November 12, 2021

Mr. Teun Muller
ICAO Dangerous Goods Panel Chairman
Ministry of Infrastructure and the Environment
Directorate-General for Mobility Division for Civil Aviation
Plesmanweg 1-6
P.O. Box 20901
2500 EX The Hague, Netherlands

Re: Proposed Amendments to Air Transportation Regulations Affecting Shipments of Medical Devices

Dear Mr. Muller:

On behalf of the undersigned organizations, representing the global medical device industry, we write to express our concerns with proposed regulations on the transport of dangerous goods aboard aircraft being considered at the International Civil Aviation Organization (ICAO) Dangerous Goods Panel on November 15th, 2021. The International Federation of Air Line Pilots' Association (IFALPA) has filed several concerning proposals impacting international air shipments of medical devices containing batteries. Two proposals in particular would have significant patient care, operational, and cost implications for the medical industry:

- Mandate that all devices containing lithium batteries have an on/off switch to allow devices to be "switched off" when shipped by air.
- Require shipments of lithium ion batteries (rechargeable) packed with or contained in equipment to be shipped at the lowest practical state of charge (SOC) not to exceed 30% SOC. Batteries in medical devices currently have no restrictions and are shipped fully charged.

Lithium ion batteries are widely used in life-saving medical devices critical to everyday patient care and the fight against COVID. Some of these technologies include but are not limited to ventilators, intravenous pumps, pacemakers, incubators, patient monitors and defibrators. Batteries designed for medical devices must meet all medical device regulations in addition to all current transportation regulations. The higher standards in place for medical devices already provide additional safety benefits without the need for additional transportation regulation. The IFALPA proposals unnecessarily subject medical devices to new air transportation requirements, presenting significant redesign issues.

The first concerning proposal would require non-rechargeable lithium battery-powered devices, including medical devices, be "switched off" when shipped via air. Portable and implantable medical devices containing lithium batteries are not equipped with on/off switches due to well-documented and obvious patient safety concerns, since even minor agitation to the switch could inadvertently shut down the device, resulting in catastrophic failure or death. Complying with the proposed amendment would require substantial device redesign and regulatory review that could increase device costs and take years to approve.

IFALPA's other concerning proposal would require batteries to be shipped at 30% SOC or less, which flatly ignores important patient safety considerations. Medical device companies ship their lithium battery-powered medical devices to patients and hospitals primarily via aircraft due to the time-critical nature of patient care; the lithium ion batteries in these devices need to be shipped at 100% SOC to allow for immediate use. Medical devices shipped at 30% SOC or lower will not have sufficient shelf life to go from finished manufacturing to the destination hospital with enough charge remaining to perform initial functionality tests. Without confirmation of device functionality,

surgery cannot proceed. Further, hospitals and clinics often do not have the resources or specialized equipment needed to recharge devices and, even if the necessary equipment is present, many devices take hours to charge, resulting in delayed or cancelled medical procedures.

Lithium ion batteries can also be permanently damaged if the SOC drops to 0% for an extended period; shipping a device with less than 30% SOC increases the likelihood of such an occurrence since devices may be stored for months at a time. If stored at 0% SOC for one month, lithium ion batteries used for devices like neuromodulation implants can permanently lose up to 5% capacity. For neuromodulation implants charged to 100% SOC, the typical shelf life is about 6 months before the battery reaches 0% SOC and needs to be recharged. However, if the SOC is initially 30% or less, shelf life is reduced to only 1-2 months. Storing devices beyond this duration can permanently damage the battery with a measurable loss in capacity.

It is also important to note that medical device manufactures are occasionally required to ship medical devices for forensic analysis. Regulatory bodies mandate that the device is not tampered with prior to appropriate analysis and specify a timeline to complete the analysis that requires air transport as the mode of shipment. As a result, the devices cannot be discharged prior to transport. Once a medical device is placed in a sterile package, it is often impossible to reduce the state of charge, other than that associated with the normal discharge rate. It is also impossible to verify the state of charge without impacting the sterility of the product.

If the 30% SOC restriction is adopted for air shipments of lithium ion battery-powered medical devices, significant changes would need to be made throughout the medical device industry, including:

1. Changing the manufacturing process to discharge devices to below 30% SOC after devices are manufactured; and
2. Changing the device itself to allow for an accurate way to determine the 30% SOC. Unlike popular consumer electronic devices, many medical devices, including implantable devices, do not have displays that allow an easy measure of SOC. Without an effective way to verify SOC, these devices would have to be shipped near 0% SOC, which would further exacerbate the recharging issue and may ultimately damage the device.

The 30% SOC limit and off-switch requirement would make air transport of lithium battery powered medical devices nearly impossible, leading to even further supply chain disruption during an already tumultuous global health pandemic. For patients requiring timely access to life-critical devices such as defibrillators or ventilators, a disruption to the supply chain poses serious threats to public health.

The medical device community produces state-of-the-art products that are already heavily regulated by international agencies to the highest standards of safety and effectiveness. The medical device industry is not aware of a single aviation incident involving lithium battery-powered medical devices, nor have IFALPA's proposals undergone any risk analysis to demonstrate that these changes would improve flight safety. To the contrary, there has been consistent concern about the public health risks of restricting air shipment of medical device batteries and has allowed for exemptions for life-saving medical devices to be flown on passenger flights.

We appreciate your consideration of these issues and welcome a chance to further engage with you if there are any comments, questions, or concerns.

Respectfully,
ABIMED - Brazilian High-Technology Health Products Industry Association
AdvaMed- Advanced Medical Technology Association
APACMed-Asian Pacific Medical Technology Association
BVMed- The German Medical Technology Association
COCIR- European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
JIRA- Japan Medical Imaging and Radiological Systems Industries Association
KMDIA- Korea Medical Devices Industry Association
KMDCIA- Korea Medical Devices Industrial Coop Association
MITA- Medical Imaging and Technology Alliance
MDTC- Medical Device Transport Council
MDMA- Medical Device Manufacturers Association
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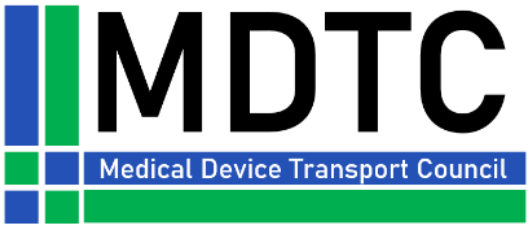
MDTC
Medical Device Transport Council


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