DANGEROUS GOODS PANEL (DGP)
WORKING GROUP MEETING (DGP-WG/15)

Montreal, 27 April to 1 May 2015

Agenda Item 5: Development of mitigating measures to address risks associated with the transport of lithium batteries including measures that address recommendations from the Second International Multidisciplinary Lithium Battery Transport Coordination Meeting

5.6: Miscellaneous lithium battery issues

AIR TRANSPORT ON MEDICAL DEVICES

(Presented by PRBA – The Rechargeable Battery Association)

SUMMARY

This information paper expresses the views of PRBA members who are medical device manufacturers. The Dangerous Goods Panel (DGP) is requested to consider the implications of further air transport restrictions on medical devices and lithium batteries designed exclusively for use in medical devices and the negative consequences these restrictions could have on patient health and the development of new devices that enhance public health.

Action by the DGP-WG: The DGP-WG is invited to consider the issues raised in this paper.

1. INTRODUCTION

1.1 As stated in PRBA's previous submission, our members include some of the largest medical device and medical battery manufacturers that are global leaders in medical device technology. These companies develop and manufacture a wide range of life-extending, life-sustaining and life-enhancing products and therapies with emphasis on providing a complete continuum of care to diagnose, prevent, treat, and monitor medical conditions such as debilitating cardiac rhythm disorders, spinal, diabetes, cardiovascular and neurological disease states as well as for use in other medical and surgical applications. These devices include implantable pacemakers, defibrillators, and neurostimulators many of which are powered by sophisticated lithium ion and lithium metal battery designs. The devices are also used for relieving pain through spinal stimulation, administering cancer treating and pain relieving drugs

through implantable drug pumps, providing insulin through diabetic pumps and providing deep brain stimulation for chronic movement disorders. Portable medical devices are used for patient monitoring and other portable medical applications where failure of the lithium battery is not an option, such as defibrillators (AED's), LVADs, and ventilators. Life-saving medical devices containing lithium batteries are required to meet high standards of quality and performance due to the fact that failure of a device generally will have life threatening implications. These devices are only offered to the public after years of research and development and being subject to clinical trials and regulatory oversight.

1.2 PRBA understands the necessity of responsible transportation regulations yet remains concerned that the International Civil Aviation Organization is overlooking the impact their decisions and the ripple effects associated with these decisions is having on the global health community. Medical devices save lives, improve health and contribute to sustainable healthcare. The prohibition on lithium metal batteries as cargo aboard passenger aircraft is already having an impact on the medical device industry. A number of airlines including Air France, Emirates and Qantas have implemented variations imposing restrictions for transporting lithium metal batteries on cargo aircraft as well. This has significantly impacted the supply chains of medical device manufacturers and has implications to global health care and patient well-being.

1.3 The majority of lithium batteries used in life-saving medical devices are shipped by air. Due to new and pending transportation restrictions, the medical device supply chain is being disrupted, resulting in untimely shipping of life-sustaining and life-enhancing medical devices to patients. In many instances, critical shipments of life saving products must be transported for same day delivery. Additionally, air transport is the only option for many rural and remote locations around the globe. Sterile medical devices, for quality reasons, cannot be transported by ocean vessel due to heat, humidity, salt, and contaminants. Ocean shipping schedules are not reliable and are more often delayed as compared to air transport. Hospitals and clinics, particularly those in remote areas only accessible by airplane, are already experiencing the impact of the recently adopted restrictions on lithium metal batteries. Hospitals and clinics are now required to establish safety stocks of expensive devices and backup batteries to serve their patients. Hospitals and clinics are absorbing the impacts from this inventory "safety stock" cost in order to respond to a slower and restricted supply chain process. The bottom-line is that the new restrictions are resulting in added hospitals costs without any offsetting benefit and are impeding time critical deliveries.

1.4 PRBA also requests that the ICAO Dangerous Goods Panel consider the impacts additional restrictions will have on hospital and clinic returns of medical devices and their batteries. Upon notice of a suspected faulty device, the United State Food and Drug Administration (FDA) requires the manufacturer to complete a full diagnosis and report within 30 days. Hospitals and clinics – infrequent shippers of dangerous goods – have difficulty navigating current transport requirements, leading to shipping delays and FDA scrutiny for medical device manufacturers. Additional restrictions will only serve to worsen this scenario.

1.5 Cells and batteries used in most medical devices often undergo extensive clinical studies that culminate in the review and clearance/approval by government agencies. In addition, medical devices comply with a range of internationally recognized standards, guidelines and regulations mandated by the FDA, the European Medicines Agency (EMA) and other agencies.

1.6 Manufacturers and distributors of medical devices are realizing significant impacts as a result of continuously mounting restrictions imposed through the International Civil Aviation Organization Technical Instructions on the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions) and independent airlines. While PRBA supports ICAO's initiative to implement risk reduction measures, it is imperative to ensure that Panel Members understand the supply chain logistics

associated with the transport of medical devices and seek reasonable alternatives to avoid unnecessary and overly burdensome regulatory requirements.

2. DISCUSSION

2.1 PRBA requests the ICAO Dangerous Goods Panel to:

a) Ensure medical device companies are provided an opportunity to participate in future multi-disciplinary meetings to demonstrate how medical device batteries are manufactured, shipped, and tested;

b) Consider public health implications of additional ICAO regulatory requirements;

c) Permit medical device companies to provide information regarding how medical devices and batteries are regulated by the FDA, the European Medicines Agency (EMA) and other agencies;

d) Work with PRBA members to better understand the supply chain logistics associated with the transport of medical devices and seek reasonable alternatives to avoid unnecessary and overly burdensome regulatory requirements on these devices; and

e) Work through the UN TDG Sub-Committee to explore the feasibility of unique UN numbers and requirements for medical device batteries.

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