Swedish Environmental Management Council
Vasagatan 15-17
11120 Stockholm
SWEDEN

To the attention of Eva Dalenstam

Brussels, 16 January 2013

Subject: COCIR contribution to the public consultation on draft GPP criteria for medical devices

Dear Mrs. Dalenstam,

COCIR values the opportunity to comment on the draft paper submitted by SEMCO for public consultation, for the development of GPP Criteria for medical devices.

COCIR shares the recognition with the European Commission and EU Institutions that GPP is a powerful tool in the context of Integrated Product Policies to boost the environmental performances of products rewarding environmentally conscious companies which invested in ecodesign programs.

On the other hand, any instrument able to directly influence competition should be carefully evaluated to ensure no barriers to trade are introduced or market distortions are caused. Moreover, in the spirit of GPP, it has to be ensured that only environmentally conscious companies and environmentally performing products are given the boost in public tenders. In particular this is important for some sectors, such as medical devices, that is highly competitive and with a limited number of players.

While many of the proposed criteria are supported by COCIR, we believe others are going to adversely affect competition and, most importantly, they are going to fail their environmental objective and would end favoring non-environmental conscious companies. Such criteria are not supported by Industry.

Although elements of the criteria are currently in use by purchasers in the medical sector, COCIR believes should not be endorsed by the EU Commission.

Please find below specific comments from COCIR on the different sections of the draft criteria document.

1. User instructions for green performance management (General criteria for all equipment)

This criterion is supported by COCIR. User behaviour can greatly affects environmental performance such as energy consumption.

2. Content of substances on the Candidate List (General criteria for all equipment)

This criterion is a constraint to competition therefore cannot be supported in its present form for the following reasons:

Favoring less environmental friendly players, distorting market

The REACH Candidate List continues to increase and according to the EC and ECHA will potentially comprise of 1500 substances by the end of 2020. The efforts to collect such information from the supply chain are huge. The process of data acquisition and management across the supply chain is vast and represents a significant burden on industry. That is why the REACH regulation sets an obligation to communicate to customers the presence of known SVHCs.

The reality is that environmentally conscious manufacturers continue to invest money and resources to collect such information and they are therefore able to provide accurate (as far as possible) declarations about the candidate SVHC content. Less environmentally conscious companies have not collected such information.

The consequence of this criterion would be to favor less-conscious companies as they will declare fewer substances than their competitors. The effect would not be to provide an incentive to reduce the SVHC content, rather a systematic disadvantage for green companies. This is even more evident if we consider that enforcement or control by the purchaser is not possible at all.

Safety of medical devices already deeply regulated

The use of chemicals affecting health and safety is already deeply regulated by existing legislation. Medical devices are included in the scope of the REACH regulation and the RoHS Directive which require the evaluation, registration, authorization for use and future restriction of targeted chemicals of concern.

CMR substances and phthalates are already regulated by the Medical Device Directive which prescribes that medical devices have to be designed to reduce risks to a minimum. Phthalates are also controlled and labeling obligations are in place. The review of the Medical Devices Directive will also include Nano-materials and endocrine disruptors. Nano-materials are already included in the REACH scope today.

Extreme care should also be applied when establishing criteria on the content of flame retardants. Fire resistance requirements for medical devices are extremely strict

considering the risks involved with ensuring patient safety or for healthcare structures and are already included in the REACH regulation.

Medical devices use such chemicals due to careful consideration of risks to patients and where required by regulations, and in considerably less volume than many high-volume consumer products such as mobile phones, computing equipment and building supplies. Furthermore, the medical device industry is not a sufficiently large user of such chemicals to drive innovation towards more environmentally preferable ingredients without raising costs of health care and potentially reducing reliability.

COCIR believes additional criterion on chemical substances in products would be redundant and burdensome and consumes valuable resources that could be applied for innovation. It will fail the objective of driving an improvement of products and risk to undermine the GPP concept itself by providing incentives to less conscious companies.

Alternative proposal

A feasible alternative could be a more generic request on the existence of Company programs/initiatives/tools to evaluate and reduce the content of SVHC/hazardous chemicals. Considered the already regulated environment for the use of chemicals, the existence of such programs is enough to ensure the use of hazardous chemicals has been reduced as much as possible without affecting safety, reliability and performances.

3. Energy performance of health care EEE

As COCIR stated already, measuring the energy consumption of products is not an easy task if such energy measurements are intended to be used to compare products. The development of a solid measurement standard could take years. COCIR experience shows that not less than a year is required (SRI Initiative). Definition of a methodology has to be complemented by field measurements to prove hypothesis and assumptions and to learn from experience.

Any simplified methodology will provide unrealistic results not depending on real equipment performances but just determined by the use scenario and the chosen assumptions. The choice of use parameters by each company will also greatly affect the final result. Just for example: it is not possible to indicate an "average" or "typical" scan power consumption for MRI as the power depends on the specific examination (head, spine etc) and many other parameters and settings. The power is also extremely variable during scan (pulse sequences) therefore how to measure and report such power would need to be defined clearly and unambiguously. For MRI and CT the formulas provided by the draft paper cannot work. The COCIR methodology for SRI provides for the correct measurement of scan energy.

Distorting competition

If the simplified methodology currently proposed is required for GPP, the result will be poorly comparable data. This will distort competition by erratically awarding purchase points. Further, public purchasers will not be able to identify the tangible energy improvements desired.

For the above mentioned reasons COCIR cannot support energy performance requirements for medical imaging equipment unless fully covered by solid measurement methodologies such as recognized standards developed by standardization bodies or industry organizations.

Alternative proposal

Energy performance data based on simplified methodology could be requested by the tender but it should be clear that no points can be allocated. The purpose of such data should be informative.

For CT and MRI COCIR already developed a solid methodology that, if used, will provide comparable results and therefore point allocation can be used. The use scenario is already set in the COCIR methodology. Methodology for x-ray will be finalized by the end of 2013.

COCIR is open to discuss how to amend (if feasible) the MRI and CT methodology so that the purchaser can specify the use scenario in the tender and Companies can adapt the results to such scenario.

4. Verification

COCIR cannot support the requirement to provide third party certified type III declarations for energy data, provided by test lab certified according to ISO 17025.
This requirement is not proportionate considering that imaging devices (CT, MRI etc.) are not household equipment which could be sent for testing to a testing laboratory. We would also like to note that due to the lack of a measurement standard testing lab cannot release any third party certification of the performed measurement.

Alternative proposal

Verification of the data provided by companies (self-certification) can be performed by the purchaser on the basis of the test report documentation. Third party certification of provided data, where possible, can be reworded with additional points but cannot be intended as a mandatory requirement.

5. Automatic low power mode for imaging equipment

COCIR cannot support this criterion as long as an unambiguous definition of low power mode is provided for each equipment in the scope.

As COCIR experience shows, for such complex equipment it is already difficult to define operator selectable power modes but it is even more challenging to define automatic power modes due to the complexity and high number of modules involved.

For most medical imaging Equipment automatic low-power/sleep modes are not even possible/advisable as the equipment has to be ready for emergency examination.

Alternative proposal

Documentation provided with the equipment has to clearly indicate how the equipment can be switched to an off/lower power mode, how long it takes for switching back to normal mode and how to best use low power modes to save energy.

7. Social responsible production (General criteria for all equipment)

COCIR supports this criterion

8. Material conscious design

COCIR supports this criterion

9. Equipment part of refurbishment system (General criteria for all equipment)

COCIR supports this criterion

12. Content of beryllium substances in X-ray and computed tomography equipment

COCIR supports this criterion

13. Environmental conscious design for leasing or service contract (General criteria for all equipment)

COCIR supports this criterion