edma DIAGNOSTICS FOR HEALTH

Position Paper

BLOOD GLUCOSE MONITORS UNDER WEEE

2 April 2013

Introduction:

Blood glucose monitors (BGM) used in households are infected at end of life and therefore should not fall under the scope of Directive 2002/96/EC nor its recast Directive 2012/19/EU which regulate the waste of electrical and electronic equipment (WEEE).

Scientific evidence and 'real life' case studies exist which demonstrate that BGM may be infectious at end of life and the European Commission has confirmed that BGM infected with blood should be considered infected at end of life. Given that the WEEE directives clearly exempt infected IVDs from their scope, all Member States should hold the position that BGM be exempt from WEEE requirements.

However a few countries hold or have held the position that BGM should not be exempt from WEEE under their implementation policies. Their position was due to one or both of these reasons: firstly because of their interpretation of the exemption under Directive 2002/96/EC and secondly regulators did not consider BGM to be infected at end of life.

If some Member States hold the position that manufacturers must include BGM under their WEEE obligations, this leads to regulatory uncertainty and fragmented internal market requirements which will have a costly impact on the IVD sector. It implies a different treatment for only certain countries across the life cycle of the BGM product. Under the WEEE legislation, Manufacturers have the following obligations in those countries where a product is placed on the market:

- Ensure that products are correctly labelled with the adequate symbol and a mark showing that the product was placed on the market after 13 August 2005;
- Register products on the national registry of products (or appoint an authorised representative to do so). They will be asked to supply the quantity (by weight) of product placed on the market by product category;
- Join a compliance scheme to ensure that products are adequately taken care of at end-of-life;
- Report (by weight) EEE or WEEE separately collected, recycled, recovered, and disposed of and or shipped within or outside the EU.

This position paper provides an outline of the relevant differences between the old WEEE directive and its new recast version and summarises the legal and scientific case for BGM to be excluded from the scope of WEEE.

Place des Maïeurs, 2 | 1150 Brussels | Tel. +32 2 772 22 25 | Fax. +32 2 772 23 29 | edma@edma-ivd.eu | www.edma-ivd.eu

The WEEE exemption for 'infected' IVD medical devices

Directive 2002/96/EC and its recast Directive 2012/19/EU[1] regulate WEEE and set out provisions for producers and Member States for the prevention, collection, treatment, recycling and recovery of WEEE. They make producers responsible for financing most of these activities. The Directives apply to electrical and electronic equipment (EEE) falling under the categories and products set out in Annexes IA and IB, which include medical devices under Category 8.

Under Directive 2002/96/EC, "all implanted and infected products" falling under Category 8 are exempted from the scope of the Directive. The rationale for this exemption is that infected devices could pose a health hazard during the handling, collection and recycling of the devices as they may carry blood borne pathogens such as HIV, hepatitis B and hepatitis C. For example in 1992 there were two documented cases of HIV infection involving transmission through wounds among waste handlers in France.[2]

Recast WEEE Directive 2012/19/EU further clarifies the exemption for products which are infected at end of life. From 13 August 2012 to 14 August 2018 there will be a transitional period during which Directive 2012/19/EU applies (as under Directive 2002/96/EC), to EEE under Annex I which includes medical devices and IVDs but excludes 'infected and implantable devices'. Article 2.4(g) states that from 15 August 2018 the Directive shall not apply to "medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices." This updated definition considerably strengthens the provision to exempt infected devices from the scope of the WEEE legislative framework.

Under Directive 2002/96/EC "all implanted and infected medical devices" are exempted from scope. These conditions had been considered by some Member States, in particular Germany, to be cumulative with the result that BGM were not exempted from WEEE in those countries. Given the clarified wording under recast Directive 2012/19/EU which applies from 15 August 2018 however, it is clear that it is sufficient for devices to be infected at end of life in order to be exempt from the scope of WEEE, and that this interpretation should be applied to the wording of the exemption given under Directive 2002/96/EC.

In 2004, EDMA queried the status of BGM under WEEE in a letter to the European Commission. In a communication from their services, the Commission confirmed that BGM which are infected with blood are out of the scope of WEEE (see letter from the Commission in annex I).

Blood glucose monitors are infected at end of life

Neither Directive 2002/96/EC nor recast Directive 2012/19/EU in any way define what constitutes an infected medical device. The European Commission FAQ on WEEE Directive 2002/96/EC states, 'Infected products are understood to be products that have come into contact with blood or other biological contaminants prior to end-of-life.'

[1] The recast Directive 2012/19/EU was published in July 2012 and entered into force on 13 August 2012. Member States must transpose the Directive 2012/19/EU into national law by 14 February 2014 at the latest (Directive 2002/96/EC is repealed from 15 February 2014).

[2] Edited by A. Prüss, Eric Giroult, Philip Rushbrook; "Safe Management of Wastes from Health Care Activities", World Health Organisation 1999.

EDMA recommends the following definition to further clarify when a device should be considered infected:

"An infected medical device for the purposes of Directive 2002/96/EC and recast Directive 2012/19/EU is any device or part of a device which has come into contact with a potentially infectious substance, such as body fluids (blood, urine etc.), tissue samples or other biological contaminants prior to end of life and which cannot be adequately decontaminated by the manufacturer's recommended procedure to the end user or in the absence of such by surface decontamination methods."

BGM use electrochemical or photochemical technology, depending on the type of meter. These devices are used both by individual patients for self-testing as well as by medical staff in healthcare environments. In order to perform a blood glucose test, the patient typically uses a finger pricking device and applies a sample of blood to a test strip, which is then inserted into the meter. Not only the finger pricking device but also the blood glucose monitor itself can become contaminated with blood as the substance may transfer to the outside surface of the device.

A multi-hospital survey by the School of Medicine, University of California,[3] demonstrates that in 21% of the meters tested, blood was found on the outside surface. Outbreaks of hepatitis C and hepatitis B have been found in France and the US respectively, where infection from these blood borne pathogens occurred from contact with a BGM previously used by another person.[4] [5] Contact with the BGM device itself was implicated as re-useable finger pricking devices were not used.

Once used, blood glucose meters should be considered to be infected with human blood at end of life according to the above definitions of an 'infected medical device' and the relevant scientific evidence noted in this paper.

Conclusion

Given the European Commission's interpretation, the scientific evidence that BGM should be considered infected at end of life and the wording under Directive 2002/96/EC and recast Directive 2012/19/EU which clearly exempts infected medical devices and IVD medical devices from scope, BGM should be exempted from the scope of WEEE. For reasons of public health and safety, it makes sense to exclude BGM from collection schemes to protect handlers of WEEE from coming into contact with potentially infectious blood borne pathogens. If only some Member States decide to include BGM in their national implementation policies for WEEE, making provision for the different treatment of BGM across its life cycle in those Member States will be a costly burden on Manufacturers operating across the internal market.

[3] Louie RF, Lau MJ, Tran NK, Tang Z, Lee JH & Kost GJ (2003); "National survey on biohazard control for point-of-care testing." Point of Care: The Journal of Near-Patient Testing & Technology. 2003. 2 (2):101–105.

[4] L'Agence française de sécurité sanitaire des produits de santé (AFSSAPS) : Retrovigilance 23 May 2002.

[5] Thompson ND & Perz JF (2009); "Eliminating the blood: ongoing outbreaks of hepatitis B virus infection and the need for innovative glucose monitoring technologies." Journal of Diabetes Science and Technology. 2009. 3(2): 283-288.

About EDMA

EDMA, European Diagnostic Manufacturers Association, advocates for the interests of the in vitro diagnostics (IVD) industry and its enormous contribution to transforming healthcare systems by improving healthcare efficiency and reducing costs. EDMA's strength lies in its close co-operation with European institutions, patients groups, trade associations, health professionals, and academia, working together to shape EU policy that will most impact the lives of Europeans and reinforce the European IVD industry's voice globally. From small businesses to major corporations, the European in vitro diagnostic industry is a market worth over 10.5 billion euro. Driven by research and development, 95% of the industry is comprised of small and medium size enterprises and approximately 1 billion euros per year is reinvested in R&D.

For more information, visit www.edma-ivd.eu.

References:

Directive 2002/96/EC on Waste Electrical and Electronic Equipment

Directive 2012/19/EU (recast) on Waste Electrical and Electronic Equipment

European Commission Frequently Asked Questions on Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE). Last updated August 2006.

Louie RF, Lau MJ, Tran NK, Tang Z, Lee JH, and Kost GJ. (2003); "National survey on biohazard control for point-of-care testing." Point of Care: The Journal of Near-Patient Testing & Technology. 2003. 2 (2):101–105.

L'Agence française de sécurité sanitaire des produits de santé (AFSSAPS) : Retrovigilance 23 May 2002.

Thompson ND & Perz JF (2009); "Eliminating the blood: ongoing outbreaks of hepatitis B virus infection and the need for innovative glucose monitoring technologies." Journal of Diabetes Science and Technology. 2009. 3(2): 283-288.

Edited by A. Prüss, Eric Giroult, Philip Rushbrook; "Safe Management of Wastes from Health Care Activities", World Health Organisation 1999.

Annex I – Letter from the Directorate-General for Environment, European Commission, 1994.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
ENV.G - Sustainable Development & Integration
ENV.G.4 - Sustainable Production & Consumption

Brussels, 14. 06. 2004
AP/cba D(2004)741211

Ms Karen Howes
Director Regulatory Affairs
EDMA
Place St-Lambert 14
B-1200 Brussels

Dear Ms Howes,

Thank you for your letter of 28 May 2004 on Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

First of all I would like to point out that the following remarks only reflect the opinion of my unit and that a binding interpretation of Community law can only be given by the European Court of Justice.

Article 3(a) of the Directive defines electrical and electronic equipment ("EEE") as "equipment which is dependent on electric currents or electro-magnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields falling under the categories set out in Annex IA and designed for use with a voltage rating not exceeding 1000 Volt for alternating current and 1500 Volt for direct current." With the exception of all implanted and infected products, medical devices are covered under category 8 of Annex IA. Therefore, used Blood Glucose Meters as described in your letter being infected with human blood are not covered by the Directive.

It should be noted that medical devices are, for the time being, excluded from recovery, reuse and recycling targets. According to Article 7(4) of the Directive, by December 2008 the Commission is supposed to propose to European Parliament and Council targets for such items.

Yours sincerely.

M. Klingbeil

Marianne KLINGBEIL
Head of Unit

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11
Office: BU-5 5-167. Telephone: direct line (32-2) 2960493. Fax: (32-2) 2963980.
P:\53.06 WEEE-ROHS\OF 7.5 Letters and Access to docs\2004\040604 MK-EDMA.doc