European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR CONTRIBUTION
To the Recast of the WEEE Directive

COCIR represents the Radiological, Electromedical and Healthcare IT Industry in Europe.

COCIR fully supports the objectives of the WEEE Directive. Since more than 10 years our industry actively contributes via dedicated take back and refurbishment programs.

The European Council is currently discussing the revision of the WEEE Directive (proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment, 5434/11, 18th January 2011). The European Parliament already adopted its first reading position on 3rd February at its plenary meeting.

While COCIR appreciates European Council and Parliament having addressed other important issues e.g. the producer definition at Member State level, there are still elements of significant importance missing. To further improve a final Recast text, COCIR recommends:

1. **To maintain the existing Annex IA[1] with its 10 categories, including a specific category for medical devices.**
   Medical devices cannot be merged with products from other industry sectors due to their specificity. A non-ambiguous scope with a separate category for medical devices is needed, otherwise the practical implementation of the WEEE Directive could be severely compromised.
2. **To maintain the responsibility of collection at Member States level according to EP first reading position.**
   Collection of WEEE is a process mostly under the control of Member States on which industry has very limited influence. COCIR supports the wording of the European Parliament that allocates correctly the responsibility of collection to Member States and not to producers.
3. **To conduct an impact assessment to set ambitious but accurate target levels.**
   Recovery, re-use and recycling targets need to undergo a proper impact assessment in order to determine realistic goals. Not doing so compromises the implementation of the WEEE Directive.
4. **To amend Annex IC[2] requirements to facilitate the rightful cross-border shipment of used medical devices.**
   While the monitoring of shipments of used EEE suspected to be WEEE is fully supported, Annex IC does not permit medical devices manufacturers a successful back-up claim for all of the rightful shipments of used EEE. Especially non-functional devices shipped outside the EU for legitimate reasons such as repair or refurbishment or reprocessing or analysis purpose are at risk of being wrongly declared 'WEEE' by the authorities.
   Thus, Annex IC should acknowledge the circumstances that can apply to the rightful shipment of non-functioning medical devices.

[1] *Categories of electrical and electronic equipment covered by WEEE Directive*
[2] *Minimum requirements for shipment of used EEE suspected to be WEEE*

DETAILED BRIEFING

1. **COCIR recommends maintaining the existing Annex IA with its 10 categories, including a specific category for medical devices.**

   The WEEE Directive clearly set out for the European Commission to propose, for the existing categories, new mandatory WEEE collection, recovery, re-use and recycling targets. In particular the re-use of whole appliances for products falling under category 8 (medical devices) of Annex IA should be assessed.
   The Council proposal defines 5 new categories which do not follow the original objectives of the Recast as mentioned above. In addition, the newly proposed categories are not consistent and unclear. This leads to grey areas and legal uncertainty.

   Maintaining medical devices in one specific category will allow regulators to define solid and realistic recovery, recycling and re-use targets according to the specificity of the medical equipment sector (long life cycle, high technological content and high residual value even at the end of life).

2. **COCIR recommends maintaining the responsibility of collection on Member States according to EP position.**

   The collection of WEEE whether from private households or business-to-business is a complex process, involving many actors such as consumers, professional end users, municipalities, waste collectors, collective schemes, etc. Producers placing products on the market have limited influence on this process. However, COCIR members are already actively taking back used EEE.

   COCIR welcomes the wording proposed by the European Parliament that maintains the responsibility for reaching the collection target on Member States and not on producers.

3. **COCIR recommends conducting an impact assessment to set ambitious but accurate target levels.**

   The WEEE Directive requires producers to collect WEEE other than private households. Currently proposed targets for recovery, re-use and recycling are not based on reliable, evidence based estimations. It further does not fully reflect the long life cycle of medical devices of 6-10 years (or longer), nor the high technological content of medical devices and therefore high residual value even at the end of its life.

   Taking this into account, the following conclusions can be drawn:

   1. A large percentage of products coming off the market are absorbed by manufacturers' activities of refurbishment, repair or reuse of parts. As an example for more than 10 years manufacturers have conducted

refurbishment[3] of "used EEE", which is an effective and well working system promoting recycling economy.

2. Due to the high residual value of medical devices and their longevity the equipment owner might not necessarily return the equipment to the producer.

Thus, COCIR believes an accurate impact assessment is needed to set ambitious target levels without compromising the WEEE Directive's underlying goals.

4. COCIR recommends to amend Annex IC requirements to facilitate the rightful cross-border shipment of medical devices

The European Commission proposal for a new Annex IC establishes criteria for monitoring of WEEE shipments in order to distinguish between legal shipments of used EEE and illegal WEEE shipments.

Annex IC requirements would essentially no longer allow the refurbishment market for professional medical devices altering the producer's possibility to perform such activities of refurbishing and re-use of systems, sub-systems, or parts. Currently, refurbished equipments help to provide quality healthcare[4] at affordable costs in Europe.

While COCIR supports the proper documentation and packing of rightful shipments, additional testing requirements and its costs are likely to exceed the residual value of the medical device, thus undermining the Directive's objective of recovery/re-use/recycling.

In practice, non-functional medical devices shipped outside of the EU for a variety of reasons, including devices that will no longer be covered by a warranty (Annex 1C, 1a.), run the risk of being declared WEEE by authorities. Reasons for such shipments can be:

- Return to the manufacturer or to a test house for investigation after an 'adverse event' in which a patient or user was harmed (Regulatory compliance or Quality assurance monitoring of devices as required by the Medical Device Directives).
- Return to the manufacturer for repair. It has been recognized under RoHS that medical devices can have a very long service life, to well in excess of ten years and therefore far exceed the warranty period. Highly specialized or intricate repairs may require that the device be returned to the manufacturer or a regional authorized repairer in another Member State, or based outside the EU.
- Return for refurbishment or reprocessing of systems, subsystems or parts under highly controlled conditions and processes. These are

[3] *COCIR (EU), JIRA (Japan) and MITA (USA) have issued a Good Refurbishment Practice Paper (see http://www.cocir.org/content.php?&level1=7&mode=14&id=46) and a related Good Refurbishment standard (see http://www.cocir.org/content.php?&level1=7&mode=14&id=38)*

[4] *An estimated 1, 6 billion Euros are spent on refurbished equipment globally, 50% of this is sold in the EU and the U.S. alone. (Source: COCIR internal data)*

necessary to ensure that the systems, subsystems or parts maintain their performance and safety when reused. Refurbishment is done by the original manufacturer of the medical device in specialised refurbishment centres of which globally only few exist.

In consequence these rightful shipments of non-functional medical devices would be declared illegal. Such equipment would never be able to meet the proposed Annex IC requirements which by default requires full functionality (Annex 1C, 1.a) and would probably be destined to be unnecessarily wasted with all the subsequent adverse environmental impacts.

Recommendation 1: delete "material" as the WEEE Directive applies only to products as suggested hereafter.

COCIR proposed amendment to Annex IC. c):
"c) a declaration made by the holder who arranges the transport of the electrical and electronic equipment that none of the ~~**material or**~~ equipment within the consignment is waste as defined by Article 3(1) of Directive 2008/xx/EC on waste, and"

Recommendation 2: Add an explicit exclusion for rightful shipments of professional medical devices as suggested hereafter.

COCIR proposed amendment to Annex IC:
Annex IC, 1b) new
"Paragraph 1 points a) and b) shall not apply to highly technological professional devices, including medical devices, theirs subsystems or parts of it, when they are sent for repair, refurbishment or reprocessing, to the producer or producer' group or their mandated companies with the intention of reuse.
For the purpose of meeting regulatory vigilance requirements (medical device reporting) under Directive 93/42/EEC or Directive 98/79/EC, paragraph 1 points a) and b) shall not apply to allow necessary shipments".