, non-verbal communication between air traffic controllers and drone operators. It enables drone operators to check flight possibility in a given area, digitally submit a flight plan and obtain permission to fly if it does not threaten the safety of aircraft. For air traffic controllers, the system provides information about drone flights planned in the vicinity of international airports (CTRs) along with simple authorisation/ non authorisation tools. The controller has also dynamic geofencing tools and can create alert zones which would order drone pilots to land in a given area. It also supports other emergency situation such as possibility to report lost connection with the drone by the operator to alert the ATC instantly.

PansaUTM is fully digital and based on non-verbal communication between air traffic controller and drone operator, what makes the whole flight-related process quick and easy. Communications are conducted via a Controller-Drone Data Link Communication (CDDLC) network, the drone equivalent of the CPDLC system. This allows PansaUTM to communicate with the drone pilot and strengthen safety by enabling a quick reaction on any reason. In order to communicate with the Air Traffic Controller via the UTM system, drone operators use dedicated mobile app integrated with the UTM – Drone Radar. As mentioned before Drone Radar is widely recognized mobile app in Poland, used by drone operators to check the possibility of the UAV flight. Thanks to integration with the UTM it supports the full picture on airspace structures as well as enables two may non-verbal communication with the ATC.

The system has been developed to ensure that all the aeronautical data which is distributed to the users is certified and comes from a reliable source. The operators can check where they can fly and under which conditions. The system supports flexible use of airspace (FUA) visualisation. It combines static and dynamic data related to UAVs from different sources including NOTAMS, and all the data is updated in real time on the screen to controllers and drone pilots.

The system supports both VLOS and BVLOS flights and automatically checks to see if the drone operator has received all the necessary approvals from the CAA for the flight. And it has also been integrated with an ACM, Automatic Capacity Management function, which will allow flight requests in certain conditions to be answered automatically depending on the flight plan and any potential conflicts identified at an early stage. The AMC function is fully customisable and depends on the decision of each ATS Unit. In Poland, the functions is being configured on the basis of years of experience to filter the operations to those which could be approved automatically, and those which require ATC attention. This allows to reduce controller workload by 75% without compromising the safety.

PansaUTM created a friendly, modern and innovative environment for a safe integration of both manned and unmanned air traffic in the airspace. Thanks to the System and close and flourishing cooperation of different stakeholders, both public and private, a level of U-space development in Poland is now the highest in Europe according to the Eurocontrol 2020 U-space services implementation monitoring report, making the Polish market well prepared for current and future challenges. The implementation of the environment based on operational PansaUTM system was the backbone of PANSA's U-space Program and their signature take to put the U-space concept into reality. Taking into account the SESAR Blueprint and functionality provided by the system – it is an upper U3 level of maturity.

During one year of operation the system along to the normal operations supported numerous test pilot-projects automatic medical BVLOS flights of such as Hermes dronoid in Warsaw on route from one hospital to the other in order to reduce the outcomes of the Covid-19 outbreak.[15] The track of the UAS was seen on the system thanks to the ADS-B miniature transponder mounted on-board of the UAS. The ground and air infrastructure based on ADS-B standard was deployed by PANSA, the UAVs equipped with the transceivers are visible on the PansaUTM display as the live tracks. Practical use of the live tracking is being tested in controlled zone in Warsaw. In 2020 PANSA conducted the series of flights to assess the range and possible use for larger scale in different cities in Poland. The covid test flights which were also repeated on different route in November 2020 are promising and probably will become more scalable in the future.

5 U-Space Developments

In parallel to the regulatory process, there are groups which links different stakeholders in order to support the process of exchange of experiences in U-space implementation. European Network of U-space Demonstrators, Civil Air Navigation Services Organization (CANSO) UAS Working Group, A6 U-space Task Force. Those foras take an active part in commenting the draft of U-space regulation prepared by EASA/ European Commission.

EASA opinion on U-space regulation from 2019 was put into the consultation process.[16] Opinion got 3 thousand replies – which put it into the one of the most commented opinions. It caused the postponing of the re-publishing of the opinion[17] and the next version of the opinion was ready in the first quarter of 2020.[18] Eventually the draft changed few times during 2020, and was eventually adopted by the EASA Committee in February 2021. As the certain elements of the regulation itself raised concerns – the European Commission assured that all the issues which are unclear will be well explained in the GM/AMC to the regulation. The delegated Regulation (EU) 2021/664 on a regulatory framework for the U-space was published on 22 April 2021 (U-space regulation). The U-space regulation is expected to be applicable in January 2023, before that date, all U-space Service Providers (USSPs) and Common Information Services Providers (CISPs) should prepare for the required certification process in order to be certified to provide U-Space Services in line with the new regulation.

6 Future of U-Space Concept and Related Projects to Enable Transport with Drones

Despite of adopting the U-space regulation, the concept itself will evolve along with the market and the efforts to show practical capabilities of certain U-space services will be continued. The most recent concept of urban air mobility gives even broader perspective on what type of operations U-space could support – the transport of people in cities with use of dedicated UAS.[19] All the stakeholders involved in the U-space deployment should make use of outcomes of demonstrations, SESAR projects or U-space related CONOPS papers and other documents. Poland also is involved in few SESAR projects – ie. GOF 2.0 showing the capabilities of U-space to support urban air mobility and PJ.34 aimed to provide the answer how to conduct non-verbal communication with the ATC. The first wave of GOF 2.0 project demonstrations conducted in September in

Estonia, Finland and Poland showed optimistic outcomes in the interconnection capabilities of different UTM systems around Europe and readiness to support different UAS operations in the same volume of airspace, including air taxi operations, CARGO operations, surveillance, photogrammetry operations. However there are also blank spots to be still covered by different projects in order to deploy safe and scalable Urban air mobility and U-space concept. It requires the common altitude reference system (CARS) in order to find reliable reference in terms of altitude for both manned and unmanned aircraft in the same volume of airspace. It is subject of different SESAR funded project - Integrated Common Altitude Reference system for U–space (ICARUS). Despite the demonstrations of capabilities to conduct flights of air taxi ready vehicles, there is a need for certification scheme to ensure reliability and scalability of such applications in everyday life. However such projects and demonstrations give a boost for necessary actions from regulators, manufacturers and finally end-users to introduce such new services available for masses.

New technical capabilities are being developed and included into the possible new services. One of the big milestone will probably be the 5G infrastructure deployment. 5G Network and related projects as 5G!Drones looks promising as a new mean which can be used in the U-space ecosystem as tracking or even UTM provision.[20] In Europe there are more and more research centers focused to support R&D projects related to drones. Among those centers, the two Polish initiatives are worth mentioning - Central European Drone Demonstrator (CEDD)[21] and Navihub Project.[22] Those and similar R&D centers will be in the future most likely involved in supporting numerous projects related to new services.

7 Use of UAVS in Medical Transport

The U-space concept offers an opportunity for UAV to be widely used in the field of day-to-day supplies as well as health-related supplies. Prior to the U-space concept, the use of drones had to be considered innovative. The dynamic development of airspace management technologies, the development of 5G research, blockchain technology, the easy availability of satellite data, opens up new opportunities for UAV and the opportunity to shift its use from recreational to professional applications and to launch new technological trends. Emerging technologies such as 5G networks have significant potential on UAVs equipped with cameras, sensors, and GPS receivers in delivering Internet of Things (IoT) services from great heights, creating an airborne domain of the IoT. However, there are many issues to be resolved before the effective use of UAVs can be made, including security, privacy, and management.

A milestone in the area of the “release” of airspace for commercial operations is the Regulation of 20 December 2018[23] which introduced, inter alia, the possibility of operations of BVLOS (Beyond Visual Line of Sight Operation). UAV perform BVLOS operations, inter alia, for automated flights operated within or for medical supply. In accordance with Article 2 (5) of the BVLOS Regulation, an automatic flight shall be understood as ‘an operation in which a unmanned aircraft automatically performs a takeoff and landing at a designated place and a flight on a programmed route, where the operator only has full remote control of the operation, while retaining the ability to take immediate remote control of the unmanned aircraft or to take other action in the event of an emergency’. The following is a reference to the appropriateness of using UAV in the medical supply process, including those with a direct relation to public health protection.

Issues relating to the use of drones for health protection purposes have so far been examined in the context of sectoral literature. The relevance of the use of UAV in an area related to human health in general has been the subject of studies in terms of radioactive radiation distribution and contamination mapping. The use of UAV in this area was intended to eliminate the health risk of personnel performing radiation mapping activities and thus to eliminate risks in the area of public health.[24] Researchers analysing the appropriateness of using drones in the area of distribution of medicinal products and medical devices indicated that drones could be potentially reliable platforms for the provision of medical microbiological and laboratory samples, pharmaceuticals, vaccines and medical equipment.[25] The use was also highlighted by researchers who, according to them, UAV play an extremely important role in search and rescue missions, the field of combat medicine[26] and tactical medicine,[27] as well as filling gaps between the third world’s health systems and their western counterparts, and between major metropolitan centres and remote rural communities.

In the context of the real use of drones in urgent cases, researchers stressed that UAV has the potential to deliver an Automated External Defibrillator (AED). The main discovery of the study was that acquiring an AED delivered by a drones was perceived by recipients as safe and less difficult than using their own mobile phone.[28] Drones are now also used for blood supply. Zipline catapults its drones into the sky to deliver blood products to hospitals across Rwanda. The drone is operated by Zipline, a California-based company focused on delivering medical supplies in areas with poor infrastructure. In a blink-and-you’ll-miss-it moment, the drone descends, opens a set of doors in its belly, and drops a small package that parachutes to the ground. The drone immediately begins to climb and vanishes over the hills as a staff member crosses the hospital parking lot to pick up the package—a shipment of blood ordered by WhatsApp less than half an hour earlier.[29] Polish researchers analysed the quality of red blood cell units, apheresis platelet units, and unthawed plasma units frozen within 24 hours of collection placed in a cooler attached to the drone and flown for up to 26.5 minutes with ambient temperatures ranged between −1 and 18 °C. They revealed that there was no adverse impact of drone transport and no evidence of red blood cell haemolysis; no significant changes in platelet count, pH, and other blood parameters limiting the possibility of using blood products.[30] This study suggested that the drone could be a good option for the transportation of blood products. A study from the Johns Hopkins University School of Medicine has shown that the transportation of laboratory specimens via drones does not affect the accuracy of routine biochemistry, haematology, and coagulation test results.[31] A 2017 study examined the effects on blood chemistry and haematology following drone flights of more than 3 hours in duration and under conditions of relatively high ambient temperatures as compared to control specimens that were neither flown or subject to high temperature.[32] Blood specimens were then analysed for serum sodium, potassium, chloride, bicarbonate, urea nitrogen, creatinine, and glucose as well as WBCs; RBCs; haemoglobin; haematocrit; mean corpuscular volume; RBC distribution width; platelet count; and lymphocyte, monocyte, neutrophil, eosinophil, and basophil levels. Results from both groups were similar for 17 of the 19 tests. The two differences were serum glucose and potassium levels. These were higher in the flown samples. It is thought to be most likely due to higher temperature exposure during flight. Consequently, it is recommended that there be rigorous temperature management in drone payload compartments.

The use of drones in the medical supply process is an innovative measure. The first mention of the topic can be found in 400 AD, in terms of renewal or change.[33] The mere use of drones to deliver supplies is not an innovative solution, but the delivery of health supplies is an innovation that leads, on the one hand, to the spread of benefits by increasing their availability and, on the other, to improving their quality. This is part of the definition of innovation distributed by the PF. Drucker, who stressed that ‘an innovation is a specific business tool by which changes are turned into an opportunity to start a new business or to provide new services (…)’.[34]

The use of UAV in health care should be divided into three basic pillars. The first one is related to medical emergency, including in hard-to-reach areas, at mass events, and to the occurrence of civil, air and water traffic accidents. Until now, the literature has mainly analysed the appropriateness of using UAV for medical emergency services[35, 36] The second pillar is directly related to the treatment of chronic diseases, including civilizational diseases. The use of drones in the area of health protection is important in view of the increasing number of civilization diseases, which imply the occurrence of events of a sudden threat of life (e.g. strokes, myocardial infarctions). It should be stressed that despite significant improvements in primary prevention and treatment over recent decades, strokes are still the cause of the highest number of deaths and health complications. Researchers stress that at the beginning of the twenty-first century the incidence of stroke in Europe was between 95 and 290/100.000 per year, and the indicators observed in young adults are increasing continuously.[37] Moreover, due to the aging population, it is likely that the number of strokes will increase rapidly in the coming years and that by 2025, about 1.5 million Europeans will suffer from strokes.

The latter pillar concerns the use of UAV in an epidemic and the associated need for distribution of medicinal products and diagnostic samples (medical supplies). Sectoral literature and legislation do not refer to the definition of medical supplies that can be carried out in BVLOS operations. Whereas, in view of the specific characteristics and needs arising from the provision of health services, provision should be made for the distribution and service of medicinal products to be provided with medical supplies, medical devices, foodstuffs, medical equipment, dressings and plasters, diagnostic samples and organs taken from dead human bodies for transplantation to another person.

8 COVID-19 Pandemic and UAVS Applications

In the context of the spread of SARS-CoV-2 virus, drones may be used to provide diagnostic screening tests, medicinal products and septic materials, transport of samples of biological material, as well as an information campaign on how to deal with an epidemic, quarantine or isolation at home. In 2014, in the sector literature, it was highlighted that the use of drones for the distribution of vaccines has a direct impact on minimizing the costs associated with the supply chain of such medicinal products.[38] Further studies on the distribution of vaccines using UAV have indicated that this activity increases the availability of vaccines and has a direct impact on the reduction of supply costs.[39] Similar conclusions were reached in the framework of the Haidari LA study.[40] Studies conducted by K. Bhatt, A. Pourmand and N. Sikka has shown a link between the use of UAV and the minimization of the time taken to perform laboratory diagnostic tests and vaccine distribution.[41]

In view of the need to carry out diagnostic tests for SARS-CoV-2 infection, it is also necessary to introduce an optimal system for the distribution of samples of biological material between the operators in which sampling was carried out and the diagnostic laboratories. The first operations related to medical distribution via UAV already mentioned in this article, took place in Poland at the turn of April and May this year.[42] The transport of blood and diagnostic samples between the National PGE and PSK of the Ministry of Interior and Administration using UAV took place in November 2020.[43] Transport using UAV has a direct impact on the optimization of delivery times as well as human resource management. Minimizing the contribution of personnel involved in the transport of samples and blood allows the use of human resources in other health-related areas.

9 Legal Requirements Concerning Medical UAV Transport

The use of UAV for medical supplies is economically and legally justified. Whereas, in view of the specific nature of medical supplies, it is necessary to lay down precise rules on liability for damage caused by the transport of dangerous goods by air, with particular regard to the rules on liability for damage arising from the operation of automatic flights and operations to be carried out by AI in future.

Medical supplies, as defined above, should be identified in many cases with supplies of hazardous materials, which is particularly relevant for the transport of samples of biological material, including potentially contaminated material.

The legal basis for the carriage of dangerous goods by air is Annex 18 to the Convention on International Civil Aviation, also referred to as the Chicago Convention, signed on 7 December 1944.[44] Details of the transport of dangerous goods are set out in the Notice of 13 December 2013[45] by the President of the Civil Aviation Office.

Airlines, cargo agents, freight forwarders, and other dangerous goods transport institutions use the regulations issued by IATA – International Air Transport Association - Dangerous Goods Regulations (IATA DGR). The technical instructions for the safe transport of dangerous goods and the Dangerous Goods Regulations shall accept the same and the only definition of dangerous goods in the literature. These are articles or substances which are capable of posing a risk to health, safety, property or the environment and which are included in the regulations on the list of dangerous goods or have been classified in accordance with those instructions/regulations of the DGR.[46]

According to IATA DGR classification, samples of biological materials, blood and plasma belong to class 6.2 (infectious materials). The rules governing the transport of dangerous products are governed by the law, but do not explicitly refer to the rules on liability for damage caused by transport and distribution of such consignments. This is particularly important for consignments transported by the UAV, which are intended to provide samples of biological materials to diagnostic laboratories. Given the epidemiological specificities of consignments, there is a high risk that damage, destruction or loss of samples during transport is a potential source of infection for many people and pathogen transmission. The first part of the article sets out the legal provisions regarding the general principles of UAV operator liability (13).

The rules on liability for damages caused by the movement of aircraft are laid down in Polish Aviation Law.[47] In accordance with Article 206 of the Act quoted, 'liability for damage caused by the movement of aircraft shall be governed by civil law rules on liability for damage caused by the use of mechanical means of communication addressed by natural forces, subject to paragraphs 2 and 3 and article 207. In principle, this means that liability for damage caused by UAV is equivalent to that of persons driving motor vehicles on the road. It follows that liability for damage caused by aircraft movements should be classified as liability on a risk basis (Article 435 or Article 436 of the Act Civil Code, hereinafter c.c.) or on a fault basis (Article 415 c.c.).

10 Liability and Responsibility

In resolution of 2017 on Civil Law Rules on Robotics, the European Parliament stressed,[48] that the future legislative instrument should be based on an in-depth evaluation by the Commission determining whether the strict liability or the risk management approach should be applied (point 53). European Parliament notes that the risk management approach does not focus on the person 'who acted negligently' as individually liable but on the person who is able, under certain circumstances, to minimise risks and deal with negative impacts (point 55). The European Parliament considers that, in principle, once the parties bearing the ultimate responsibility have been identified, their liability should be proportional to the actual level of instructions given to the robot and of its degree of autonomy, so that the greater a robot's learning capability or autonomy, and the longer a robot's training, the greater the responsibility of its trainer should be; notes, in particular, that skills resulting from 'training' given to a robot should be not confused with skills depending strictly on its self-learning abilities when seeking to identify the person to whom the robot's harmful behaviour is actually attributable; notes that at least at the present stage the responsibility must lie with a human and not a robot (point 56). The European Parliament points out that a possible solution to the complexity of allocating responsibility for damage caused by increasingly autonomous robots could be an obligatory insurance scheme, as is already the case, for instance, with cars; notes, nevertheless, that unlike the insurance system for road traffic, where the insurance covers human acts and failures, an insurance system for robotics should take into account all potential responsibilities in the chain; 18.7.2018 EN Official Journal of the European Union

C 252/249 Thursday 16 February 2017 58, considers that, as is the case with the insurance of motor vehicles, such an insurance system could be supplemented by a fund in order to ensure that reparation can be made for damage in cases where no insurance cover exists; calls on the insurance industry to develop new products and types of offers that are in line with the advances in robotics (point 57–58).

In the context of the operation of intelligent robots, it is also necessary to refer to the rules of liability on a fault basis. According to Article 415 Civil Code, no one is liable for a case, even if the machine or its autonomous decision to correct the source code, provided that the machine is authorized to be placed on the market, is duly certified and its operator has not made a mistake, contributing to damage. Responsibility on the basis of fault can only be borne by anyone who knows of the danger that has emerged from the robot algorithm itself, or by a person who should know of the danger, provided that he or she has a legal obligation to prevent the danger. As noted by the European Parliament in its 2017 resolution, responsibility can be shared not only by those who acted uncaring, but also by a person who can, under certain circumstances, minimize risks and take action with regard to negative effects. Liability on a fault basis (Article 415 c.c.) does not justify the attribution of liability for the effect itself, on a risk basis. In particular, the operator cannot be held liable for unpredictable, unsafe and damaging robot behaviour. It would not be possible to continuously control the standalone robot – all the more so since the user will not in principle have source codes or specialist knowledge.

Whether we take the principle of risk or guilt as the source of responsibility, it will be necessary to demonstrate as a basis of liability the causal link between the operator or the machine itself and the injury. The demonstration of a causal link is particularly relevant for BVLOS operations which are carried out of sight, but with the involvement of the operator. The BVLOS regulation provides for the need to participate in such operations by an operator who holds a valid certificate of qualification. Those certificates remained valid until 1.7.2021. For this type of operation, the premise of a causal link will have to be applied not only to human activity but also to the operation of machinery, which requires consideration to be given to the legitimacy of the latter.

A separate analysis is required, if the damage is caused by an autonomous decision of the UAV operating system. According to Konert A., the solution could be to adopt new rules with the introduction of a legal causal link, as in the case of air carrier liability under the Montreal Convention of 1999.[49] In addition, consideration should be given to the introduction of uniform rules on the liability of artificial intelligence for damage resulting from the participation of AI in drone software or the decision to use it. It should be noted that the use of Artificial Intelligence (AI), which deep learning, which is the most advanced machine learning, can increase company revenue by up to 9%.[50]

Over the years, there have been many proposals for extending some kind of legal personality to emerging digital technologies, some even dating from the last century. Still, the experts believe there is currently no need to give a legal personality to emerging digital technologies. Harm caused by even fully autonomous technologies is generally reducible to risks attributable to natural persons or existing categories of legal persons, and where this is not the case, new laws directed at individuals are a better response than creating a new category of legal person. Any sort of legal personality for emerging digital technologies may raise a number of ethical issues. More importantly, it would only make sense to go down that road if it helps legal systems to tackle the challenges of emerging digital technologies. Any additional personality should go hand-in-hand with funds assigned to such electronic persons, so that claims can be effectively brought against them. This would amount to putting a cap on liability and – as experience with corporations has shown – subsequent attempts to circumvent such restrictions by pursuing claims against natural or legal persons to whom electronic persons can be attributed, effectively ‘piercing the electronic veil’. In addition, in order to give a real dimension to liability, electronic agents would have to be able to acquire assets on their own. This would require the resolution of several legislative problems related to their legal capacity and how they act when performing legal transactions. In previous studies on artificial intelligence and robotics, the issue of machine liability has not been comprehensively analysed[51–53].

In the European Parliament resolution of 16.2.2017,[54] a differential concept has been put forward. It appears that “creating a specific legal status for robots in the long run” and “creating the status of electronic persons responsible for making good any damage they may cause, and possibly applying electronic personality to cases where robots make autonomous decisions or otherwise interact with third parties independently” – this means a potential constitution of a new legal category, different from natural persons, legal persons or imperfect legal persons – “electronic persons”.

Given that the first medical supplies provided by UAV have been positively tested, it is likely that they will soon be part of the daily medical transport scenario. It is therefore necessary to establish uniform and clear rules on liability for damage, loss or destruction of the contents of medical supplies. It is also necessary to establish a common framework for liability for damage caused by intelligent robots or damage caused during operations performed and supervised by AI.

11 The Use of UAVS for the Transport and the re-Education of Greenhouse Gases

Irrespective of the economic, temporary and logistical benefits of using UAV for the transport of medical supplies, it should be noted that these activities remain directly linked to the reduction of greenhouse gases. Issues relating to the reduction of greenhouse gases are regulated both under Polish and European law. The preamble to the United Nations Framework Convention[55] on climate change (hereinafter: Convention) states that climate change and its negative effects are one of the key problems facing humanity. At the same time, it was noted that the highly developed countries have the largest share of global greenhouse gas emissions. The objective of the Convention is, in accordance with the wording of Article 2 thereof, to “stabilize greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system (...)”.

It should be stressed that, in accordance with the abovementioned Convention, “emission” should be understood to mean the release of greenhouse gases and/or their substances into the atmosphere over a given area over a given period. In turn greenhouse gases themselves are defined as gaseous components of the atmosphere, both natural and anthropogenic, which absorb and reproduce infrared radiation.

Between 1 and 10 December 1997, the Kyoto meeting held the third Session of the Conference of the Parties to the United Nations Framework Convention on climate change. The outcome of the meeting was the adoption of the Kyoto Protocol[56] of 11 December 1997 to the United Nations Framework Convention on climate change.

On 12 December 2015 in Paris, at the Conference of the Parties to the United Nations Framework Convention on climate change, 195 States adopted the text of the new climate agreement, which is the Paris Agreement.[57] The Agreement was signed on 22 April 2016 in New York. It should be noted that the entry into force and the binding force of the Paris Agreement were conditional upon ratification by at least 55 States Parties to the Convention, which account for 55% of global CO2 emissions. The Paris Agreement entered into force on 4 November 2016, but it became effective at the beginning of 2020, replacing the Kyoto Protocol. Two types of measures have been required by individual countries, including those aimed at reducing CO2 emissions, as well as extending their absorption by, inter alia, increasing afforestation.

In accordance with Article 4 of the Agreement, emission reductions are to be implemented as soon as possible, in accordance with the best available scientific knowledge and due diligence. Individual countries are required to identify their contributions to the fight against climate change, referred to as INDC (Intended Nationally Determined Contributions) - and to gradually increase them.

The use of UAV for medical supplies is undoubtedly a contribution to reducing greenhouse gases due to the abandonment of conventional road transport. The above is a part of the amendments adopted by the European Parliament on 8 October 2020 on the proposal for a regulation of the European Parliament and of the Council establishing the framework for achieving climate neutrality.[58] The European Parliament suggests to increase greenhouse gas emission reductions for 2030 to 60% compared to 1990 emissions and achieve climate neutrality by 2050 for all countries.

12 Summary and Conclusions

The progressive automation of airspace management poses new challenges for the legislator, especially in the area of sectoral regulation. The U-space environment from the operational and regulatory side is a multidisciplinary approach that requires the interaction of aviation, law, medicine, robotics, mechatronics and engineering experts.[59] The legal framework and practical implementation of the concept is undoubtedly one of the pillars of the U-space, which can both stimulate and hamper its development. The legal framework for the development of U-space should be taken into account, as well as sector-specific regulations taking into account the principles of the use of drones in strictly defined areas, including in the process of medical supply, and liability for damage caused by UAV medical supply or AI-controlled intelligent machines. The already recorded numbers of operations via existing UTM systems shows the unprecedented growth of operations. Example of Poland and PansaUTM system showed that UAS operations submitted in 2021 almost doubled comparing to those submitted in 2020.

The outcomes of the UAS related projects and already existed UTM systems and capabilities are promising, however there are still much to be done on technical/ procedural and regulatory level to achieve ultimate goal – scalable drone operations with mixed services in unsupervised environment. The forthcoming U-space regulation with described U-space services might be next step forward to the uncertainties still to be answered.

Transport using UAV is crucial for the speed of medical supplies and for minimizing health risks due to the elimination of interpersonal contacts and therefore pathogens. The health regimes and the associated restrictions were mainly based on limiting face-to-face contacts, which is particularly important in the context of combating and combating COVID_19. While at the beginning of the COVID_19 pandemic the use of drones was primarily considered in the context of preventive and intervention measures, the focus of the use of UAV should now be shifted to the transport of equipment monitoring the course of complications after the infections. Extending the availability of remotely monitored patient health bands by providing them using UAV to locations that are difficult to access provides a guarantee of effective and prospective observation of the development of complications, causes of mortality, and the development of preventive health programs. Transport using UAV is an alternative to part of medical supplies, which is due to the improvement of the quality of the health protection of the individual as well as of public health. At the same time, medical transport using UAV has an impact on minimizing greenhouse gas emissions, to which both developed and developing countries are required.

Authors Contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Mateusz Kotlinski and Justyna Król-Calkowska. The first draft of the manuscript was written by Mateusz Kotlinski and extended by Justyna Król-Calkowska. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding No external funding was used to support a study. Study supported with data and resources by the Polish Air Navigation Services Agency and Lazarski University.

Data Availability References Are Available in the Separate Bullet Point. Data and Materials Presented in the Study Available at Respective Owners of the Data and Materials

Declarations

Ethical Approval This is an observational study with no human subjects involvement. No ethical approval is required.

Consent to Participate Research did not involve human subjects. There was no consent required to participate in the study.

Consent to Publish No human object have taken part in the study. There is no need for consent to publish from third parties. Both Authors hereby grant a consent to publish.

Competing Interests Authors confirms that there is no indication of competing interest and potential bias judgements impacting results of the study. For information purposes - Author Mateusz Kotlinski was employed by the Polish Air Navigation Services Agency when engaged in the study and directly involved in the subject of the study.

References

1. See: https://www.faa.gov/uas/programs_partnerships/data_exchange/[Access: 28.02.2020] (2020)
2. Rios L. Joseph, (…), UTM UAS Service Supplier Development (n.d.)
3. Warsaw Declaration: 'Drones as a leverage for jobs and new business opportunities' (https://ec.europa.eu/transport/modes/air/european-unmanned-aircraft-systems-uas/warsaw-declaration_en) [Access: 28.02.2020] (2020)
4. See: SESAR U-space Blueprint (n.d.)
5. European ATM Master Plan: Roadmap for the safe integration of drones into all classes of airspace (SESAR 2018), pp. 32 (2018)
6. Scott B. I., The Law of Unmanned Aircraft Systems, pp. 365 (n.d.)
7. Commission Implementing Regulation (EU) 2019/947 of 24 May 2019 on the rules and procedures for the operation of unmanned aircraft, Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems (2019)
8. https://www.unmannedairspace.info/emerging-regulations/eu-states-to-request-postponement-of-eu-drone-implementation-rules/. Access: 23.05.2020
9. Journal of Laws [Dz. U.] of 2002, No. 130, item 1112, as amended, hereinafter: Aviation Law (n.d.)
10. Ostrihansky M., Szmigiero M.: Prawo Dronów, Bezzałogowe statki powietrzne w prawie Unii Europejskiej oraz krajowym, Warsaw, p. 232 (2020)
11. Konert A., Kotlinski M.: "How come I cannot fly a drone above the prime minister's office?" – criminal and civil liability of a drone operator in Poland, Ius Novum, vol. 12, Number 4, (2018)
12. Konert A., Mateusz Kotlinski: Polish regulations on Unmanned Aerial Vehicles, Transportation Research Procedia,Volume 35, (2018)
13. http://www.swiatdronow.pl/droneradar-polska-aplikacja-mobilna-dla-operatorow-dronow. Access: 28.02.2020
14. European ATM Master Plan: Roadmap for the safe integration of drones into all classes of airspace, Supra, pp. 28, 30, 31 (n.d.)
15. http://cedd.pl/2020/05/04/lot-testowy-dronem-w-warszawie/. Access: 30.04.2020
16. https://www.urbanairmobilitynews.com/utm/who-should-manage-urban-airspace-civataglobal-webinar/. Access: 7.03.2021
17. https://airtrafficmanagement.keypublishing.com/2019/12/11/utm-industry-dismayed-at-delay-of-euro-u-space-rules/. Access: 28.02.2020
18. https://www.easa.europa.eu/document-library/opinions/opinion-012020. Access: 23.05.2020
19. Konert A., Smereka J., Szarpak L., The Use of Drones in Emergency Medicine: Practical and Legal Aspects (n.d.)
20. https://5gdrones.eu/. Access: 28.02.2020
21. www.cedd.pl. Access: 28.02.2020
22. https://www.pansa.pl/en/navihub/. Access: 28.02.2020
23. Regulation of the minister of infrastructure of 20 December 2018 amending the regulation on the exclusion of the application of certain provisions of the act — air right to certain types of aircraft and the definition of the conditions and requirements for the use of those vessels, J. Laws., item. 94 (2019)
24. Zhang, S., Liu, R., Zhao, T.: Mapping radiation distribution on ground based on the measurement using an unmanned aerial vehicle. J. Environ. Radioact. **193-194**, 44–56 (2018). https://doi.org/10.1016/j.jenvrad.2018.08.016 Epub 2018 Sep 3
25. Rosser JC Jr., Vignesh V., Terwilliger BA., Parker BC., Surgical and medical applications of drones: a comprehensive review., JSLS. 2018 22(3). pii: e2018.00018. https://doi.org/10.4293/JSLS.2018.00018
26. Braun, J., Gertz, S.D., Furer, A., Bader, T., Frenkel, H., Chen, J., Glassberg, E., Nachman, D.: The Promising Future of Drones in Prehospital Medical Care and its Application to Battlefield Medicine. J. Trauma Acute Care Surg. (2019). https://doi.org/10.1097/TA.0000000000002221
27. Bradley, K.: The good, the bad, and the future of drones in tactical/operational medicine. J Spec Oper Med. Winter. **19**(4), 91–93 (2019)
28. Sanfridsson, J., Sparrevik, J., Hollenberg, J., Nordberg, P., Djärv, T., Ringh, M., Svensson, L., Forsberg, S., Nord, A., Andersson-Hagiwara, M., Claesson, A.: Drone delivery of an automated external defibrillator - a mixed method simulation study of bystander experience. Scand. J. Trauma Resusc. Emerg. Med. **27**(1), 40 (2019). https://doi.org/10.1186/s13049-019-0622-6
29. https://spectrum.ieee.org/robotics/drones/in-the-air-with-ziplines-medical-delivery-drones. Access:29.11.2020
30. Amukele, T., Ness, P.M., Tobian, A.A., Boyd, J., Street, J.: Drone transportation of blood products. Transfusion. **57**(3), 582–588 (2017)
31. Amukele, T., Sokoll, L.J., Pepper, D., Howard, D.P., Street, J.: Can unmanned aerial systems (drones) be used for the routine transport of chemistry, hematology, and coagulation laboratory specimens? PLoS One. **10**, e0134020 (2015)

32. Ling, G., Draghic, N.: Aerial drones for blood delivery. Transfusion. (2019). https://doi.org/10.1111/trf.15195
33. Leszczyński M.: The innovation of the economy as a factor in the perception of the state in the international environment of the European Union [W]: innovation challenge for the modern economy, K. Pająk, p. 212 (2016)
34. Drucker, P.F.: Innovation and Entrepreneurship. Practice and Principles, p. 29, Warsaw (1992)
35. Robakowska, M., Ślęzak, D., Tyrańska-Fobke, A., Nowak, J., Robakowski, P., Żuratyński, P., Ładny, J., Nadolny, K.: Operational and financial considerations of using drones for medical support of mass events in Poland. Disaster Med Public Health Prep. **13**(3), 527–532 (2019). https://doi.org/10.1017/dmp.2018.106
36. Augusto de Alcantara, F., Andrade, A.A., Netto de Lima, L., Rodin, C.H., Johansen, T., Storvold, R., Moraes Correia, C., Haddad, D.: Autonomous Unmanned Aerial Vehicles in Search and Rescue Missions Using Real-Time Cooperative Model Predictive Control. Sensors (Basel). **19**(19), 4067 (2019). https://doi.org/10.3390/s19194067
37. Béjot, Y., Bailly, H., Durier, J., Giroud, M.: Epidemiology of stroke in Europe and trends for the 21st century. Presse Med. **45**(12 Pt 2), e391–e398 (2016). https://doi.org/10.1016/j.lpm.2016.10.003 Epub 2016 Nov 2
38. Lydon, P., Gandhi, G., Vandelaer, J., Okwo-Bele, J.M.: Health system cost of delivering routine vaccination 259 in low- and lower-middle income countries: what is needed over the next decade? Bull world health 260. Organ. **92**, 382–384 (2014)
39. Haidari, L.A., Brown, S.T., Ferguson, M., Bancroft, E., Spiker, M., Wilcox, A., Ambikapathi, R., Sampath, V., Connor, D.L., Lee, B.Y.: The economic and operational value of using drones to transport vaccines. Vaccine. **34**(34), 4062–4067 (2016). https://doi.org/10.1016/j.vaccine.2016.06.022 Epub 2016 Jun 20
40. Haidari, L.A., Brown, S.T., Ferguson, M., Bancroft, E., Spiker, M., Wilcox, A., et al.: The economic and operational value of using drones to transport vaccines. Vaccine. **34**, 4062–4067 (2016)
41. Bhatt, K., Pourmand, A., Sikka, N.: Targeted applications of unmanned aerial vehicles (drones) in telemedicine. Telemed. J. E Health. **24**(11), 833–838 (2018 Nov). https://doi.org/10.1089/tmj.2017.0289
42. https://www.isbzdrowie.pl/2020/09/drony-pomoga-w-walce-z-covid-19-i-nie-tylko-wideo/. Access: 29.11.2020
43. PAP, https://www.pap.pl/aktualnosci/news%2C751542%2Cdrony-pomoga-w-walce-z-covid-19-przewozac-probki-i-krew-do-badan-miedzy. Access: 29.11.2020
44. The Convention on International Civil Aviation, signed at Chicago on 7 December 1944, the Chicago Convention, 1959, No 35, item 212, with amendments, Notice No 6 of the President of the Civil Aviation Authority of 12 April 2018, on the publication of the text of Annex 18 to the Convention on International Civil Aviation, Done at Chicago on 7 December (1944)
45. Notice No 7 of the President of the Aviation Office on Technical Instructions for the safe Transport of dangerous goods by Air of 20 may 2016, Official Journal [OJ. ULC] of 2016, item. 54 (2016)
46. IATA Dangerous Goods Regulations 61th Edition, https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr61-addendum1-en.pdf. Access:29.11.2020
47. Journal of Laws of 2002, No. 130, item 1112, as amended, hereinafter: Aviation Law (2002)
48. European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), OJ C 252/239 (n.d.)
49. Konert A.: UAV. A new era in aviation law. Civil law issues CH Beck, (2020)
50. McKinsey: Notes from the AI frontier insights from hundreds of use cases. Retrieved from www.mckinsey.com/~/media/McKinsey/Featured Insights/Artifcial Intelligence/Notes from the AI frontier Applications and value of deep learning/Notes-from-the-AI-frontier-Insights-fromhundreds-of-use-cases-Discussion-paper.ashx (2018)
51. Alarie B., Niblett A., Yoon AH., How artificial intelligence will affect the practice of law, Univ. Toronto Law J. 2018, t. 68, p. 106 i n
52. Devarapalli, P.: Machine learning to machine owning. Redefining the copyright ownership from the perspective of Australian, US, UK and EU law. Eur. Intellect. Prop. Rev. **t. 11**, 722 (2018)
53. Alarie, B., Niblett, A., Yoon, A.: Law in the future. University of Toronto Law Journal. **t. 66**, s (2016) 423 i n
54. European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), OJ C 252/239 (n.d.)
55. United Nations Framework Convention on Climate Change, 9 May 1992, https://unfccc.int/resource/docs/convkp/conveng.pdf. Access: 29.11.2020
56. Kyoto Protocol to the United Nations Framework Convention on Climate Change, 11 December 1997, https://unfccc.int/resource/docs/convkp/kpeng.pdf. Access: 29.11.2020
57. INTERNATIONAL AGREEMENTS COUNCIL DECISION (EU) 2016/1841 of 5 October 2016 on the conclusion, on behalf of the European Union, of the Paris Agreement adopted under the United Nations Framework Convention on Climate Change 12 December 2015, OJ L 282/1, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D1841&from=PL. Access: 29.11.2020
58. Amendments adopted by the European Parliament on 8 October 2020 on the proposal for a regulation of the European Parliament and of the Council establishing the framework for achieving climate neutrality and amending Regulation (EU) 2018/1999 (European Climate Law) (COM(2020)0080 – COM(2020)0563 – C9–0077/2020–2020/0036(COD)), https://www.europarl.europa.eu/doceo/document/TA-9-2020-0253_EN.html. Access 29.11.2020
59. Polish Economics Institution, White Paper UAV.. U-spacje- rynek-wizja rozwoju. https://www.gov.pl/attachment/bba34b69-36c1-48d6-9309-71852a7b1457. Access: 29.11.2020

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Mateusz Kotlinski - Air Traffic Management Expert at International Civil Aviation Organization (ICAO) in Montréal, Canada. Former U-space Program Manager and Head of the Unmanned Aircraft Systems Projects Department at the Polish Air Navigation Services Agency (PANSA) in Warsaw, Poland. Responsible for operational deployment of PansaUTM – UAVs flight coordination system in Poland in years 2019-2022. On a daily basis he is cooperating with the international aviation organisations and agencies on drone issues. Member of the A6 U-Space Task Force, European Network of U-space Demonstrators, CANSO U-space WG. He has experience in UAS flight coordination within the CTRs in FIR EPWW. As the former Senior Specialist at CAA Poland was involved in the process of creation of the first Polish regulations concerning drone operation and co-founder of Safety Campaign for drone users "Fly Wisely be Safe". Author of publications concerning aviation law, especially related to unmanned aviation. He is an active airplane/ glider and drone pilot.

Justyna Król - Całkowska - PhD (law), PhD (medical science) Associate professor of Lazarski University in Warsaw.

A lawyer specializing in protecting the rights of doctors and people working in other medical professions.

Head of the Department of International and European Law at the Lazarski University in Warsaw.

Associate professor at the Department of Medical Law of the Medical University in Lodz.

Head of Postgraduate Studies "Medical Law in Healthcare" at the Faculty of Postgraduate Education at the Medical University in Warsaw.

Head of Postgraduate Studies in Telemedicine and Telecare at Medical University in Lodz.

Lecturer of legal subjects at the Executive Master of Business Administration in Healthcare, Medical University in Warsaw – Warsaw school of Economics.

Lecturer of legal subjects at the "MBA in Healthcare" studies, Medical University of Lublin.

Lecturer of legal subjects at the "MBA in Healthcare" studies, Lazarski University in Warsaw.

Author of several monographs in the field of medical and pharmaceutical law.

Member of the Council of Experts established at the Patients' Rights Ombudsman.

Authors and Affiliations

Mateusz Kotlinski[1] · **Justyna Krol Calkowska**[2]

Justyna Krol Calkowska
kancelaria.prawomed@gmail.com

[1] Polish Air Navigation Services Agency, 8 Wiezowa st, 02-147 Warsaw, Poland

[2] Lazarski University, Swieradowska 43, 02-622 Warsaw, Poland