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Review

How Do Dangerous Goods Regulations Apply to Uncrewed Aerial Vehicles Transporting Medical Cargos?

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Abstract: Commercial operations of uncrewed aerial vehicles (UAVs or drones) are expanding, with medical logistics using UAVs as part of health service supply chains being targeted. The ability to transport cargos that include items classified as Dangerous Goods (DG) is a significant factor in enabling UAV logistics to assist medical supply chains, but DG regulations for air transport have developed from the perspective of crewed aircraft and not UAVs. This paper provides an important audit of the current DG regulations, best practice in their application and the development of much-needed new governance that will be required to fully exploit UAVs for the safe transport of DG in medical logistics. Findings from the audit provide a summary of the circumstances and potential challenges resulting from the application of DG regulations as they stand to UAV operations, particularly for medical logistics, and convenient guidance on the practical implications of DG regulations for UAV operators. The main conclusion is that this is an under-researched domain, not yet given full consideration in a holistic way by regulators, governments, industry bodies, practitioners or academia.

Keywords: UAV; drone; Dangerous Goods; regulations; logistics; medicine; healthcare

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1. Introduction

Commercial operations of uncrewed aerial vehicles (UAVs, commonly known as drones) have been expanding in recent times for purposes such as last-mile logistics, video/photography, mapping, inspection of agriculture and infrastructure, environmental monitoring, emergency response and humanitarian aid [1–7].

One area where commercial UAV operations could offer benefits in terms of reduced service times, energy use and atmospheric emissions is medical logistics, particularly in areas where hospitals, clinics, doctors' surgeries and laboratories are hard to reach by existing surface transport [2,4,8,9]. Medical logistics can also be extended to include supply chains for veterinary services, with UAVs offering similar potential benefits.

Recent examples include Matternet, who has used UAVs to deliver medicines in Switzerland, the Dominican Republic, New Guinea and Haiti (after the 2010 earthquake), and is routinely transporting laboratory specimens via UAV for a North Carolina health service in the USA [2,9]. Zipline is using UAVs to deliver blood for transfusion to 25 hospitals and clinics across Rwanda, overcoming the challenges of the region's poor road infrastructure [4,10]. Apian is trialling a UAV delivery service for COVID-19 samples, which it hopes to scale into the National Health Service (NHS) Air Grid (NAG), a network of UAV corridors connecting health service sites across the UK for delivery of pathology samples, medical equipment, medications and blood [11].

Skyports has been conducting UAV delivery trials within a network of two NHS hospitals and a doctors' surgery in the Scottish highlands, transporting medical cargos including COVID-19 testing kits and Personal Protective Equipment (PPE) over distances up to 48 km [12,13]. DHL has investigated the use of UAVs for delivering medicines and blood in Germany, while Flirtey has used UAVs to deliver healthcare items in the USA, Australia and New Zealand. Wing (a subsidiary of Google's parent company Alphabet) is using UAVs to deliver medicines in Canberra, Australia, and there are many other small-scale pilot projects taking place around the world [2,4,9]. O'Keeffe et al. [14] reported the first documented delivery by UAV of insulin for a diabetic patient, via a flight from Galway, Ireland to the Arran Islands (~20 km) in 2019; and O'Keeffe et al. [15] reported the first medication delivery (insulin and glucagon) by UAV with return diagnostic specimen (blood sample) collection, also via a Galway–Arran flight.

The ability to transport cargos that include items classified as Dangerous Goods (DG) is an important factor in enabling UAV medical logistics as many routine medical products are classified as DG (e.g., patient diagnostic samples and cytotoxic medicines). The global principles governing the safe transport of DG by air are described in Annex 18 to the Convention on International Civil Aviation (the Chicago Convention) [16]. These broad principles have been amplified into the detailed 'Technical Instructions for the Safe Transport of Dangerous Goods by Air' (Doc 9284) (the latest edition of ICAO Doc 9284 (2021–2022 Edition) was published subsequent to the edition purchased for the purposes of this research (2019–2020 Edition), but no revisions were found that materially affected research findings) published by the International Civil Aviation Organisation [17]. In addition, these technical instructions are reproduced in the 'Dangerous Goods Regulations' (DGR) published by the International Air Transport Association [18]. The regulations define the procedures and requirements for transporting DG by air; in particular, classification of goods, packing requirements and training requirements. International civil aviation operations involving the carriage of cargo classified as DG are obliged to comply with the provisions of the regulations, and domestic civil aviation operations are encouraged to do likewise [19].

Commercial UAV operations are a relatively new addition to the aviation ecosystem, first emerging in the late 2010s, with the DG regulations having already been developed exclusively from the perspective of their application to crewed aircraft. Consequently, carriage of DG by uncrewed aircraft is a new area in terms of regulation and governance, and it is unclear how the current DG regulations should apply. Whilst the research reported in this paper often refers to situations in the UK and Europe, this study is relevant to other national systems of regulation because they are all derived from the same overarching ICAO technical instructions (Doc 9284), which apply internationally.

The main scope of the research in this paper was the application of the DG regulations to UAVs, but a related issue is the potential involvement of other regulatory authorities involved in the transportation of medical products. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) Good Distribution Practice (GDP) guidelines [20] are key, in that medical logistics operators must demonstrate that transport by UAV would not adversely affect the quality and stability of the medical cargo as a result of in-flight conditions experienced during transit.

The aims of the research described in this paper were threefold: (1) to audit the current regulations, governance and best practices for transporting DG by air as they relate to cargos carried by commercial UAV logistics operations, in particular for medical goods classified as DG, and the associated issue of compliance with good distribution practice to maintain cargo quality; (2) to summarise the current situation and potential challenges regarding the application of the existing DG regulations to UAV logistics; and (3) to provide guidance for commercial UAV operators intending to transport cargos classified as DG.

2. Methodology

The methodology centred around an extensive audit of: (i) the current standards, recommendations and legal requirements that have been published primarily by the regulators, but also through governmental white papers and documents published by industry bodies, both in conventional aviation and in the emerging UAV sector; (ii) use cases disseminated by practitioners and aviation developers; and (iii) the frameworks and research findings published in peer-reviewed academic journals. Based on the results of the audit and dialogue with UAV operators and regulators, guidance for commercial UAV operators was produced.

The research focussed on how DG regulations apply to UAV logistics operations (in particular for medical goods), and therefore the 'Technical Instructions for the Safe Transport of Dangerous Goods by Air' (Doc 9284) published by ICAO [17] was inherently the primary reference source. ICAO Doc 9284 is re-issued every two years, and subject to amendments in intervening periods via addenda based on recommendations from ICAO's DG Panel. ICAO Doc 9284 and the IATA DGR are very closely aligned (the IATA DGR derived from Doc 9284, but re-issued annually), and the general abbreviation DGR is used in this paper to refer to both documents simultaneously.

3. Results and Discussion

3.1. Substances Classified as DG for Transport by Air

DG are substances (or articles) classified under one (or more) of nine UN hazard classes: (1) explosives; (2) gases; (3) flammable liquids; (4) flammable solids, substances liable to spontaneous combustion, and substances that emit flammable gases on contact with water; (5) oxidizing substances and organic peroxides; (6) toxic and infectious substances; (7) radioactive material; (8) corrosive substances; and (9) miscellaneous dangerous substances and articles, including environmentally hazardous substances. Over 3000 substances have been classified as DG when transported by air, and each is individually listed in the DGR, along with instructions on how it should be packed for safe air transport (i.e., packing instructions). Whilst not exhaustive, the list includes all dangerous substances deemed to be of commercial importance [17].

The transport of radioactive material (hazard class 7) by air involves a considerable number of additional supplementary requirements and is typically treated as a separate subject (e.g., by DG training providers). For this reason, radioactive materials were excluded from the scope of this research.

When providing medical logistics services (for both human and veterinary applications), typical UAV payloads are likely to be: (1) diagnostic specimens; (2) pharmacy products (both prescription-only and over-the-counter medicines); (3) blood and organs for transfusion or transplant; and (4) medical devices and emergency equipment (e.g., defibrillators). These four types of payload are likely to involve transporting substances classified as DG listed in the first column of Table 1 by United Nations (UN) number and Proper Shipping Name (PSN). Other information contained in Table 1 is discussed in Section 3.5, but brief details are as follows: packing group (PG) relates to a substance's degree of danger (I = high, II = medium, III = low)—for example, UN1851 substances are split into two PGs (II and III) based on toxicity; Excepted Quantities (EQs) relate to small quantities of substances ($\leq$~1 kg in Table 1); Limited Quantities (LQs) relate to slightly larger quantities ($\leq$~10 kg in Table 1); and pax/cargo (i.e., aircraft carrying passengers and cargo) and cargo-only relate to the largest quantities allowed on the respective aircraft types.

Table 1. DG likely to be involved in UAV medical logistics.

UN No. ***PSN*** **Class (Sub. Class)**	**PG**	**EQs** **Packing Instructions** **Max. Quantities**	**LQs** **Packing Instructions** **Max. Quantities**	**Pax/Cargo Aircraft** **Packing Instructions** **Max. Quantities**	**Cargo-Only Aircraft** **Packing Instructions** **Max. Quantities**	**Example Medical Goods**
UN3373 *Biological substance, Category B* 6.2	na	Not permitted as EQs	Not permitted as LQs	PI 650: −I ≤ 1 L/4 kg −O ≤ 4 L/4 kg	As for Pax/Cargo	Diagnostic specimens (lower risk)
UN2814 *Infectious substance, affecting humans Category A* 6.2	na	Not permitted as EQs	Not permitted as LQs	PI 620: −I ≤ 50 mL/50 g −O ≤ 50 mL/50 g	PI 620: −I ≤ 4 L/4 kg −O ≤ 4 L/4 kg	Diagnostic specimens (high risk to humans)
UN2900 *Infectious substance, affecting animals only* 6.2	na	Not permitted as EQs	Not permitted as LQs	PI 620: −I ≤ 50 mL/50 g −O ≤ 50 mL/50 g	PI 620: −I ≤ 4 L/4 kg −O ≤ 4 L/4 kg	Diagnostic specimens (high risk to animals)
UN1851 *Medicine, liquid, toxic, n.o.s.* 6.1	II	E4: −I ≤ 1 mL −O ≤ 500 mL	PI Y641: −I ≤ 0.1 L −O ≤ 1 L	PI 654: −I ≤ 1 L *(m: 2.5 L)* −O ≤ 5 L	PI 662: −I ≤ 2.5 L *(m: 5 L)* −O ≤ 60 L	Liquid cytotoxic (Chemotherapy) drugs
UN1851 *Medicine, liquid, toxic, n.o.s.* 6.1	III	E1: −I ≤ 30 mL −O ≤ 1 L	PI Y642: −I ≤ 0.5 L −O ≤ 2 L	PI 655: −I ≤ 2.5 L *(m: 5 L)* −O ≤ 60 L	PI 663: −I ≤ 5 L *(m: 10 L)* −O ≤ 220 L	Liquid cytotoxic (Chemotherapy) drugs
UN3248 *Medicine, liquid, flammable, toxic, n.o.s.* 3 (6.1)	II	E2 −I ≤ 30 mL −O ≤ 500 mL	PI Y341: −I ≤ 0.5 L −O ≤ 1 L	PI 352: −I ≤ 1 L −O ≤ 1 L	PI 364: −I ≤ 2.5 L *(p: 5 L, m: 10 L)* −O ≤ 60 L	Topical sprays
UN3248 *Medicine, liquid, flammable, toxic, n.o.s.* 3 (6.1)	III	E1 −I ≤ 30 mL −O ≤ 1 L	PI Y343: −I ≤ 1 L −O ≤ 2 L	PI 355: −I ≤ 2.5 L *(p/m: 10 L)* −O ≤ 60 L	PI 366: −I ≤ 5 L *(p: 10 L, m: 25 L)* −O ≤ 220 L	Topical sprays
UN3249 *Medicine, solid, toxic, n.o.s.* 6.1	II	E4 −I ≤ 1 g −O ≤ 500 g	PI Y644: −I ≤ 0.5 kg −O ≤ 1 kg	PI 669: −I ≤ 1 kg *(p/m: 2.5 kg)* −O ≤ 25 kg	PI 676: −I ≤ 2.5 kg *(p/m: 5 kg)* −O ≤ 100 kg	Powders for solution for injection
UN3249 *Medicine, solid, toxic, n.o.s.* 6.1	III	E1 −I ≤ 30 g −O ≤ 1 kg	PI Y645: −I ≤ 1 kg −O ≤ 10 kg	PI 670: −I ≤ 5 kg *(p/m: 10 kg)* −O ≤ 100 kg	PI 677: −I ≤ 5 kg *(p/m: 10 kg)* −O ≤ 200 kg	Powders for solution for injection

Table 1. *Cont.*

UN No. ***PSN*** **Class (Sub. Class)**	**PG**	**EQs** **Packing Instructions** **Max. Quantities**	**LQs** **Packing Instructions** **Max. Quantities**	**Pax/Cargo Aircraft** **Packing Instructions** **Max. Quantities**	**Cargo-Only Aircraft** **Packing Instructions** **Max. Quantities**	**Example Medical Goods**
UN3091 *Lithium metal batteries contained in equipment* 9	na	Not permitted as EQs	Not permitted as LQs	PI 970: −I ≤ 5 kg −O ≤ 5 kg	PI 970: −I ≤ 35 kg −O ≤ 35 kg	Defibrillator
UN3481 *Lithium ion batteries contained in equipment* 9	na	Not permitted as EQs	Not permitted as LQs	PI 967: −I ≤ 5 kg −O ≤ 5 kg	PI 967: −I ≤ 35 kg −O ≤ 35 kg	Defibrillator
ID8000 *Consumer commodity* 9	na	na	PI Y963: −I ≤ 0.5 L/0.5 kg −O ≤ 30 kg (G)	As for LQs	As for LQs	Drugs packaged for retail sale to patients
UN1845 *Dry Ice* 9	na	Not permitted as EQs	Not permitted as LQs	PI 954: −I ≤ 200 kg −O ≤ 200 kg	As for Pax/Cargo	Refrigerant for diagnostic specimens

(Sub. Class) is the subsidiary hazard class for substances with more than one hazard class. EQs is Excepted Quantities; LQs is Limited Quantities. Toxic substances (6.1) and infectious substances (6.2) are sub-divisions of Class 6. na is not applicable. n.o.s. is not otherwise specified. I is inner packing container; O is outer packing container; multiple inners may be packed within a single outer (subject to maximum quantity limits). m is metal and p is plastic, relating to container construction material. (G) is gross mass (i.e., total mass of package including both substance quantity and packing materials). Source: [17].

Medicines can contain specific substances classified and listed in their own right as DG. For example, arsenic trioxide (a chemical compound used in chemotherapy medicine as a treatment for acute promyelocytic leukaemia) is classified and listed as UN1561 [17,21]. This study considered medicines more generally, and therefore the non-specific listings for medicines (n.o.s. means not otherwise specified) were included in Table 1 (UN1851, UN3248 and UN3249) to provide generic examples. When more specific UN numbers apply, substance-specific instructions in the DGR should be followed.

Consumer commodities (ID8000 in Table 1) are DG that are packaged and distributed in a form suitable for retail sale for household use or personal care. This definition includes items administered or sold to patients by doctors or medical organisations. Substances that can be re-classified under ID8000 (provided they do not also have a subsidiary hazard) are limited to: non-toxic aerosols (part of gases, hazard class 2); flammable liquids (hazard class 3) with PG II or III; toxic substances (sub-division 6.1 of hazard class 6) with PG III; and certain other specific substance listings (UN3077, UN3082, UN3175, UN3334 and UN3335). Dry ice (UN1845, i.e., solid carbon dioxide (CO_2)) was included in Table 1 because it is sometimes used as the refrigerant within packages of other medical DG (e.g., diagnostic specimens) [17].

There are a number of biological materials considered sufficiently low risk as infectious substances to avoid classification as DG altogether (i.e., excluded from sub-division 6.2 (infectious substances) of hazard class 6 containing UN3373, UN2814 and UN2900 in Table 1). These exceptions include substances unlikely to cause disease in humans or animals; substances containing micro-organisms non-pathogenic to humans or animals; substances containing neutralised or inactivated pathogens no longer presenting a health risk; blood collected for the purposes of transfusion (once checked free from contaminants) and any tissues/organs intended for transplant; and patient specimens where there is minimal likelihood that pathogens are present. The exceptions are not subject to the provisions of the DGR; although patient specimens with minimal likelihood of pathogens are subject to a small number of conditions specifically listed in the DGR, e.g., packaging must prevent any leakage and be marked as 'Exempt human/animal specimen' [17,22].

A small number of DG substances are defined as high-consequence DG, which means they have the potential for misuse in a terrorist event, resulting in serious consequences (e.g., mass casualties, mass destruction or mass socio-economic disruption). Any organisation involved in transporting high-consequence DG must implement a security plan that comprises elements such as specific allocation of responsibility for security to suitably qualified personnel; assessment of operational vulnerabilities (e.g., inter-modal transfer, temporary storage); statement of measures implemented to reduce security risks (e.g., training policies, verification of new employees, access to DG in temporary storage); procedures for reporting/dealing with security threats/incident; procedures for periodic testing/updating of security; and measures to ensure the security of information contained in the security plan itself. Of the substances listed in Table 1, UN2814 and UN2900 are high-consequence DG [17].

3.2. Application of Air Transport DG Regulations

The DGR are principally concerned with the operation of large, crewed, fixed-wing aeroplanes of the type typically used to transport the vast majority of airfreight, but also apply to the transport of DG by any aircraft type, including helicopters and UAVs. Whereas helicopter operations are addressed in the text of ICAO Doc 9284, UAV operations are not mentioned [17].

The way in which the DGR are applied to helicopter operations, whereby NAAs are allowed to approve DG carriage without all the normal requirements of the regulations being fulfilled in recognition of the different types of operations carried out by helicopters compared to aeroplanes [17], provides a useful precedent for application to UAV operations. Explicit inclusion of UAV operations in the DGR could be initially achieved by the addition

of a provision allowing NAAs to grant permission for UAV operators to transport DG without fulfilling requirements identified as less relevant or unnecessary.

This approach would be convenient for UAV logistics because they typically do not cross national borders, and for domestic operations, NAAs are only encouraged (rather than obligated) to comply with the DGR [19]. There is a risk however that different regulations for UAVs evolving in different countries could lead to problems for multi-national logistics companies who would have to operate across different regulatory environments. If/when UAV logistics operations become a more influential part of the airfreight sector, it is likely that inclusion of UAVs in the DGR would have to be made more explicit (e.g., DG packing instructions specifically for UAVs), with an international approach being more favourable.

Global logistics necessitates that goods are transported by various modes other than air, such as road, rail or sea, and these modes have their own equivalent regulations for the transport of DG. The United Nations (UN) publishes the 'European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)' [23]; the Intergovernmental Organisation for International Carriage by Rail (OTIF) publishes the 'Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)' for member nations across Europe, Asia and Africa [24]; and the International Maritime Organization (IMO) publishes the 'International Maritime Dangerous Goods Code (IMDG)' [25]. Whilst the regulations for the different modes are not the same, there is much commonality between them.

Road vehicles are the mode most likely to interface directly with UAV operators in mixed-mode logistics, transporting payloads to/from UAV landing site locations, although cycle couriers and porters on-foot could also be involved. The ADR regulations specifically consider mixed-mode logistics (described as 'transport chains'), stating that packages which do not entirely meet the ADR requirements are still acceptable for carriage in a transport chain involving road vehicles, as long as the packages conform to the DGR for air [23]. This suggests that for mixed-mode logistics, compliance with the DGR for air is also sufficient for safe transport by road. It would be prudent, however, for operators always to check the specific regulations by substance according to the mode of transportation as part of best practice techniques [26].

There are no regulations specifically covering the transport of DG by cycle couriers or porters. It would seem reasonable therefore to assume that the transport of DG in accordance with the regulations for air and road, alongside any additional procedures that may be stipulated by the organisations involved (e.g., health service organisations, cycle courier or porter service providers), would be sufficient to ensure safe transportation.

Road transport is also seeing the emergence of uncrewed vehicle technology in the form of autonomous vehicles [27,28] and due to the parallels, research investigating the application of the ADR to uncrewed road vehicles was also reviewed relevant to the application of the DGR to UAVs. Engler [29] highlighted that the ADR do not include specific mention of applicability to uncrewed vehicles. Bhargava et al. [30] found that tunnel closures necessary to allow passage of vehicles carrying DG (as required by the ADR) could be reduced through replacing conventional with autonomous vehicles, thereby significantly improving road traffic congestion. This research was based on a simulation of the Dartford–Thurrock River Crossing Tunnel in the UK, but did not consider the application of the ADR in general. Sindi and Woodman [31] interviewed experts in logistics and autonomous technology from the UK about the barriers to using autonomous road vehicles for last-mile delivery and the carriage of DG and application of the ADR were not barriers identified by participants at the time.

The national government in the USA has begun to consider the challenges involved in the transport of DG via autonomous road transport. The Pipeline and Hazardous Materials Safety Administration (PHMSA, part of the US Department of Transportation) has issued a request for information (RfI) to obtain public comment on how the Hazardous Material Regulations (HMR, USA-specific DG regulations) can best account for the development of automated vehicle technologies in surface modes such as road and rail [32]. In parallel

to this RfI, the PHMSA also commissioned exploratory research to start identifying risks and potential regulatory requirements associated with the transport of DG by uncrewed vehicles across all modes (i.e., not just road), with the eventual aim of producing a "robust roadmap" for the safe introduction of uncrewed vehicle technology [33].

3.3. Training of Personnel

There are 12 categories of personnel that can be involved with transporting DG by air defined in the DGR. Each category has a different requirement with regard to the specific aspects of DG that must be included in the associated training course syllabus (Table 2). All personnel must undertake initial and recurrent training appropriate to their category every two years (and pass an exam to verify understanding) to ensure knowledge of the DGR (which change over time due to amendments/re-issue) is kept current. A record of this training must be retained by employers for a minimum of three years [17].

Table 2. Training requirements for personnel involved with transporting DG by air.

Aspect of DG Required in Training Course Syllabus	1	2	3	4	5	6	7	8	9	10	11	12
General philosophy	x	x	x	x	x	x	x	x	x	x	x	x
Limitations	x		x	x	x	x	x	x	x	x	x	x
General requirements for shippers	x		x			x						
Classification	x	x	x			x						x
List of DG	x	x	x			x				x		
Packing requirements	x	x	x			x						
Labelling and marking	x	x	x	x	x	x	x	x	x	x	x	x
DG transport document and other relevant documentation	x		x	x		x	x					
Acceptance procedures						x						
Recognition of undeclared DG	x	x	x	x	x	x	x	x	x	x	x	x
Storage and loading procedures					x	x		x		x		
Pilots' notification						x		x		x		
Provisions for passengers and crew	x	x	x	x	x	x	x	x	x	x	x	x
Emergency procedures	x	x	x	x	x	x	x	x	x	x	x	x

1: Shipper; 2: Packer; 3: Freight forwarder processing DG; 4: Freight forwarder processing cargo/mail (other than DG); 5: Freight forwarder handling, storing and loading cargo/mail; 6: Operator (and ground handling agent) accepting DG; 7: Operator (and ground handling agent) accepting cargo/mail (other than DG); 8: Operator (and ground handling agent) handling, storing and loading cargo/mail/baggage; 9: Passenger handling staff; 10: Flight crew, loadmaster, load planner and flight operations officer/flight dispatcher; 11: Crew member (other than flight crew member); 12: Security staff who screen passengers/crew and their baggage/cargo/mail. Source: [17].

Broadly, the categories most likely to be directly involved in UAV logistics operations can be grouped conveniently as follows:

1. Shippers (including Categories 1 and 2 in Table 2), with responsibility for:
   - Packing DG in accordance with the regulations (Section 3.5).
   - Producing a 'Shipper's Declaration for Dangerous Goods' document to accompany consignments of DG packages (Section 3.5).
2. Operators (including Categories 6, 8 and 10 in Table 2), with responsibility for:
   - Receiving DG and accompanying documentation from the shipper, and checking they are intact and correct (Section 3.5).
   - Producing an 'Air Waybill' document as a receipt for the goods accepted for carriage (done for all goods, not just if DG are involved) (Section 3.5).
   - Loading DG onto the UAV (Section 3.6).

- Producing the 'Notification to Captain (NOTOC)' document listing all DG for signing by the pilot in command (PIC) (Section 3.5).
- Flying the UAV to the destination.
- Unloading DG off the UAV and delivering to the recipient (Section 3.6).

Logistics operations utilising UAVs place a time-consuming and expensive yet important obligation on shippers to undertake training in transporting DG by air (Category 1 requirements in Table 2). For UAV medical logistics, 'shippers' are likely to be health service organisations. As an example, in the Invitation To Tender (ITT) to supply a traditional, road-based pathology courier service issued to potential logistics operators by a health service in the UK (The East and South East London NHS Pathology Partnership), the conditions stipulated that health service staff will be responsible for packing samples in compliance with DG regulations for road transport [34]. Whilst typically the operator's responsibility, it is also possible that health service staff may be involved in loading/unloading UAVs, and would therefore require appropriate DG training (Category 8 requirements in Table 2); although there are specific automated payload collection/release systems that may negate this requirement (refer to Section 3.6). DG training for carriage by air to accommodate UAV operations would be an extra requirement, in addition to existing requirements for DG by road training (i.e., DG by air and DG by road involve separate training courses), to which shippers (e.g., health service organisations) may be resistant.

A solution to this potential barrier could be for the UAV operator to assume the training obligation on behalf of the shipper, and provide a combined packing and transport service; although this may prove difficult in practice for medical logistics as a UAV operator would need to supply appropriately trained staff across multiple health service sites. A combined service could be particularly appealing because the UAV operator would need to train at least some staff to Category 6 requirements in Table 2 in order to discharge the operator's responsibility for receiving and checking DG packages and documentation, and Category 6 covers all the requirements (and more) of Category 1.

Other UAV operator staff will need to be trained to the less onerous Category 8 (for loading/unloading UAVs, Table 2) and Category 10 (for piloting the UAV, Table 2). In general, given the limited types and quantities of substances likely to be carried in UAV payloads in logistics operations, there may be an argument for abridged training courses focussing only on the relevant substances and PIs, where UAV medical logistics would focus on the substances listed in Table 1.

3.4. Operator Approval

In general, in order to transport DG by UAV, operators are required to obtain approval from the National Aviation Authority (NAA) in the intended country of operation. As a typical example, the situation in the UK (based on European Law retained post-Brexit) is that DG must not be carried by UAVs without approval from the UK Civil Aviation Authority (CAA) [35]. The European Union (EU) has recently implemented (applicable from 30 December 2020) new regulations relating to UAV operations. However, the situation in Europe remains similar to the general situation (as typified by the UK) regarding uncertainty over how the DGR should be applied to UAV operations [36,37].

In the UK and throughout Europe, UAV operations are categorised as open, specific or certified. Only specific and certified categories are allowed (subject to approval) to transport DG [35,37]. Details of the UK/European operations categories are as follows [22,35,37]:

- Open category operations apply to situations presenting a low risk to third parties, and can be conducted without NAA authorisation. The boundaries of the category are: UAV maximum take-off mass (MTOM) below 25 kg; within Visual Line Of Sight (VLOS) and below 120 m (400 ft) above ground level (agl); and not over assemblies of people (gatherings where people are unable to move away due to crowd density).
- Specific category operations apply to situations where any of the requirements of the open category are exceeded, and require the UAV operator to obtain an operational authorisation from the NAA, which involves the operator submitting a Risk Assess-

ment (RA) for the proposed operation, for example using the Specific Operations Risk Assessment (SORA) methodology developed by the Joint Authorities for Rule-making on Unmanned Systems (JARUS). Alternatively, Standard Scenarios (STSs) and Pre-Defined Risk Assessments (PDRAs) are options available to operators (depending on the system adopted in the nation of operation) both designed to reduce the need for evidence of risk mitigation for pre-determined types of operation defined by prescriptive conditions (in essence 'off-the-shelf' RAs for particular operation types). (For example, UKPDRA01 published recently by the UK CAA is for an operation type defined by the following conditions: VLOS only, maximum 500 m horizontally from remote pilot; use of a UA observer situated next to the remote pilot, is permitted; maximum height not to exceed 120 m (400 ft) agl; flight permitted within 150 m of any Residential, Commercial, Industrial or Recreational Area for UAV; no flight within 50 m of any uninvolved person, except that during take-off and landing this distance may be reduced to 30 m; no flight within Flight Restriction Zones (FRZs) unless permitted by the relevant aerodrome; no flight over or within 150 m of open-air assemblies of more than 1000 persons; UAV mass of less than 25 kg (fixed wing or rotary wing to be defined); UAV equipped with a mechanism that makes it land in the event of loss or disruption of Command and Control (C2) Link; insurance cover to meet insurance regulatory requirements [35].) DG can be carried in specific category operations, unless they are assessed during the RA as presenting a high risk to third parties in the event of an accident. In the UK, applications for an operational authorisation and a DG approval must be submitted separately because they are processed by different teams within the CAA, but may be submitted at the same time.

- Certified category operations apply to situations presenting a high risk, specifically: flying over assemblies of people by UAVs with a characteristic dimension greater than 3 m; carrying passengers; or carrying DG assessed during the RA as presenting a high risk to third parties in the event of an accident. These operations present a risk equivalent to that of crewed aircraft operations, and are therefore subject to the same authorisations, namely certification of the aircraft, certification of the UAV operator, and licensing of the remote pilot. In the UK, regulations for certified category operations are still under development and not yet published, and therefore the principles from the relevant crewed aviation regulations will be used as the basis for regulation of this category in the meantime.

There is also provision in the UK and Europe for granting a Light UAS operator Certificate (LUC), which is an organisational certificate provided by NAAs to UAV operators who have demonstrated an ability to assess operational risk for themselves (i.e., the LUC is essentially an augmented operational authorisation). Holders of a LUC are allowed to self-authorise their operations, but this does not remove the requirement to obtain approval for carriage of DG [35,37].

ICAO recently published guidance on the use of UAVs to provide humanitarian aid and emergency response (U-AID), which considered (inter alia) issues associated with the transport of DG by UAVs [19]. This guidance acknowledges that there may be hazards unique to the transport of DG by UAVs, and explicitly states that NAAs can grant approval for UAVs to carry DG without complying with the DGR when authorities are satisfied with the UAV operator's RA and risks have been mitigated to an acceptable level.

The U-AID guidance suggests that the following items should be accounted for in UAV operators' RAs:

- Mitigation of risks unique to UAV operations.
- Adequate DG training to ensure personnel are competent, commensurate with their responsibilities.
- For incidents or accidents: an emergency response plan, procedures for communicating with appropriate authorities (when necessary) and with people who may be unfamiliar with labelling/marking of DG, and procedures for recording/reporting safety data.

- Risks associated with unintentional release (i.e., leak/spill) of DG (e.g., infectious substances, toxic/corrosive substances).
- Risks associated with transport over populated, remote or environmentally sensitive areas.
- Risks associated with securing DG payloads by direct attachment to UAVs or as underslung loads.
- Risks associated with DG payloads being released by dropping from UAVs.
- Potential for dangerous reactions resulting from unintentional mixing of incompatible DG.
- Packing in accordance with the provisions of the DGR to the extent possible. Where deviation occurs, an equivalent level of safety must be established accounting for: UAV cargo compartment conditions (e.g., airflow, precipitation ingress, temperature, pressure, vibration), lowest volume DG containers necessary for intended purpose, measures to prevent leaks/spills, full and easily accessible DG documentation, and the effects on packing if DG are to be released by dropping.

DG issues identified in the U-AID guidance are discussed in quite a general way, devolving to NAAs the detailed responsibility for approving the application of (or deviation from) the DGR on a case-specific basis considering UAV operators' RAs (either full RA or STS/PDRA), without necessarily providing conclusive or definitive guidance on the procedures UAV operators should follow. This is likely to be a reflection of the novel and evolving nature of the DGR in this area both nationally and internationally, and the U-AID guidance acknowledges that it is only applicable in countries that have already implemented (or at least begun to promulgate) regulations for UAVs (i.e., the guidance is only seen as a supplement to national regulations).

One potential issue for UAV operators seeking DG approval is an absence of staff at flight origin and destination locations. As the DGR are written from the perspective of crewed aircraft, they assume that operators will have staff present at both origin and destination points, which is not necessarily the case for UAVs. Absence of operator staff raises concerns such as (i) how operators will receive DG from shippers and check that packages and accompanying documentation are intact and correct (Section 3.5); (ii) who is responsible for loading/unloading of DG packages on UAVs (Section 3.6); (iii) how and by whom are pre/post-flight inspections for damage/leaks/spills achieved (Section 3.7); and (iv) how the training requirements for shippers' staff will be achieved (Section 3.3). UAV operators will need to address these concerns (and any associated deviations from the DGR that may be necessary) to the satisfaction of NAAs during the DG approval process.

In the UK, a small number of commercial UAV operators have applied (or are considering applying) for DG approval from the NAA (i.e., UK CAA). Several of these operators were consulted about their practical experiences of the approvals process: (1) Skyports, a UAV infrastructure and logistics service provider, who was the first UK operator to obtain approval for the carriage of DG (UN3373 Biological Substance, Category B); (2) Flyby Technology, a professional UAV training and consultancy service provider; and (3) Apian, a company attempting to establish a UAV medical logistics service for the UK NHS. The consultations revealed that the reality of the situation when interacting with the CAA during applications for DG approval (and associated operational authorisation) involves practical complexities and uncertainties related to the novelty of applying the DGR to UAV operations. The key issues highlighted by the consultation case studies are summarised in Table 3.

Table 3. Key issues identified from case studies of the DG approvals process for UAV operators in the UK.

Issue Encountered
An important part of the DG approvals process is the assessment by the CAA of the Quality Assurance (QA) procedures an operator has in-place to ensure on-going compliance with the DGR (or permitted deviations therefrom) once CAA approval has been granted.
Operators can expect to be audited for compliance with the DGR by the CAA before approval is granted (i.e., prior to commencement of operations), which can delay the approvals process somewhat, and then further auditing on a regular basis thereafter. There is currently no specific approach for the audit of UAVs in this regard and the CAA will need to develop a process which improves on the current system used for conventional crewed aviation which has been described as overly cumbersome and not fit-for-purpose.
The CAA's Dangerous Goods Office (DGO) processes DG approvals, and is separate from the department within the CAA responsible for processing operational authorisations. This can lead to uncertainty because it is not clear whether the DGO has sight of all documents submitted by UAV operators (including the entirety of operations manuals and RAs), or just the parts relating specifically to DG approvals.
Historically, DG approvals have been granted for aircraft that are type certified (i.e., airworthiness certification as would normally be the case for crewed aircraft) and there is likely to be some residual cautiousness over granting DG approvals for UAVs because there is no regime for UAV airworthiness certification. The separation within the CAA between the teams processing operational authorisations (including the UAVs involved) and DG approvals may mean that the DGO stray into questions concerning UAV reliability and safety, which should not be a concern if the UAV has been assessed as airworthy during the operational authorisation. This could delay the DG approval process until the DGO become accustomed to granting approvals when aircraft are not type certified.
In addition to meeting Category 8 requirements for DG training (Table 2), any health service staff involved in loading/unloading UAVs will also need to be trained in all the UAV operator's procedures for carriage of DG, which adds to training burdens and limits operational freedoms and opportunities for cost saving.
LUC holders with an operational authorisation based on a STS/PDRA that provides DG approval could (potentially) self-authorise operations involving DG carriage. However, it is possible that there may be mismatches between the requirement to comply with the DGR (or deviations therefrom) for every operation and the operational freedoms/limitations specified in the STS/PDRA, leading to uncertainty for operators over appropriate compliance.
The way in which regulations for UAV operations in the certified category are likely to develop is that the DGR will apply without UAV-specific deviations either: (1) until ICAO adapts their safety management Standard and Recommended Practices (SARPs, provided to assist nations in managing aviation safety risks) and/or provides specific guidance for DG carriage by UAVs in the certified category; or (2) operators of UAVs in the certified category can produce an acceptable Alternative Method of Compliance (AMoC).

3.5. Packing, Marking, Labelling and Documentation

In general, the shipper is responsible for packing, marking (PSN, UN number, name/address of shipper/consignee) and labelling (hazard class, special handling) packages of DG according to the instructions laid out in the provisions of the DGR. In the case of UAV medical logistics, the shipper is likely to be a designated health service employee or department (refer to Section 3.3).

The procedure for packing DG for air transport involves matching the specification supplied in the manufacturer's Safety Data Sheet (SDS) accompanying the goods to be packed (UN number, PSN and packing group), against the list of DG classified in the DGR, and then using the relevant listing to identify the correct packing instructions for the goods in question. The packing group (PG I, II or III) assigned to a listing (e.g., Table 1, Column 2 for the substances involved in medical logistics) indicates their degree of danger (I = high, II = medium, III = low), which can necessitate the use of different packing instructions. Where there is a desire to pack two or more different DG together in a single package, the regulations provide a procedure designed to ensure this is achieved safely taking into account the compatibility of different DG with each other. If dry ice (UN 1845, Table 1) is packed with other DG (e.g., as refrigerant for UN3373, UN2814 or UN2900 in Table 1), it does not need to be taken into account, as long as CO_2 gas can dissipate through the packing and the net mass of dry ice is marked on the package [17].

There are several hundred (>200) packing instructions (PIs) specified in the DGR. Typically, the instructions describe the physical characteristics of the containers to be used (e.g., metal, plastic, glass), the maximum quantities that can be packaged, and the marking and labelling requirements for the package exterior. Packing instructions can be divided broadly into three main categories: (1) instructions for Excepted Quantities (EQs); instructions for Limited Quantities (LQs); and (3) standard instructions for all other quantities allowable for transport by aircraft carrying either passengers and cargo (pax/cargo) or cargo-only. For the substances involved in medical logistics, maximum quantities that can be packaged in an inner container, and then packaged together as multiple inner containers in an outer container are shown in Table 1 for the different categories of packing instructions. UN-specified packing (i.e., UN tested and approved containers) should be used for outer packing, but is not required for inner packing [17].

EQs relate to the transport of small quantities of substances (e.g., ≤~1 kg for the substances in Table 1). The requirement to comply with the provisions of the DGR is relaxed to a large extent, including removal of the requirements for: hazard/handling labels, a 'Shipper's Declaration of Dangerous Goods' document (described later in this Section) and UN-specified packing. If non-UN-specified packing is used, drop and stack tests as detailed in the DGR (and Table 4) must be conducted to demonstrate package integrity [17].

Table 4. Integrity tests for EQs and LQs packing.

Packing Instruction Category	Test Type	Procedure
EQs	Drop	Five sample packages dropped from a height of 1.8 m, one sample dropped in each of the following orientations: - flat onto base; - flat onto top; - flat onto longest side; - flat onto shortest side; - onto a corner.
EQs	Stack	Force applied to top of sample package for 24 h equivalent to being the bottom package in a 3 m stack.
LQs	Drop	One sample package dropped from a height of 1.2 m in the orientation likely to cause most damage (usually onto a corner).
LQs	Stack	Force applied to top of sample package for 24 h equivalent to being the bottom package in a 3 m stack.

Tests must be documented (recorded, photographed and reported). Source: [17].

LQs relate to the transport of larger quantities of substances (e.g., ≤~10 kg for the substances in Table 1). The gross mass of a LQs package (i.e., total mass of a package including both substance quantity and packing materials) is limited to 30 kg. The requirement to comply with the provisions of the DGR is relaxed to a small extent, including removal of the requirement for UN-specified packing. Similar to EQs, use of non-UN-specified packing means drop and stack tests (Table 4) must be conducted to demonstrate package integrity [17]. LQs packing instructions are denoted by a PI number with a Y prefix (e.g., PI Y641) in the DGR [17].

Standard packing instructions (denoted by a PI number in the DGR, e.g., PI 654) are relevant to the transport of quantities beyond the maximums allowed for LQs (e.g., ≤~200 kg for the substances in Table 1), and can be different for pax/cargo and cargo-only aircraft. UN-specified packing is required. For UAV logistics operations, PIs for pax/cargo aircraft are not relevant because UAVs do not carry passengers, and considering the quantities associated with likely payloads for UAV logistics (e.g., ≤~20 kg for medical logistics), it seems that the less stringent EQs or LQs packing instructions would be

sufficient in most circumstances (although these are not available for UN3373, UN2814 and UN2900). Some of the maximum quantities shown in Table 1 for standard packing instructions (particularly cargo-only PIs) are likely to be well in excess of the payload carrying capabilities of UAVs, but are retained for completeness [17].

In addition, individual packages containing DG may be grouped together (typically for convenient handling of loads for individual consignees) in further packing known as overpacks. The requirements specifying the marking and labelling that must be reproduced on the exterior of overpacks (from the packages contained therein) are contained in the DGR [17].

The shipper is responsible for producing the 'Shipper's Declaration of Dangerous Goods' document, which must accompany a consignment of DG packages. This document provides detailed information on all the DG contained in a consignment (e.g., UN number, PSN, hazard class, packing group, quantity and type of packing, packing instruction, additional handling instructions) and includes the name and address of the shipper and consignee. During the acceptance process, when a consignment is presented by the shipper for carriage, the operator is responsible for checking that the Shipper's Declaration and the way the consignment has been packed are correct and in agreement, and that the packing is free from any damage, leaks or spills. Checking for damage/leaks/spills involves a visual inspection of the package exterior, and should not necessitate breaking any tamper seals that may have been used. The Shipper's Declaration, and the other documentation associated with the transport of DG, must be retained by the shipper for a minimum of three months [17].

The 'Air Waybill' is a document that accompanies goods (not just DG) shipped by air, describing a consignment and allowing it to be tracked. It is produced by the operator and acts as a receipt for the goods accepted for carriage, transferring liability for the cargo (e.g., loss, damage or delay) to the operator. The issue of cargo values in excess of an operator's limited liability (currently 22 Special Drawing Rights per kg of cargo, ~$32/kg) is usually tackled by declaring a value for the cargo and paying a small supplement to the operator to act as insurer for the declared value, as set out in the Warsaw Convention (a treaty regulating international carriage by air). However, Air Waybills and the Warsaw Convention (as amended) are only requirements for international flights (although Air Waybills are routinely used for domestic flights as well), and as most UAVs are likely to be operated domestically, the parties involved could negotiate their own arrangements regarding liability [38]. When an Air Waybill is produced for a consignment containing DG, it must include a statement to indicate that the DG are as described on the accompanying Shipper's Declaration [17].

The operator is responsible for producing the 'Notice to Captain (NOTOC)' document. This document provides the PIC with written details of all DG on-board, including station of loading/unloading, Air Waybill number, UN number, PSN, hazard class, number of packages, quantity per package, packing group and position of loading (i.e., which aircraft hold). A straightforward method to prepare this document is by reference to the information provided on the Shipper's Declaration. A copy of the NOTOC must be left on the ground, a requirement fulfilled by default during UAV operations because the PIC remains on the ground. Some DG are not required to be listed on the NOTOC, including DG packed in EQs and Biological Substance, Category B (UN3373) [17].

Substances classified as UN3373 (Biological Substance, Category B) are a special case to an extent, in that the associated packing instructions (PI 650) remove the requirement to comply with any of the provisions contained in the DGR, except for those specifically listed within PI 650 itself [17]. Provisions specifically listed for compliance are:

- Packages to be marked with "Biological Substance, Category B", the name/address of shipper and consignee, and name/telephone number of person responsible for the package (details of the person responsible can be provided on accompanying documentation instead);
- Requirements for accidents/incidents to be reported to NAAs (Section 3.7);

- Requirements for packages to be inspected for damage/leaks/spills prior to loading and after unloading (Section 3.7).

Substances re-classified as ID8000 (consumer commodities, i.e., packaged for retail sale, Section 3.1) are exempt from the requirement for UN-specified packing as long as they are packed in accordance with the associated packing instruction (PI Y963), which requires the LQs drop and stack tests (Table 4) be conducted for non-UN-specified packing. In addition, packages should be marked, labelled and documented as ID8000, rather than as the original classifications of the underlying substances [17].

3.6. Loading

Typically, the operator is responsible for loading/unloading DG onto/off an aircraft, which requires staff trained to Category 8 requirements in Table 2. DG must be loaded securely (in accordance with any package orientation arrows) so as to prevent any movement, and in such a way that they are protected from damage, including by the movement of other cargo or baggage [17]. Packages containing substances of certain hazard classes must be segregated from those containing substances of certain other hazard classes (i.e., not stowed next to each other or in a position that would allow interaction in the event of leaks). Details of hazard classes that must be segregated from each other are provided in the DGR. However, the substances likely to be involved in medical logistics (Table 1) are largely unaffected; although flammable liquids (hazard class 3, which includes UN3248 in Table 1) must be segregated from explosives (hazard class 1), oxidising substances (sub-division 5.1 of hazard class 5) and lithium batteries packed on their own (i.e., not in/with equipment) (part of hazard class 9) [17].

In general, DG must be loaded into a cargo compartment that includes systems for fire detection and extinguishing/suppression (as would be available on the large, crewed, fixed-wing aeroplanes usually used to transport airfreight). Exceptions to this requirement include flammable liquids (hazard class 3) assessed as low risk (PG III) unless they have a subsidiary hazard class 8 (corrosive substances); toxic substances (sub-division 6.1 of hazard class 6) unless they have a subsidiary hazard class 3 (flammable liquids); infectious substances (sub-division 6.2 of hazard class 6); and miscellaneous DG (hazard class 9).

UAV payload compartments (and payload compartments on light aircraft (<5700 kg MTOM) and helicopters to an extent) are unlikely to meet requirements for fire detection/extinguishing/suppression, and the DGR do not appear to consider UAV operations in this context. In contrast, helicopter operations are considered in the DGR, and the regulations specify carriage in the cabin (with NAA approval), in non-compliant cargo compartments (with NAA approval) or externally (e.g., underslung loads) as exceptions to the requirements [17]. These two factors (non-compliant UAV cargo compartments and the availability of a case-specific NAA approvals process for helicopters) combine to highlight the need for applications by UAV operators to NAAs for DG approvals to be considered on a case-specific basis based on RAs. For example, placing DG packages within a fireproof bag/container may be a way to satisfy requirements that is acceptable to a NAA in the circumstances of a particular case.

Packing in accordance with the DGR provides payloads with protection from in-flight conditions considered normal for air transport. These are defined in the regulations as: temperature from −40 to 55 °C; atmospheric pressure from 100 kPa (i.e., 1 Bar) to 25 kPa (i.e., a differential pressure of 75 kPa); and vibration force from 1 to 8 g [17]. It must be remembered, however, that the DGR are written from the perspective of packages loaded into the holds of crewed aircraft, and the levels of protection the conditions in such holds afford to the cargos contained within. The conditions in UAV payload compartments or underslung loads (e.g., airflow, precipitation ingress, temperature, pressure, vibration) may be different from their crewed counterparts (although there is similarity to helicopter underslung loads, which are excepted from the requirements of the DGR with NAA approval), potentially affording less protection to DG packages.

As an example, UAV in-flight conditions (~10 km flown in 18 min at ~60 m above ground by a Clogworks Dark Matter HX multi-rotor UAV in the UK) were found to be 1.8 g and 11 °C for vibration force and temperature, respectively [39]. These measurements are well within the ranges considered normal for air transport, but this does not account for the impact of other UAV-specific conditions that could adversely affect package integrity such as airflow or precipitation ingress (e.g., water damage). It would appear inadvisable to assume that DG packing provides sufficient protection for packages on UAVs, meaning package integrity is likely to need testing on a case-specific basis, i.e., UAV operators conducting tests to demonstrate package integrity as part of RAs. Eventually, once sufficient testing has taken place, it may be possible to establish a comprehensive evidence base that avoids the need for further testing.

At both origin and destination locations, there will need to be staff trained to Category 8 requirements in Table 2 (and trained in all the UAV operator's procedures for DG carriage, Table 3) to supervise the safe loading/unloading of payloads onto/off UAVs (including inspecting for damage/leaks/spills, Section 3.7) and onward delivery of DG. Such staff can be provided by the UAV operator (typically responsible for loading/unloading), or may be provided by the dispatching/receiving organisation (e.g., health service staff). It may be possible to avoid this training requirement in circumstances where payload collection/release can be automated (i.e., staff are not required to physically insert, attach, extract or detach UAV payloads, and are therefore not strictly loading/unloading the aircraft). For example, using a parachute drop delivery system in which the aircraft ejects the payload without landing or having a separate cargo capsule that can be detached automatically on landing. In the case of medical logistics, if health service staff physically interact with UAVs for loading/unloading purposes in any way, then they must have DG by air training to Category 8 (Table 2); whereas if cargo collection/release can be automated so that health service staff do not need to touch UAVs, then the training requirement could be avoided.

3.7. Non-Normal Procedures

For non-normal procedures, it is convenient to distinguish between three situations: (1) an in-flight emergency for an aircraft carrying DG; (2) an aircraft accident, serious incident or incident that may involve DG; and (3) an aircraft payload where a package containing DG appears to be damaged, leaking or spilled. These three situations are not mutually exclusive.

In the event of an aircraft experiencing an in-flight emergency whilst carrying DG, the PIC is required as soon as the situation permits to inform the local air traffic services unit of the details of the DG on-board, including UN number, PSN and hazard class (or of a telephone number where this information can be obtained). This information is then disseminated to local airport authorities to make them aware that an aircraft carrying DG may be landing following an in-flight emergency [17]. In contrast to crewed aircraft, UAVs do not need to land at aerodromes, and the air traffic services unit would have to disseminate the DG information to non-aerodrome locations, which could present a challenge from the perspective of maintaining suitable contact details for all potential UAV landing sites. ICAO also publish guidance for aircraft flight/cabin crews on the appropriate actions to take in relation to problems arising with DG in-flight [40]. This guidance is not relevant for UAV operations because, by definition, the aircraft do not carry crew.

In the event of an aircraft accident or serious incident that may involve DG, the operator is required to inform the responding emergency services of the details of the DG on-board, including UN number, PSN and hazard class, without delay. The operator must also provide this information as soon as possible to the NAAs of both the operator and the country where the accident/serious incident occurred. For any other incident (i.e., less severe than a serious incident), the operator need only provide DG information to the emergency services or NAAs if requested to do so [17]. The international definitions of aircraft accidents and incidents are as follows [41]:

- Accident is an occurrence in which: (a) a person is fatally or seriously injured; (b) the aircraft sustains damage or structural failure which adversely affects the structural strength, performance or flight characteristics of the aircraft, and would normally require major repair or replacement of the affected component; or (c) the aircraft is missing or is completely inaccessible.
- Incident is an occurrence, other than an accident, which affects or could affect the safety of operation.
- Serious incident is an incident involving circumstances indicating that there was a high probability of an accident.

Packages must be inspected prior to loading and after unloading. In the event of a package containing DG appearing to be damaged, leaking or spilled (which would also constitute an aircraft 'incident' by the definitions in the previous paragraph), the operator is required to remove and safely dispose of the package (or arrange for its removal and disposal by an appropriate authority/organisation, e.g., appropriately trained health service personnel in the case of medical logistics), and to ensure no other parts of the payload are contaminated or damaged.

Other sensible precautions include avoiding contact with the package contents, washing thoroughly with plenty of water and removing contaminated clothing if contact is unavoidable, keeping hands away from face, seeking medical assistance, seeking clean-up advice from an appropriate authority/organisation, and recording the names of any personnel involved. In addition, for infectious substances (UN3373, UN2814 and UN2900 in Table 1), the operator is also required to: (1) avoid (or keep to a minimum) handling the package; (2) inform the local public health/veterinary authority (and provide information on any other countries of transit where people/animals may have been exposed to danger), and (3) notify the shipper and/or the consignee [17,42].

For medical logistics operations, it is likely that the health service organisations involved will specify additional non-normal procedures over-and-above the requirements of the DGR. These procedures would be an area for discussion between UAV operators and health service organisations during contract negotiations for provision of logistics services. Based on information relating to medical logistics by road contained in the ITT issued by the East and South East London NHS Pathology Partnership [34] and obtained from two large UK hospitals (Queen Alexandra Hospital, Portsmouth and St Mary's Hospital, Isle of Wight), the following are some typical examples of additional requirements for operators that might be expected:

- In the event of accidents or incidents (e.g., vehicle accident/breakdown, package with damage/leak/spill), inform the health service organisation without delay so that expert advice can be provided (e.g., by the designated Safety Officer) before packages are handled, assistance can be provided with any clean-up/disinfection operations necessary, and the occurrence can be recorded in the health service's own risk management reporting/recording systems.
- In the event of any circumstances occurring during transport that could affect the integrity of the goods being transported (e.g., excessive delays, extremes of temperature), inform the health service organisation so they can take the appropriate action.
- Availability and use of spill-kits at origin and destination, including items such as PPE (e.g., gloves, apron, mask, over-shoes), water for irrigation, absorbing material, scoop, waste disposal bags and hand sanitiser.
- Cooperating with health service organisations in conducting temperature audits of vehicles by carrying in-vehicle temperature recording devices. However, this could present a challenge if the recording devices were powered by lithium batteries, which are subject to the DGR (Table 1). In addition, other devices could be used to monitor in-vehicle conditions. For example, 3-axis accelerometers can be positioned on the craft and/or payload in a similar arrangement to trials in the UK monitoring in-flight dynamics such as vibration [43], which can negatively impact on the stability of

medical cargos (refer to Section 3.8). These could be integrated into flight systems such that live updates can be given to UAV operators.

The mechanism by which UAVs will be managed, controlled and integrated into shared airspace alongside crewed aircraft is yet to be decided. However, the UAV Traffic Management (UTM) concept (the equivalent concept in Europe is known as U-Space) under consideration for these purposes around the world (including in the UK) will inevitably involve some form of tracking of UAVs [44,45]. Thus, the proposed implementation of UTM represents an ideal opportunity to enable the monitoring of safe flights for UAVs carrying DG, and also the expedient locating of any UAVs that may be experiencing non-normal situations.

3.8. Other Regulatory Considerations

In addition to the DGR, depending on the type of goods transported, other regulatory authorities may be involved. For medical goods in the UK, logistics operators must adhere to the GDP guidelines compiled by the MHRA [20], which are intended to provide assurance that the conditions encountered during transportation do not adversely affect the stability of cargos (i.e., the quality of medicines or medical products is not affected by transportation). The DGR were not designed with the intention of ensuring medical product stability, and therefore cannot be relied upon in this respect.

Surveillance and measurement of the conditions that influence stability form part of this process, ensuring the cargo has been maintained within specification and highlighting where potential out of specification risks may occur. Recognised approaches to stability testing are based on the climactic zones that represent the expected environments in which medicines will be distributed and dispensed [46,47], and typical specifications to maintain quality during distribution therefore relate to temperature and humidity.

Advantages of integrating UAVs into medical supply chains include their speed of delivery and flexibility in terms of landing sites, which open new logistical opportunities for the transportation of important medicines with very short expiry dates that conventional road transport cannot meet (e.g., chemotherapy medicines, some of which can have a shelf-life of between 4 and 48 h). The disadvantage of UAVs is that as an emerging logistics platform, there is a paucity of information concerning to what extent their design and operation could negatively impact on the stability of medical cargos. Rapid acceleration and deceleration, along with extreme manoeuvrability, especially during collision avoidance, could impart considerable g-forces onto a cargo. Furthermore, as many UAVs employ multiple propellers for propulsion, how well vibration is balanced and controlled is not clear.

It is to be expected that most medicines will not be sensitive to such vibrations as they have been successfully transported using conventional aircraft and helicopters. However, biopharmaceuticals such as monoclonal antibodies are known to aggregate and lose potency when shaken or dropped [48], and thus there is a need to monitor vibration and shock when transporting sensitive medicines. Recent work undertaken by the authors has shown that the range of frequencies that UAV cargos may encounter is much wider than other forms of transport, and is influenced by both the rigidity of the packaging and the type of aircraft platform used [43].

Recent examples of research into the effects of UAVs on medical cargos include Amukele et al. [49], who investigated the stability of biological samples (packed in accordance with the DGR) transported on long-range UAV flights in the USA (258 km flown in 174 min), concluding that long-range UAV transport was feasible, but only with stringent environmental controls to mitigate the effects of vibration, acceleration and temperature. Beck et al. [39] investigated the feasibility of delivering adrenaline auto-injectors (e.g., EpiPen) by UAV, and found that in-flight conditions (~10 km flown in 18 min) did not have an adverse impact on adrenaline stability.

In general, in-flight stability appears to be an area where further research is required to generate the evidence base necessary to support the widespread and routine use of UAVs

in medical logistics operations. Establishing a register of potential vibrational stresses and g-force ranges for regulatory consideration in order to manage potential risk to specific medical cargos is one area warranting further research. The on-going trials taking place in the arena of UAV medical logistics represent an opportunity for live monitoring of in-flight conditions and the associated impacts on product stability as a way to begin building this evidence base.

3.9. Summary Guidance for UAV Operators Intending to Transport DG

The key points have been extracted from the results and discussion of the research and formulated as a list of issues UAV operators should consider when making an application to transport DG (Table 5). It should be remembered that this is an evolving area of regulation, meaning that there is often no definitive rule or procedure to follow. Guidance for operators transporting the DG identified as likely to be involved in UAV medical logistics (Table 1) is provided as a flow chart in Figure 1.

In general, as part of the DG approvals process, UAV operators need to provide NAAs with an operations manual and a RA (either full RA or STS/PDRA) that explains how they will account for the issues summarised in Table 5. Achieving this will require operators to have detailed knowledge of ICAO Doc 9284 (i.e., the DGR) and detailed case-specifics such as substances for transport, quantities involved, staff involved, UAV type, unloading procedures, and ground environment under the flight path (e.g., rural/urban, population density).

Table 5. Issues to consider for UAV operators intending to transport DG as part of logistics operations.

Issue to Consider
Substances Classified as DG for Transport by Air (Section 3.1**)**
• UAV medical logistics operations are likely to involve transporting substances classified as DG in hazard classes 3, 6, and 9. • Transport of radioactive material (hazard class 7) by air is typically treated as a separate subject (e.g., by DG training providers), and was therefore excluded from the scope of the research. • UN2814 and UN2900 are high-consequence DG, and their transport therefore requires operators to implement security plans.
Application of Air Transport DG Regulations (Section 3.2**)**
• The DGR apply to transport by any aircraft type, including UAVs. • For domestic operations, compliance with the DGR is not obligatory, but is encouraged and likely to be regarded as best practice by NAAs. • For mixed-mode logistics (i.e., transport chains), packages complying with the DGR for air are acceptable for road transport as well, although best practice would involve checking the individual listings for the DG concerned in the regulations for both air (DGR) and road (ADR).
Training of Personnel (Section 3.3**)**
• Recurrent training must be undertaken by personnel every two years, and a record of that training kept for three years by employers. • Shippers are responsible for packing DG in accordance with the regulations and for producing the Shipper's Declaration for Dangerous Goods, which requires staff trained to Categories 1 (Shipper) and 2 (Packer). • Operators are responsible for receiving/checking, loading, transporting and unloading consignments containing DG, which requires staff trained to Categories 6 (accepting DG, highest level of training), 8 (loading/unloading) and 10 (pilot). • Operators may want to provide a combined packing and transport service to relieve shipping organisations of time-consuming and expensive training obligations, and hence remove a potential barrier to UAV logistics. • Abridged training courses focused on UAV operations could be an option to simplify training requirements.

Table 5. *Cont.*

Issue to Consider
Operator Approval (Section 3.4**)** • Operators require approval from NAAs to transport DG based on the specifics of intended operations. • Approval can be granted by NAAs to carry DG without complying fully with the DGR, as long as an Authority is satisfied with the operator's RA. • Items for operators to consider when applying for DG approval include mitigation of any risks unique to UAVs; DG training requirements; emergency response plan; unintentional release of DG; ground environment under the flight path; and packing that complies with the DGR, and accounts for UAV payload compartment conditions and the effects if DG are to be released by dropping. • Absence of operator staff at flight origin/destination locations raises issues that will need to be addressed to the satisfaction of NAAs as part of DG approval. • Operators must detail the QA procedures in-place to ensure on-going compliance with the DGR (or permitted deviations therefrom) once approval has been granted, and can expect to be audited for compliance by NAAs prior to approval and on a regular basis thereafter. • An important aspect of DG approval is demonstrating UAV airworthiness (as part of obtaining operational authorisation) because (in contrast to crewed aircraft) there is currently no regime for UAV airworthiness certification. • In the UK and Europe, UAV operations are categorised as open, specific or certified, with only specific and certified allowed to carry DG. • In the UK and Europe, STSs/PDRAs are alternatives to full RAs designed to reduce the need for evidence of risk mitigation from operators for pre-determined operation types. • In the UK and Europe, granting of a LUC does not remove the need to obtain DG approval. • In the UK, applications for DG approval and operational authorisation can be submitted at the same time, but must be submitted separately because the DGO is separate from the CAA team responsible for processing operational authorisations. This can cause uncertainty regarding whether the DGO has sight of all documentation relating to an application or just that relating to DG.
Packing, Marking, Labelling and Documentation (Section 3.5**)** • DG packing procedure involves following the detailed, substance-specific instructions listed by UN number and PSN in the DGR. • EQs packing instructions apply to small quantities (e.g., $\leq$~1 kg for substances in Table 1) and are the least stringent. Shippers must perform drop and stack tests (as detailed in the DGR) if UN-specified packing is not used. • LQs packing instructions apply to larger quantities (e.g., $\leq$~10 kg for substances in Table 1) and are more stringent than EQs packing instructions. Shippers must perform drop and stack tests (as detailed in the DGR) if UN-specified packing is not used. • Standard packing instructions apply to the largest quantities (e.g., $\leq$~200 kg for the substances in Table 1) and are the most stringent. UN-specified packing must be used. • Typical UAV payload quantities mean that EQs and LQs packing instructions are likely to be sufficient (although these are not available for UN 3373, UN 2814 and UN 2900). • Shippers must produce the Shipper's Declaration for Dangerous Goods detailing the DG contained in the consignment it accompanies. A copy must be retained by the shipper for a least three months. • The Air Waybill is a receipt for goods accepted for carriage, and must refer to the Shipper's Declaration when DG are present. • Operators must produce the NOTOC informing the PIC of DG on-board. DG packed as EQs and Biological Substance, Category B (UN3373) are not required to be listed on the NOTOC. • Substances classified as Biological Substance, Category B (UN3373) are a special case to an extent because PI 650 removes the requirement to comply with any of the provisions contained in the DGR except for those specifically listed within PI 650 itself. • Substances re-classified as consumer commodities (ID8000;, i.e., packaged and distributed in a form suitable for retail sale for household use or personal care, including items administered or sold to patients by doctors or medical organisations) do not require UN-specified packing (LQs drop/stack tests required), and can be marked, labelled and documented as ID8000 rather than their original classification.

Table 5. *Cont.*

Issue to Consider
Loading (Section 3.6**)** • DG must be loaded securely, preventing movement and protection from damage. • In general, DG must be loaded into cargo compartments with systems for fire detection, extinguishing and suppression; although there are DG that are excepted from this requirement. UAVs are likely to have non-compliant cargo compartments, and therefore need NAA approval on a case-specific basis. • Packing in accordance with the DGR cannot be assumed to protect from in-flight conditions on UAVs because UAV payload compartment conditions may be different from crewed aircraft counterparts. This should be considered as part of the RA when applying to the NAA for DG approval and may require in-flight testing of packing by the operator. • Loading/unloading DG requires personnel trained to the requirements of Category 8 (Table 2) and trained in all the UAV operator's procedures for DG carriage. However, it may be possible to avoid this requirement if personnel do not have to interact physically with UAVs in any way (e.g., automated payload collection/release systems).
Non-Normal Procedures (Section 3.7**)** • Actions for in-flight emergencies when carrying DG: ○ As soon as the situation permits, the PIC must inform local air traffic services of the details of DG carried on-board (UN number, PSN, hazard class, or telephone number where this information can be obtained). • Actions for aircraft accidents/serious incidents (as per international definitions): ○ Without delay, the operator must inform responding emergency services of the details of DG carried on-board (UN number, PSN, hazard class). ○ As soon as possible, the operator must inform NAAs (of both the operator and country of occurrence) of the details of DG carried on-board (UN number, PSN, hazard class). ○ For other (non-serious) incidents, information need only be supplied if requested. • Actions for DG incidents where a package appears to be damaged/leaking/spilled: ○ The operator must arrange the removal and safe disposal of the package by appropriately trained personnel. ○ The operator must ensure no other parts of the payload are contaminated or damaged. ○ Other sensible precautions: ■ Avoid contact with package contents. ■ If contact is unavoidable: wash thoroughly with water and remove contaminated clothing, keep hands away from face, and seek medical assistance. ■ Seek clean-up advice from an appropriate authority/organisation. ■ Record names of personnel involved. ■ In addition, for infectious substances (hazard class 6.2), the operator must minimise handling and inform the public health/veterinary authorities and the shipper/consignee. • For medical logistics, health service organisations are likely to have additional requirements (over-and-above those in the DGR) for operators non-normal procedures, such as: ○ Inform the health service organisation of accidents/incidents so they can provide expert advice on package handling and clean-up, and occurrences can be recorded in the health service's risk management reporting system. ○ Inform the health service organisation of any transport circumstances that could affect the integrity of goods (e.g., excessive delays, temperature extremes). ○ Stipulations on the carriage and use of spill-kits. ○ Requirements to conduct in-vehicle temperature audits.
Other Regulatory Considerations (Section 3.8**)** • For medical logistics, compliance with distribution guidelines issued by regulatory authorities (such as the MHRA in the UK) will be required to ensure the stability of medical goods transported by UAV. This is likely to involve testing to demonstrate that goods remain stable under in-flight conditions.

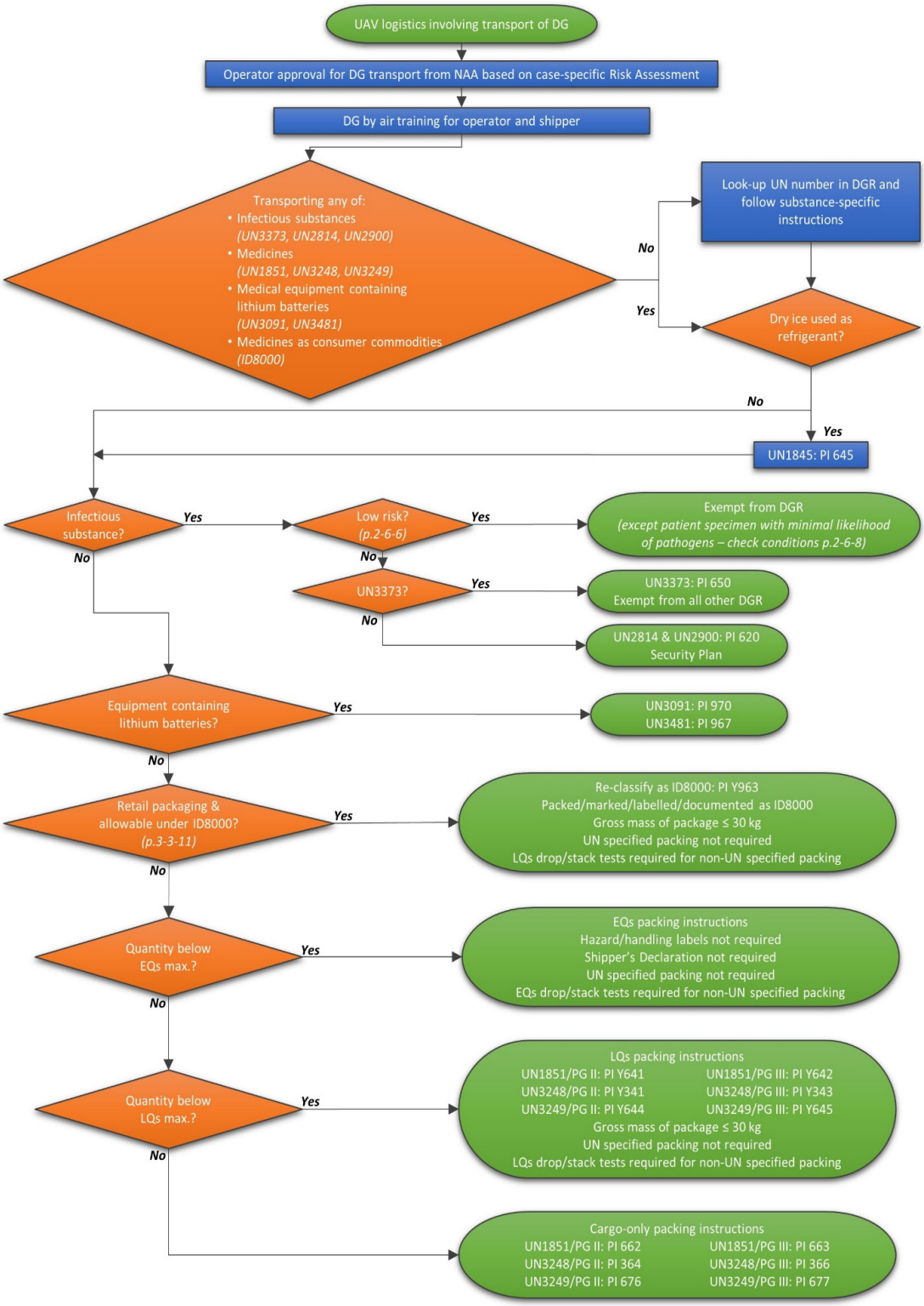

Figure 1. Guidance for transporting the DG likely to be involved in UAV medical logistics. Page number references relate to ICAO Doc 9284 [17].

4. Conclusions

The increasing interest in utilising UAVs for logistics operations requires the DGR for air transport to be considered, but this research has found that little literature addresses how the DGR should be applied to UAV logistics operations. The UK CAA explicitly

acknowledges that carriage of DG by UAVs is a new and developing area where regulations, policies and guidance are likely to evolve as experience and evidence accumulates [35].

The contributions of this paper have been threefold: (1) a summary of the current circumstances and potential challenges of the DGR as they stand in relation to UAV operations has been provided, particularly in the arena of medical logistics; (2) convenient guidance on the practical implications of applying the DGR for UAV operators has been addressed; and (3) identifying the potential impacts of carriage by UAV on medical cargos and the wider implications for medical product regulators.

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