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Diabetes Federation
Europe



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SUSTAINABLE
HEALTHCARE
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comité
développement
durable
santé



Royal College
of Physicians



FRIENDS OF THE EARTH GERMANY



Institut für Nachhaltigkeit im Gesundheitswesen
Institute for Sustainable Healthcare



Asociación Española de Afectados por Mercurio
de Amalgamas Dentales y Otras Situaciones



Stockholms läns landsting
Stockholm County Council



Minister for Health

Minister for the Environment

Brussels, [...] February 2014

European healthcare professionals demand support for phasing out hazardous chemicals in medical devices

Dear Ministers,

Copied to: EU Health and Environment Ministers

With this letter the undersigned European and international organisations representing healthcare professionals and patients in Europe would like to call on you to support the phase out of hazardous chemicals in medical devices during the debate in the Council of the European Union on the new European Commission's Regulation's proposal on medical devices (COM2012 542).

As you are probably already aware the European Parliament has voted favourably to an amendment to Annex I of the new EC Regulation proposal, stating that chemicals that are carcinogenic, mutagenic and reprotoxic (CMRs), such as certain phthalates and metals, or that have endocrine disrupting properties (EDCs), and which are contained in medical devices that are invasive or come into contact with the body of patients or are used to administer, transport or store medicines, body fluids or other substances, including gases in concentrations above 0.1% by weight, shall be banned. The amendment still allows the use of CMRs and EDCs in medical devices for a period not exceeding four years through a derogation process. Manufacturers may ask for exemption in the case that the elimination or substitution of these substances is technically impracticable, the reliability of the substitute substance is not ensured or if the negative impact caused by the substitution outweighs the benefits on the patient's health and safety. Finally, the amendment also introduces that EDCs are to be identified not only through the procedure specified in REACH, but also by scientific evidence of their effects on human health or the new criteria being developed by the European Commission.

We call on you and the other EU Health and Environment Ministers to support this proposal for a phase out of CMRs and EDCs in certain medical devices, whenever safer alternatives are available, a phase out that gained overwhelming support in the European Parliament but that will not translate into EU law without the wide support of the European Member States. The phase out has also found the backing of the medical device manufacturing

industry, which is already developing new solutions that are safer for patients, healthcare workers and the environment. Although many lists of safer medical products and substances already exist, HCWH Europe has decided to undertake the project of developing an online database that allows procurers of healthcare facilities to select phthalate-free or PVC-free medical devices. The database (www.safermedicaldevices.org) includes products of European and global manufacturers and enables decision-making for procurers on substituting medical devices. Human health and the environment are threatened by the presence of hazardous chemicals in many products, including medical devices that are intended to contribute to the treatment of diseases¹. Several health systems and hospitals throughout Europe have already recognised the need to avoid harmful chemicals and have voluntarily started phasing out medical equipment containing phthalates and other hazardous chemicals. For example, the Vienna Hospitals Association has adopted a PVC free policy in their Neonatal Intensive Care Unit. The PVC-free products include invasive consumables and products that come into contact with the skin of babies. In the Neonatology Unit of the Glanzing Children's Hospital in Vienna the phase out of PVC started in 2000. The PVC content of invasive medical products was halved by 2010 with an increase in price of less than 15%². The Stockholm County Council (SLL) has been phasing out PVC and phthalates from its hospitals since 1997. To date, 90% of the examination gloves are PVC-free and DEHP is almost phased-out. Moreover, the phase out of PVC products is also taking place in some hospitals in the Czech Republic, Slovakia, Germany and France.

We recognise that a wider and profound change across Europe will not be possible without the leadership and courage of political leaders like yourself, the support and goodwill of industry, the examples of already existing good practices in the European healthcare sector and the partnership of civil society. The benefits related to creating a healthcare system that uses medical devices free of hazardous chemicals will contribute to healthier environments and communities for European citizen whilst reducing externality costs.

Many thanks for your consideration.

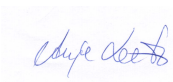
Yours sincerely,

Representatives of European and international organisations representing healthcare professionals and patients in Europe, as detailed below

¹ To know more about the hazard of CMRs and EDCs please see HCWH Europe's factsheets: <http://noharm-europe.org/documents/hazardous-chemicals-medical-devices-bisphenol-bpa> ; <http://noharm-europe.org/documents/hazardous-chemicals-medical-devices-phthalates>.

² Lischka et al, 2011, J Environ Sci Eng 5: 1162 - 1166

Signatories



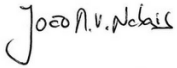
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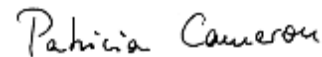
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Health Care Without Harm Europe (HCWH Europe), founded in 2003, is a coalition of hospitals, medical associations, healthcare professionals, local authorities, and environmental and health organisations working together to transform the European healthcare sector. HCWH Europe has 73 members in 25 European countries.

The **Association of European Cancer Leagues** (ECL) is a pan-European umbrella organisation of national and regional cancer leagues in the extended Europe from Iceland to Turkey. For over 30 years, ECL has been providing a unique and important platform for cancer societies making a difference in cancer prevention and control.

The **Austrian Doctors for a Healthy Environment** (AeGU/ISDE Austria) is a politically independent association of doctors working on the health impact of environmental problems that was established in 1989. AeGU is a founding member of the International Society of Doctors for the Environment (ISDE).

BUND/Friends of the Earth Germany is a non-profit, non-partisan, and non-religious grassroots organization for nature conservation and environmental protection. Among other goals Friends of the Earth Germany is especially committed to reducing the amount of toxic chemicals in everyday life, always providing alternative solutions.

The **Centre for Sustainable Healthcare** (CSH) (formerly known as the Campaign for Greener Healthcare) is working mainly in the UK since 2008, and has developed a range of projects to green healthcare concentrating on three areas: engagement, knowledge sharing and transformation. CSH works with healthcare professionals and managers, industry, patients and researchers to develop their understanding of the connections between health and environment and the importance and benefits of putting sustainable practices at the heart of healthcare.

The **Committee for Sustainable Development in Healthcare / Comité pour le Développement Durable en Santé** (C2DS) is an independent French non-profit organisation founded in 2006 by healthcare professionals committed to sustainable development. The C2DS is formed by 400 hospital members; public and private hospitals, private non-profit hospitals, cancer treatment centres, social and medical institutions and retirement homes, which represent more than 150 000 employees. The aim of the C2DS is to raise awareness among key players in the healthcare sector and to promote the advantages of better practices in order to master the environmental, human and economic impacts of healthcare activities.

The **Danish Ecological Council** (Det Økologiske Råd) is a Danish NGO founded in 1991 with the objective to promote a sustainable development, where environmental concerns, social justice and human well-being are main focal points. The Ecological Council is different from other Danish NGOs in the way that it is an academic organisation dealing with environmental policy on a scientific basis, but at the same time trying to inform and have a dialogue with both politicians and the general public.

The **Ecobaby Foundation** (Stichting Ecobaby) is a Dutch non-governmental organisation, founded in 1996, which examines the harmful environmental factors to achieve prevention or healing of damage in the perinatal period.

The **European Specialist Nurses Organisations** (ESNO) is the recognised and unified voice of specialist nurses in Europe. Members of ESNO consist of individual European specialist nurses organisations. The goal of ESNO is to facilitate and provide an effective framework for communication and co-operation between the European Specialist Nurses Organisation and its constituent members in order to represent the mutual interests and benefits of these organisations to the wider European community, for the interest of the public health.

IDF Europe is the European chapter of the International Diabetes Federation (IDF). IDF Europe is an umbrella organisation representing 69 diabetes organisations in 47 countries across Europe. IDF Europe is a diverse and inclusive multicultural network of national diabetes associations, representing both people living with diabetes and healthcare professionals. Through their activities, IDF Europe aims to influence policy, increase public awareness and encourage health improvement, promote the exchange of best practice and high-quality information about diabetes throughout the European region.

The **Institute for Sustainable Healthcare** (INGES) is an Austrian non-profit association since 2001. INGES is promoting the development of the healthcare system towards sustainability by creating awareness through

pilot projects and scientific studies. INGES is member of HCWH Europe.

The **International Society of Doctors for the Environment** (ISDE) is an association mainly of national medical/environmental organisations from all continents representing many thousands of individual doctors.

The **Irish Doctors Environmental Association** (IDEA) is a group of Irish health professionals who are working to improve environmental degradation in order to protect human health and biodiversity. IDEA is member of ISDE.

MERCURIADOS (Asociación Española de Afectados por Mercurio de Amalgamas Dentales y Otras Situaciones / Spanish Association of People Injured by the Mercury of Dental Amalgam Fillings and Other Sources) is a Spanish non-profit association composed of people injured by different mercury sources, mainly by mercury from dental amalgam fillings (including dentists, dentists' assistants, and medical personnel). Their objectives are to inform about the risks of mercury, particularly the mercury that evaporates from dental amalgam fillings, and to create a free and public arena for opinion-reflection on the dental mercury issue.

The **Royal College of Physicians** is an independent professional membership organisation and registered charity, representing over 29,000 physicians in the UK and internationally.

The **Stockholm County Council / Stockholms läns landsting** (SLL) is responsible for all publicly-financed healthcare and public transport in Stockholm County. The County Council is one of Europe's largest healthcare providers, offering everything from telephone advice about self-care to advanced specialist care at university hospitals. The SLL is also responsible for other overall issues within the county, such as regional planning and cultural subsidies.