# JOINT COCIR and EDMA CONTRIBUTION TO WEEE II DIRECTIVE ANNEX VI FOR THE EC GUIDANCE DOCUMENT (FAQs)

COCIR, the European Coordination Committee of Radiological, Electromedical and Healthcare IT Industry and EDMA, the European Diagnostic Manufacturers Association, are pleased to submit their position on the interpretation of Annex VI of the WEEE II Directive 2012/19/EU. We would like to draw your attention to elements which, when interpreted, risk to impact the medical technology sector and as a consequence the healthcare infrastructure in the EU and globally.

## SHIPMENT REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

WEEE II Directive Annex VI lays down minimum requirements for the shipment of used EEE. In this Annex, the repair, refurbishment and root cause analyses derogations were introduced in the context of business to business transfer agreements. However, the derogation for used EEE for refurbishment and repair in section 2(b) was linked to shipments to OECD countries only.

COCIR and EDMA wish to comment on paragraph 2(b) as the formulation of this exclusion is currently not clear and open to interpretation, in particular with regards to the applicability of the restriction to countries where Decision C(2001)107/Final of the OECD Council applies:

WEEE II, Annex VI.2.b)

*(b) the used EEE for professional use is sent to the producer or a third party acting on his behalf or a third-party facility in countries to which Decision C(2001)107/Final of the OECD Council concerning the revision of Decision C(92)39/Final on control of transboundary movements of wastes destined for recovery operations applies, for refurbishment or repair under a valid contract with the intention of re-use; or*

The OECD Limitation can be interpreted as applying to shipments:

1. To the manufacturer, to a third party acting on his behalf and to a third party facility;
2. To a third party facility.

**COCIR and EDMA support the second interpretation: Geographical limitation applies to shipments directed to third-parties only, which are not acting on behalf of the original manufacturer. Producers should have the ability to ship EEE for repair, refurbishment, remanufacturing to third countries outside the OECD either within their own company or to a third party acting on their behalf.**

This position is supported by the following considerations:

## 1. Commission Communication COM(2012)139 from 11 April 2012

In its communication "The Commission underlines that the minimum requirements for shipments should not hinder the legal trade of used equipment. Where there is a suspicion that the shipment is de facto an illegal shipment of waste, Annex VI gives Member States the legal instrument to clarify the situation." COCIR and EDMA support this statement in particular its balanced approach to ensuring intelligent implementation of the WEEE legislation which upholds legal trade while deterring illegal shipments of waste.

## 2. Allow legitimate activities

Intra-company shipments organized by medical devices manufacturers in the context of an established operation (business-to-business transfer agreement) for repair or refurbishment never involve illegal waste dumping. Used medical devices eligible for refurbishment are typically high technology products designed to have long life spans and are therefore valuable assets for the manufacturer as well as any healthcare system. The above holds equally true when the EEE is managed by the producer or when the refurbishment facility is managed by a third company which acts on behalf of the manufacturer for the logistic and refurbishment/repair operations. In the first case, ownership of the device has not been transferred and in the second case, the contractual relationship ensures traceability and responsibility.

Waste dumping is an illegal practice run by criminal organizations offering low cost waste treatment solutions to holders of waste. Instead of proceeding with environmentally sound treatment and disposal, waste is shipped to developing countries for disposal (e.g. landfill). The original manufacturer of the equipment is never involved nor is there a contractual relationship between the producer and a third party acting on their behalf. By contrast, the lack of a direct relationship between the producer and a third party which is not contracted by the producer may leave scope for abuse of WEEE and illegal dumping in some cases.

COCIR and EDMA believe that implementation of Annex VI.2.b. should be risk appropriate and the OECD limitation should be linked to the third party facility where there is no direct demonstrable relationship to the producer. Furthermore, this would also enable enforcement activities by competent authorities to be focused where a risk of illegal shipment of waste is really entailed considered the already limited resources.

## 3. Consequences on medical devices availability and healthcare in EU

The typical life of a new MD/IVD equipment installed within a given hospital or laboratory is 5 to 7 years, at which time the hospital or laboratory will upgrade its system for a newer or different model. The equipment is designed and maintained to operate much longer; therefore, when it is de-installed, it is typically refurbished and resold. The use of refurbished devices can be the preferred option. It is a viable alternative for keeping costs under control in hospitals and clinical laboratories and providing reliable results for the safe management of patients in the healthcare system.

Used medical devices are sourced, refurbished and remanufactured worldwide. Companies employ a global network of specialized facilities to ensure equipment can be properly assessed, repaired and returned to the market for continued use. These existing operations (many of which are located in developing countries) reduce the generation of e-waste by extending the useful life of electrical and electronic equipment and also make important contributions to local and regional economies and health care infrastructure

The OECD requirement will not only divert resources from control activities but will also limit refurbishing and remanufacturing facilities to OECD countries. Furthermore, when strictly applied, this requirement would limit intra-company movement of used EEE consignments from moving through or being consolidated in non-OECD countries, severely crippling intra-company logistics operations.

As result, putting at risk availability and affordability of equipment to healthcare providers will reduce healthcare access to patients in Europe.

## 4. Healthcare without borders

The ability to send devices either to the manufacturer's facilities or to outsourced facilities in third countries can make an important difference in the cost for repair/refurbishment and to the price hospitals and laboratories pay for such refurbished devices in both developed and developing markets.

Where the devices are being repaired/refurbished to adapt them to the local market conditions and technical specifications outside of the OECD, it will be necessary to ship them to facilities with specialized local knowledge. Preventing this possibility would not only adversely affect cost and therefore affordability of refurbished medical devices but also the ability to adapt technology to the needs of hospitals and laboratories in non-OECD countries.

As result, availability and affordability of equipment to healthcare providers will reduce healthcare access to patients in non-OECD countries.

## COCIR AND EDMA RECOMMENDATION

For the above mentioned reasons COCIR and EDMA consider that the only reasonable way to interpret annex VI, 2(.b) exclusion is to apply the OECD shipment limitation to shipments for 'a third party facility' only, as this category would not necessarily be acting under the behalf of the producer. Any other interpretation will unnecessarily extend requirements and controls to legitimate activities where there is a low risk of entailing illegal waste dumping and would negatively impact such activities which are well established practices providing environmental and social benefits to the global healthcare sector.

COCIR and EDMA submit this recommendation for the consideration of the European Commission and ask that it be included in the WEEE FAQ Guidance document which is going to be released early in 2013 to ensure harmonized implementation.

**COCIR**
*COCIR, the European leading industry voice in medical imaging and health ICTs, is a non-profit organisation founded in 1959.* In 2007, COCIR opened an office in Beijing, the COCIR China Desk, to support its members present on the Chinese market. COCIR members, companies and national trade associations, *play a driving role in defining a sustainable future for healthcare in Europe and worldwide.*

**EDMA**
*Committed to raising awareness of the important role of diagnostics in the entire healthcare equation, the European Diagnostic Manufacturers Association (EDMA) provides services and activities to members engaged in the research, development, manufacturing or distribution of in vitro diagnostic (IVD) products in Europe. Founded in 1979, EDMA advocates for an appropriate regulatory system and a realistic economic environment for healthcare in Europe.*