Joint Medical Technology Industry Contribution

Concerning the Draft Technical Guidelines

on Transboundary Movements of E-Waste *(Version: 22 December 2012)*

On February 28, 2013, DITTA submitted to the Secretariat a detailed explanation of the medical technology industry joint position concerning the draft Technical Guidelines on e-waste shipments dated 22 December 2012. DITTA continues to support this joint position, which strives for a clear framework allowing the continued international trade of used medical devices and parts for repair and refurbishment to maintain an adequate supply of affordable refurbished devices and repaired parts. Repaired parts from service and reuse operations are critical in keeping older equipment functional.

In addition, DITTA would like to propose a new approach that could be successfully adopted to find a good compromise between protecting legitimate activities and stopping illegal waste dumping. Due to the large variety in equipment, practices and business models, DITTA believes that developing exemptions which would work for all sectors is extremely difficult, as shown by the discussions during the past 2 years. DITTA believes that specific exemptions should be developed for each sector whose legitimate repair and refurbishment activities could be hindered by the additional requirements on shipment. Each exemption and relevant criteria/definitions should be proportionate to the risk involved by the specific re-use activity.

Therefore, DITTA shares in this document results of a survey on global shipments of used medical devices and proposes a wording for a new exemption specific to used medical devices and parts, which are sent by and to the manufacturer, or third parties acting on its behalf, for repair, refurbishment or root cause analysis. DITTA considers the proposed exemption for medical devices to be judicious, loopholes free, and supported by the results of the survey.

1. DITTA Survey on global shipments of used medical devices

The intent of the survey was to gain fact-based data and show transparency to the majority of the global legitimate movement of used devices and parts for repair, refurbishment and root cause analysis. The survey provided the following results:

- Approximately 15814 metric tons of used parts and devices are shipped globally for repair or refurbishment every year by and to the leading medical device manufacturers or third parties acting on their behalf.
- 672 metric tons of used parts and devices are shipped globally for root cause analysis every year by and to the leading medical device manufacturers or third parties acting on their behalf as required under current regulations and industry standards.
- Total shipments of used parts and devices are valued at more than 3,4 billion USD providing an inventory of refurbished medical devices and repaired parts for servicing and maintaining installed equipment.
- 90,8% of total used products and parts are shipped to OECD countries for repair, refurbishment and root cause analysis where 100% of waste from these activities

are locally managed according to local environmental management standards.

- Only 9,2% of total used products and parts are shipped to non-OECD countries for repair, refurbishment, and root cause activities, mainly China, India, and Malaysia.
- For shipments to non-OECD countries, 100% is shipped to APAC countries, 84 metric tons of waste is generated from repair, refurbishment and root cause analysis activities per year, 99,9% of the waste generated from these activities are managed in country, and 100% of the facilities have environmental certifications to standards or local regulations.
- 71,5% of shipments to non-OECD countries for repair or refurbishment includes financial assurance from the shipper that the shipment can be returned to the company when necessary.
- 5,2% of shipments can be tested for functionality per industry protocol prior to shipment.
- 100% of total used devices and parts are packaged separately, 100% are protected against damage during transport, 93,4% include an invoice with a description of the contents, 100% of shipments are insured, and 63,3% include a copy of contract relating to the sales and/or transfer of ownership.

In summary, used medical devices and parts are not a significant contributor towards the total quantity of used electronics shipped globally. The majority of used medical devices and parts are repaired, refurbished or undergo root cause analysis in OECD countries. These shipments have a high monetary value and provide manufacturers with the necessary inventory of high quality and affordable refurbished equipment and repaired service parts to maintain and extend the lifetime of existing installed equipment. Testing for functionality is not a common practice per industry protocol prior to shipment. Currently, all repairs, refurbishment, and root cause analysis activities in non-OECD countries occurs in APAC. Manufacturers take care in packaging and shipping used devices and parts, providing financial assurance for used parts and products shipped to non-OECD countries for repair or refurbishment and traceability in accompanying shipping papers.

Reuse of used medical devices and parts improves resource efficiency, enables circular economy, keeps system and service costs down, extends product lifetime, and reduces the quantity of e-waste generated, reducing the cost of healthcare and avoiding adverse environmental, social, and health impacts. Circular economy and resource efficiency must be encouraged and not blocked as critical resources are being exhausted.

2. Proposed Exemption for Used Medical Devices and Parts in the Basel E-waste Technical Guidelines

Hereafter is a proposed alternative wording for clause 26 (b):

26 (b) Unless stipulated otherwise by the provisions of national law of one of the Countries Concerned (import, export or transit), the following used equipment should not be considered waste where the criteria in paragraph 24 (c) and (d) are met and it is documented that:

i. Used medical device [1]and their components sent by and to the manufacturer or third party acting on behalf of the manufacturer, for any of the following purposes:

- *root cause analysis,*
- *refurbishment, or*
- *repair*

under a valid agreement [2](such as a purchase order, contract or warranty); and

ii. Hazardous [3]wastes resulting from the operations in 26(b)(i) are shipped for environmentally sound management to Annex VII Countries or to non-Annex VII countries as long as systems are in place to achieve the equivalent level of environmental protection.

DITTA

DITTA is the global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers to better communicate, coordinate and collaborate on matters of common interest between participating associations and member companies. DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders.

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1 ***Definition of Medical Device in GHTF in SG1(PD)/N71R04. Click here to go to the document.***

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices,*
- *providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;*

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Note 1: *Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, include:*

- *disinfection substances,*
- *aids for persons with disabilities,*
- *accessories to a medical device (see Note 2),*
- *components of a medical device,*
- *devices incorporating animal and/or human tissues.*

Note 2: *Some jurisdictions include accessories to a medical device within the definition of a medical device. Other jurisdictions do not adopt this approach but still subject an accessory to the regulatory controls (e.g. classification, conformity assessment, quality management system requirements etc.) that apply to medical devices.*

2 ***Proposed definition to be added in the definition section for 'valid agreement':*** *a long term contract between the manufacturer and the third party shipping or performing the refurbishment, repair or root cause analysis identifying responsibilities and procedures for the correct handling of used EEE.*

3 *As per definition under Basel Convention*