Environmental and Health Public Interest Organisations and NGOs[i], first submission to the Commission review of the availability of safer alternatives to Measuring Devices containing mercury

Brussels, 23 September 2008

Introduction

In September 2007, directive 2007/51/EC relating to restrictions on the marketing of certain measuring devices containing mercury, was adopted. The directive establishes a ban on the use of mercury in new fever thermometers intended for sale to the public and professionals; and in other measuring devices intended for sale to the general public. Furthermore, the Commission must carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury-containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. On the basis of the review and if appropriate, the Commission will present a legislative proposal to extend the restrictions mentioned above to these devices.

The NGOs welcomed this initiative, although our position has been and remains that blood pressure devices for professional use which contain mercury should be banned, because safe, precise and reliable alternatives are available, and economically affordable when the entire costs related to mercury use are taken into account. We have provided such information to the EU institutions during the debate:

- Zero Mercury: Key issues and policy recommendations for the EU Strategy, Dec. 2005 http://www.zeromercury.org/Zero_Mercury_Policy_Paper_EN.pdf
- Report from the Conference EU Mercury Surplus management and Mercury use restrictions in measuring and control equipment , June 2006 http://www.zeromercury.org/EU_developments/0606_EEB_Mercury_Conference_ReportFINAL.pdf Website of conference with presentations etc : http://www.zeromercury.org/EU_developments/060619-BXL-conference.html
- Environment and Health NGOs' comments on the Working document for a directive relating to restrictions on the marketing of certain measuring devices containing mercury. Brussels 3/6/2005 http://www.zeromercury.org/position_papers/050603_NGOs_comments_WD_measuring_equipment_directive.pdf
- Briefing: Limitations on Marketing & Use of Mercury-Containing Measurement and Control Equipment, Prague & Brussels, 5 September 2006 http://www.zeromercury.org/EU_developments/060905NGOs_key_demands_MeasControl_Equip_dirFINAL.pdf
- Environmental and Health NGOs' Call for a Strong Directive – Balancing Content and Timetable – on Measurement & Control Equipment Containing Mercury, 7 May 2007 http://www.zeromercury.org/EU_developments/070507NGOscommentsMeasDevicesENVIonCCP.pdf
- Health Care Without Harm Factsheet, October 2006: Substituting Mercury Sphygmomanometers http://www.noharm.org/details.cfm?ID=1409&type=document

These devices can pose a risk to human health and the environment during usage because their leaks are often undetected, they can break or spill and release significant amounts of mercury, and after usage because they end up in the waste stream often without a method of final disposal that ensures the mercury will not contaminate the environment and harm public health. These measuring devices found in healthcare facilities and schools are of particular concern because of the potential exposure to young children. There is increasing evidence that indoor inhalation can be

a source of significant mercury exposure[1]. The leaks, breakages and spills often result in substantial cleanup expenditures and disruptions, such as temporary school closures. In addition, mercury-containing devices are often improperly disposed of at end of life, resulting in mercury emissions from garbage and medical waste incinerators and landfills.

- Mercury-free sphygmomanometers do not cause problems in clinical diagnosis and monitoring of difficult cases, including arrhythmias, pre-eclampsia and accelerated hypertension[2]. In Sweden, Denmark, Austria and the Netherlands, positive experiences from the use of mercury-free devices have been reported. There are many mercury-free sphygmomanometers on the European market from major medical equipment suppliers, (9 brands identified to date)[3]. Many of them satisfy the criteria of professional organisations such as the British Hypertension Society, the European Hypertension Society, and the Association for the Advancement of Medical Instrumentation.
- Sphygmomanometers are used widely in hospitals, in private medical practices, etc. Of all mercury instrumentation used in health care, sphygmomanometers represent one of the largest mass of mercury per device (approximately 100 g/unit), posing a commensurate risk.
- Their widespread use collectively makes them one of the largest mercury reservoirs in the health care setting, and therefore a significant danger.
- Mercury-free sphygmomanometers can greatly reduce the risk of mercury exposure to patients, staff, and the environment. When properly calibrated, they are as accurate - if not more so - than the older mercury models.
- Mercury-free devices offer the most accurate results when serving as the reference for calibrating other sphygmomanometers. When a mercury sphygmomanometer is calibrated to another mercury device, the individual unit's variability of +/- 3 mm Hg is compounded to +/- 6 mm Hg, a level which is +/- 1 mm Hg beyond what is usually considered acceptable by medical associations. This variability can be greatly reduced by using mercury-free devices to calibrate mercury-free sphygmos (Appendix I)[4]. The (validated) digital mercury devices have a higher accuracy range and therefore the total compounded accuracy range for the calibrated device is improved.

Experiences in Europe

The feasibility of mandating mercury-free professional devices is proven by such countries as **Norway**[5], **Sweden**[6], **Denmark**, the **Netherlands** and **France**[7], which have national restrictions on mercury use in measuring devices. Additional restrictions exist in individual cities such as the Vienna Hospital Association and Styrian Hospital Association[8] in **Austria**, which do not use sphygmomanometers containing mercury.

Furthermore, in **Ireland** although there are no legislative restrictions imposed on the use of medical instruments containing mercury, 2004 guidelines from the Department of Health and Children for the segregation, packaging and storage for healthcare risk waste state that, "Due regard should be had to any recommendations in circulation for the elimination of mercury from use in clinical practice where there is a suitable alternative" [9]. Due to recommendations in purchasing policy and the availability of alternative non-mercury medical products, many hospital and health care settings in Ireland have now replaced mercury products and used mercury free alternatives. The Irish Heart Foundation, in a statement on blood pressure measurement, clearly outlines that mercury is toxic to

[1] A. Carpi and YF Chen. Gaseous Elemental Mercury as an Indoor Air Pollutant. Environ. Sci. Technology Vol 35:4170-4173 (2001).
[2] KEMI – Swedish Chemical Inspectorate (2005b) Mercury-free blood pressure measurement equipment – Experiences in the Swedish healthcare sector. Sundbyberg. November 2005, p. 4.
[3] http://www.env-health.org/IMG/pdf/Sphygmo.pdf
[4] See appended memo from WELCH ALLAN on the calibration of sphygmomanometers, 2002.
[5] http://europa.eu.int/comm/environment/chemicals/mercury/pdf/norway.pdf
[6] http://europa.eu.int/comm/environment/chemicals/mercury/pdf/sweden.pdf, http://www.zeromercury.org/EU_developments/Petra%20Hagstrom%20presentation%20Hg%20Madrid%20042205.pdf
[7] French response to Consultation document Development of an EU Mercury Strategy, Invitation to Comment, http://europa.eu.int/comm/environment/chemicals/mercury/pdf/france_en.pdf
[8] http://www.cleanmed.org/europe/2004/english/docs/press/press_vienna_declaration.pdf
[9] Segregation Packaging and Storage Guidelines for Healthcare Risk Waste. (3rd Edition) April 2004. Department of Health and Children: Dublin

the environment and mercury sphygmomanometers should be replaced by accurate alternative devices.[10]

Dublin City General Hospital (350 beds) has phased out the used of all mercury equipment in the hospital campus. The hospital environmental manager actively promotes the hospital as a mercury free hospital and found the main hindrance to maintaining a mercury free hospital are the stored, hidden and forgotten sphygmomanometers and thermometers which are usually discovered during renovation work.

In Dublin, the Mater Private Hospital (190 beds) has phased out the use of all mercury equipment in the hospital over the past 10 years, starting in 1995. In the last 5 years all sphygmomanometers were gradually replaced with aneroid sphygmomanometers so that at the present time there is no mercury equipment used in the hospital. A mercury spill kit and health and safety policy is still in place as a patient or practitioner may unintentionally bring into the hospital equipment with mercury. The overall phasing out of mercury equipment had been straightforward with the only obstacle, a single practitioner who initially refused to change his reliance on mercury sphygmomanometers. The Mater Private Hospital is now a mercury free environment.

In **France**, the Hospital of Chartres is a mercury-free hospital. They purchase their mercury-free sphygmomanometers from several companies - Welch Allyn, Vaquez Laubry, Sodis, Comeda, Medilis, Hospal, Philips, DLM Guichard, UGAP, General Electric, and obtain several different types and sizes: Velcro sphygmomanometers, wall sphygs, sphygs with wheels, wrist sphygs, manual and electronic ones. The certification used is Norme CE93/42 and NF1060. No problems were reported on calibration - the personnel follow the procedure indicated by the producer in the device's instructions. The reliability of the mercury-free devices was good also when used in special clinical situations such as pregnancy and hypertension. No negative experiences are reported by the hospital, but a few recommendations in the use of the mercury-free equipment exist to the effect that the patient should not move during use since there are some limitations of the technique.

In general the hospital reports that the average life of a small sphygmomanometer is between 6 months and a year, considering use by the healthcare services and potential breakage. For the other sphygmomanometers (wall, on wheels) the average life is 2 to 3 years and for the automatic ones even more. With respect to costs of waste disposal of mercury-free sphygmomanometers – these enter the ferrous metal waste and the cost is 0.0808 Euro per Kg without tax. The automatic ones go in the WEEE.

The private French clinic Tivoli, which has 96 beds for surgery (14 for cancer related medicine, 6 places for emergency surgery and 16 posts for chemotherapy), is also mercury free and uses electronic sphygmomanometers in all departments. No problems have been noted concerning calibration which is done by the biomedical service of the clinic.

Other countries where mercury free sphygmomanometers are being used both in hospitals and in private clinical practice across all different medical specializations include **Italy**, **Poland** and the **Czech Republic**. Many mercury free sphygmomanometers are being sold via the Telemedicine market on the internet. One of the large international manufacturers, A&D, is currently supplying nearly half a million units of mercury-free sphygmomanometers in Europe per year. Initial sales of A&D's newest mercury-free sphygmomanometer, the UM-101 which does auscultatory measurement, has seen initial sales in the Primary Care sector who are perhaps more familiar with alternatives to the dangers of mercury and the mechanical issues of aneroid sphygmomanometers. A&D is also currently conducting several large trials of the Telemedicine market in **Germany** and the **UK**[11].

Mercury free hospitals around the world

The growing transition to mercury-free health care around the world has been attested to in the 2007 report "The Global Movement for Mercury-Free Health Care", " by Health Care Without Harm. (Appendix II). This transition includes not only the resource rich countries of the OECD, but also countries in developing regions.

[10] http://www.irishheart.ie 2007
[11] Personal communication with A&D European Medical Business Manager, April 2008.

In a recent **UNEP** 2008 report on *'The major mercury-containing products and processes, their substitutes and experience in switching to mercury-free products and processes'*[12], based upon the responses provided, it was shown that sphygmomanometers have alternative technologies available, and successful transitions to these non-mercury alternatives have been demonstrated. Sixty-nine percent of the respondents indicated that these alternatives are available in the market and commonly used without any negative experiences. Three countries reported zero demand for mercury containing sphygmomanometers.[13]

The same report addresses the accuracy of the mercury free devices, noting the example of the Mayo Clinic in the United States, which in order to assess the level of accuracy of aneroid sphygmomanometers, conducted an assessment of 283 aneroid sphygmomanometers. The Mayo study found that virtually 100% of the values from the aneroid sphygmomanometers were within the 4 millimeters of mercury range recommended by the Association for the Advancement of Medical Instrumentation. The study concluded that aneroid sphygmomanometers provide accurate pressure measurements when a proper maintenance protocol is followed (Canzanello, 2001).[14]

Examples of mercury-free hospitals from around the world include:

Experiences from the **USA** have very recently been collected and are now presented in the new Health Care Without Harm report "The End of an Era: the phase-out of mercury-based Blood Pressure Measurement Devices in the USA and its implications for Europe and the rest of the world" (Appendix III). Hundreds of hospitals and hospital systems have successfully phased out mercury column sphygmomanometers and substitute them with viable, cost effective, accurate alternatives. They report little or no problem during or after the transition.

The Philippines. Recently, in August 2008, the Department of Health (DOH) in the Philippines[15] has ordered the gradual phase out of devices containing mercury in all health care facilities. In an administrative order, Health Secretary Francisco Duque III has given all hospitals, infirmaries, birthing homes and clinics two years to switch to alternative instruments.

New healthcare facilities applying for license to operate are required to submit an inventory of all mercury-containing devices that they will use and a corresponding mercury elimination program.

In **India**, many hospitals have already replaced mercury thermometers and shpygmomanometers with mercury-free ones, as can be seen below. Apart from these many hospitals under the city of Delhi government are also proposing to phase out of mercury thermometer and blood pressure instruments.

Name of the Hospital	Address	Mercury Thermos Phase out	Mercury Sphygs Phase Out	Contact Person
Max Super Speciality Hospital	New Delhi	yes	yes	Dr Garima Trivedi
Max Devki Devi Heart & Vascular Institute	New Delhi	yes	yes	Dr Garima Trivedi
Escorts Heart Institute & Research Centre	New Delhi	yes	yes	Dr. Anita Arora
Chacha Nehru Bal Chikitsalya	New Delhi	Yes	Yes (Aneroid)	
Sanjay Gandi Hospital, Government of Delhi	New Delhi	Yes	Yes	Dr. Kishore

[12] http://www.chem.unep.ch/mercury/OEWG2/documents/g7)/English/OEWG_%202_7.pdf
[13] Idem page 6
[14] Idem, page18
[15] http://www.abs-cbnnews.com/storypage.aspx?StoryId=128956

At the Max Healthcare , (Dr. Arti Verma, Dr. Garima Trivedi) the following experiences were documented:

When Max Saket was under construction, Toxics Link (Indian environmental NGO) was invited to develop a waste management plan for the hospital, so that hospital waste management became an integral part of the system. It was then suggested that mercury is a toxic that the hospital would have to deal with. The Director (Administration) was very proactive and immediately decided that the hospital would be mercury free. Max (Saket) started as a mercury free hospital and thus did not face any resistance from the staff. There was no accuracy debate in the hospital and everyone was comfortable with the system that was in place. At a Pan Max (Inter Max) meeting it was decided that all the other Max hospitals would also phase out Mercury equipment. It was very easy for the group of hospitals because there is centralised purchasing. All the mercury equipment was picked up from the hospital and replaced with non- mercury alternatives. The cost implications were not much (~10,000 INR (around 150 EUR) for thermometers and 210,000 INR (around 3000 EUR) for sphygmomanometers for 3 hospitals).

With respect to accuracy:

Himalayan Institute Hospital Trust (HIHT) experience – ***"****The mercury-free instruments we are now using are more sensitive than the Indian mercury BP instruments".*

Ganga Ram Hospital- "Many of our senior consultants have tested the aneroid blood pressure apparatus and their apprehensions are now fading. We plan to document their findings. Also CERC's (Ahmedabad) document on accuracy of mercury thermometers has again shown that most of them are not accurate".

In **South Africa,** the Health Department of the Province of Kwazulu Natal issued in 2003 a recommendation to Hospital Managers and Clinical Practitioners that new mercury column sphygmomanometers must no longer be purchased.

Ngwelezane hospital in north Kwa Zulu Natal, is a mercury free hospital. In Kwa Zulu Natal, mercury thermometers and blood pressure gauges have been replaced in all most all healthcare settings. Mercury use has declined to approximately 15%, reflective of most other KZN institutions which are also in the transition process to phase it out.

Further information concerning experiences in other countries outside Europe, both developed and developing, will be submitted in due course.

Closing Remarks

This is an initial submission from the public interest organisations and NGOs, and more information is being collected and will be submitted as it becomes available. We kindly ask the European Commission, while drafting the report and recommendations regarding a restriction of mercury-containing devices in healthcare, to consider the above evidence as well as the materials that will be submitted in the future.

The World Health Organisation has concluded that there is *no safe level of mercury exposure*. We need to address all sources in order to safeguard people's health.

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Appendices:

I. Memo from Welch Allyn, 2002, on the calibration of mercury sphygmomanometers
II. The Global Movement for Mercury-Free Health Care, Health Care Without Harm, 2007.
III. The End of an Era: The the phase-out of mercury-based Blood Pressure Measurement Devices in the USA and its implications for Europe and the rest of the world, Health Care Without Harm, 2008.

[i] Environmental and Health Public Interest Organisations and NGOS include:

The **European Environmental Bureau, (EEB)**, www.eeb.org, is a federation of more than 145 environmental citizens' organisations based in all EU Member States and most Accession Countries, as well as in a few neighbouring countries. These organisations range from local and national, to European and international. The aim of the EEB is to protect and improve the environment of Europe and to enable the citizens of Europe to play their part in achieving that goal.

The **Zero Mercury Working group**, www.zeromercury.org, is an international coalition of more than 69 public interest non-governmental organizations in 35 countries from around the world formed in 2005 by the European Environmental Bureau and the Mercury Policy Project/Ban Mercury Working Group. The aim of the group is to reach 'Zero' emissions, demand and supply of mercury, from all sources we can control, towards eliminating mercury in the environment at EU level and globally."

Health Care Without Harm Europe, www.noharm.org, belongs a global coalition of more than 450 groups in 55 countries. We are working together to transform the healthcare industry so that, without compromising patient safety or care, it is ecologically sustainable and no longer a source of harm to people and the environment.

Health and Environment Alliance, www.env-health.org, aims to raise awareness of how environmental protection improves health. It achieves this by creating opportunities for better representation of the perspectives of citizens and health experts in the environment and health-related European policy-making. Our membership includes a diverse network of more than 50 citizens', patients', women's, health professionals' and environmental organisations across Europe and has a strong track record in increasing public and expert engagement in both EU debates and the decision-making process.