NGOs Position Paper on the EC proposal for a Medical Device Regulation COM(212) 542

On 26th September 2012 the European Commission (EC) adopted a package of proposals on medical devices consisting of

- a communication on safe, effective and innovative medical devices and in-vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals COM(2012) 540 final,
- a proposal for a regulation on medical devices COM(2012) 542 final and
- a proposal for a regulation on in vitro diagnostic medical devices COM(2012) 541 final.

Health and environment NGOs call on the European institutions to adopt the precautionary and substitution principles by **phasing out, within specified deadlines, the use of hazardous chemicals in medical devices,** including chemicals that are carcinogenic, mutagenic and toxic to reproduction (CMRs) and endocrine disrupting (EDCs), **unless no safer alternatives are available.** European healthcare practitioners are rightly concerned about patients being exposed to hazardous chemicals as a result of the use of medical devices during medical treatment. In particular, patients such as children, pregnant and nursing women, dialysis patients and others whose immune system is already suppressed are most vulnerable. Therefore the new regulation on medical devices should establish the mechanisms to move us as quickly as possible to a European healthcare system that does not use hazardous chemicals in medical devices. Note that making medical devices toxic free would be only one component of moving towards a toxic free European healthcare. Health and environment NGOs therefore advocate that the Regulation on medical devices currently in Co-Decision in the European Parliament and Council is amended to reflect the policy recommendations outlined below.

1. Phase out CMRs in all medical devices unless no safer alternatives are available

Substances that are carcinogenic, mutagenic and reprotoxic (CMRs category 1A and 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (REACH)), such as certain phthalates (i.e. DEHP,

DBP, DIBP, BBP) and metals (e.g. cadmium, cobalt, chromium), may be released from medical devices. Although CMRs (categories 1A and 1B) that leach or leak from the device are mentioned in the current medical device regulation proposal, NGOs demand that all CMR substances category 1A and 1B are phased out within specified deadlines, as exposure is unavoidable and these substances are already banned in other EU legislation, for example in cosmetics and toys to prevent exposure from those products. Where no safer alternatives exist, manufacturers should label the devices containing CMRs, provide proof that they have carried out a thorough investigation of alternatives and submit the results of such an investigation to the notifying bodies. The European Commission should thoroughly monitor this process. The authorisation of any medical device containing CMRs should be limited and reviewed every 5 years. When safer alternatives become available, the authorisation granted to the devices should be immediately terminated.

An example of a CMR substance that may leach or leak from a device is the phthalate di-(2-ethylhexyl)phthalate (DEHP) which is classified as Toxic to Reproduction (category 1B) in Europe. Phthalates are abundant in PVC based medical devices such as blood bags, intravenous bags, tubes, catheters and disposable gloves, primarily in the form of DEHP. Studies have found some phthalates and their metabolites in the urine of adults and neonates, blood, naval cord blood, semen, breast milk, placental tissue and amniotic fluid. According to the current legislative proposal, medical products containing DEHP should be labelled, whilst the use of DEHP in toys and childcare products is prohibited according to Directive 1999/815/EC. However, there are many alternatives to medical devices containing phthalates, and various listings have been made by, amongst others, the Danish EPA[1] and HCWH[2]. Other substances of concern are those used in metal-on-metal devices, which are known to release metal ions into the body and can cause serious health effects to patients, including damaging muscles and bones[3]. NGOs therefore believe that all CMR substances should be phased out, unless no safer alternatives are available.

2. Identify Endocrine Disrupting Chemicals (EDCs)

The European Commission is currently developing criteria for identifying endocrine disrupting chemicals. The criteria will be issued in the form of a policy recommendation. Health and environment NGOs believe that a reference to these forthcoming criteria should be added to the medical device regulation. At present there is only reference to the EDCs identified within the REACH process (Art59). The reference to the REACH identified-EDCs is inadequate given the fact that so far only a limited number of endocrine disrupting chemicals have been identified and it is not clear how the new criteria will affect the REACH EDC identification process or vice versa.

[1] http://www.eco-forum.dk/medicoartikler/Produktliste.pdf
[2] http://www.noharm.org/lib/downloads/pvc/PVC_Alternatives_Europe.pdf
[3] Cohen (2012) How safe are metal-on-metal hip implants? BMI: 344:e1410

3. Phase out known and suspected EDCs in all medical devices unless no safer alternatives are available.

Endocrine Disrupting Chemicals can interfere with the endocrine system of living creatures, which is potentially very damaging, as the endocrine system controls our hormones which have important roles in many biological functions, including reproduction and metabolism. EDCs have been increasingly linked to a range of health problems including altered brain development giving raise to behavioural and cognitive (for example attention deficit) disorders[4,5], hormone-related cancers (particularly breast, prostate and testicular cancer)[6,7], diabetes[8], reproductive disorders[9], and impaired fertility[10] in wildlife and humans[11]. EDCs such as Bisphenol A (BPA) are present in many medical devices spanning from tubing and catheters to cardiopulmonary bypasses, and can constitute a significant source of exposure for certain patients. A recent study has linked the use of tubes and other medical devices containing BPA in neonatology departments to traces of BPA in the urines of babies[12]. In addition, scientific studies have linked exposure to low doses of BPA to a wide range of effects in animals and humans, including negative effects on the female reproductive system[13], altered hormone levels in men[14], and behavioural problems in children[15]. Different studies have also documented the endocrine disrupting abilities of different phthalates, including the ones classified as CMRs (Cat 1A and 1B) and many others[16].

NGOs believe that both known and presumed EDCs should be phased out unless no safer alternatives are available. In the case of suspected EDCs, the precautionary principle applies. We advocate that if a substance has endocrine disrupting properties, the absence of precise scientific knowledge on how it exerts its effects (mechanisms of action) should not hinder or slow the control of such chemicals. Where no safer alternatives exist, manufacturers should be subject to the same requirements detailed above for CMRs – to label the devices containing EDCs, provide proof that a thorough investigation of alternatives has been carried out by the medical device manufacturer and submit the results of such investigation to the notifying bodies to be thoroughly monitored by the European Commission. The authorisation of any medical device containing EDCs

[4] Ishido et al., 2007, Mesencephalic neurodegeneration in the orally administered bisphenol A-caused hyperactive rats. Toxicol Lett, 173:66–72

[5] Jurewicz and Hanke, 2011, Exposure to phthalates: Reproductive outcome and children health. A review of epidemiological studies. Int J Occup Med Env Health, 24:115-141

[6] Soto and Sonnenschein, 2010, Environmental causes of cancer: endocrine disruptors as carcinogens. Endocrinology, 6:363-370

[7] Jenkins et al., 2007, Prenatal TCDD exposure predisposes for mammary cancer in rats. Reprod Toxicol, 23:391-396

[8] Lim et al., 2008, Association of brominated flame-retardants with diabetes and metabolic syndrome in the U.S. population, 2003–2004. Diabetes Care, 31:1802–1807

[9] Markey et al., 2005, Long-term effects of fetal exposure to low doses of the xenoestrogen bisphenol-A in the female mouse genital tract. Biol Reprod. 72:1344-1351

[10] Cohn et al., 2003, DDT and DDE exposure in mothers and time to pregnancy in daughters. Lancet, 361:2205-2206

[11] Bergman et al., 2013, State of the science of endocrine disrupting chemicals - 2012. UNEP/WHO. United Nations Environment Programme/World Health Organization. 296 pp.

[12] Duty et al., 2013, Potential sources of bisphenol A in the neonatal intensive care unit. Pediatrics, 131(3):483-9.

[13] Fujimoto et al.,2011, Serum unconjugated bisphenol A concentrations in women may adversely influence oocyte quality during in vitro fertilisation. Fertil Steril 95: 1816-1819.

[14] Meeker et al., 2009, Urinary Bisphenol A concentrations in relation to serum thyroid and reproductive hormone levels in men from an infertility clinic. Environ Sci Technol 44 (4): 1458–1463.

[15] Braun et al. (2009). Prenatal Bisphenol A exposure and early childhood behavior, Environ Health Persp 117 (12): 1945–1952.

[16] Swan et al., 2005, Study for future families research team. Decrease in anogenital distance among male infants with prenatal phthalate exposure. Environ Health Persp. 113, 1056–1061.

should be limited and reviewed every 5 years. When alternatives become available, the authorisation granted to the devices should be immediately terminated.

4. More stringent pre-market authorisation of medical devices

The pre-market authorisation process of medical devices should be more stringent, as should be the post-market surveillance. In order to avoid cases such as the widespread use of the breast implants containing industrial-grade silicone (PIP), and metal-on-metal hip implants leaching metal micro particles such as cadmium, cobalt and chromium into the body, all medical devices should undergo rigorous pre-market authorisation and clinical trials. Furthermore, the process of attaining a European conformity assessment (CE) marking should be urgently reviewed, since an undercover investigation by the British news agency the Telegraph and the British Medical Journal has shown corruption within the procedure for approval of devices[17]. Finally, as mentioned above, if CMRs, EDCs and in particular phthalates are present in medical devices because no safer alternatives are available, the medical device manufacturer should provide proof that he has undertaken an investigation of alternatives, and the results of such an investigation should be submitted to the notifying bodies and monitored by the European Commission. The authorisation of medical devices containing CMRs and EDCs should be limited and reviewed every 5 years. When safer alternatives become available, the authorisation granted to the devices should be immediately terminated.

[17] http://www.telegraph.co.uk/health/9626756/Faulty-medical-implants-investigation-Patients-health-put-at-risk-by-unscrupulous-EU-regulators.html?goback=.gde_4478619_member_179649728#