TOWARDS NON TOXIC HEALTHCARE

21/03/13

European Parliament's Lunch Workshop Report

Towards Non Toxic Healthcare

ALTERNATIVES TO PHTHALATES IN MEDICAL DEVICES

INTRODUCTION

Medical devices are essential in healthcare as they play an important role in the prevention, monitoring and treatment of diseases, contributing to an improved quality of life for patients suffering from different illnesses. Medical devices cover a range of products including any instrument, apparatus, appliance, software, material or other article that is used alone, or in combination, for diagnostic or therapeutic purposes, and which manufacturers intend for use in human beings (EU definition). There are an estimated 1.5 million different medical devices, from simple bandages and surgical gloves to pacemakers, incubators, insulin pumps, and sophisticated life-supporting products. Contrary to medicinal products, medical devices achieve their purpose without chemical action within or on the body. Nonetheless, in their composition they may be made up from a number of different chemicals. This is why several concerns have been raised on the high risk of exposure of patients to harmful chemicals during medical treatment and their detrimental long-term effects on patients' health. In particular, phthalates, a group of plasticisers, which are used to soften PVC, have been the topic of different scientific studies in the past decades. Several animal studies have shown that phthalates can damage the liver, kidneys, lungs and the reproductive system. Due to these concerns, many healthcare facilities around the world are switching to safer and cost-effective medical devices that do not contain PVC, and which do not require phthalates or other softeners.

In September 2012, the European Commission proposed a new legislative package 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. With the goal of influencing and contributing to the current debate in the European Parliament on the new EC proposals on medical devices, HCWH Europe organised on 21st March 2013 a lunch workshop in the European Parliament to discuss how to move towards a non-toxic healthcare system at European level and to demand for legislation that promotes the use of alternatives to harmful chemicals in medical devices. The event, hosted by MEP Corinne Lepage (ALDE), brought to the European Parliament medical device producers, hospitals facility managers and health practitioners who shared their experience in producing, purchasing and using medical devices free of harmful chemicals, in particular phthalates. The key issues raised

during the workshop were:

- The lack of awareness from patients and health professionals on the presence of harmful chemicals in medical devices.
- The French ban on the use of tubes containing di-(2-ethylhexyl) phthalate (DEHP) in paediatrics, neonatology and maternity wards in hospitals by 1st July 2015, as a first step towards the phasing out of phthalates in all medical devices in Europe.
- The existence of medical devices that do not contain PVC and phthalates and the successful examples of many European healthcare facilities that have switched to these alternatives, showing that phasing out PVC and/or phthalates is not only possible but in many cases already a reality.
- The need for healthcare systems procurers from different regions and countries to work together and show the industry an increased demand for phthalates-free medical devices.

The debate also focussed on the need for a European legal framework that ensures a high level of protection of human health by requiring the phase out of harmful chemicals in medical devices, including phthalates, unless no substitutes are available for specific uses. Such a regulatory framework would pressure industry to invest in innovative solutions that do not cause harm to patients, healthcare professionals and the environment.

PARTICIPANTS

Name	Organisation
AGGERHOLM Kristensen Eline	Danish Ecological Council
ALMEIDA Ana	European Public Health Alliance
AMARAL Maria José	HCWH Europe
BILLOD-MULALIC Rachel	Comité développement durable santé, C2DS
BOTTARD Silvia	European Hospital and Healthcare Federation
BRASK Charlotta	Stockholm County Council
CIOCI Grazia	HCWH Europe
CLOCCHIATTI Alessia	European Federation of Nurses Associations
DE GEER Kristina	Region Skåne
LEETZ Anja	HCWH Europe
LEPAGE Corinne Office	European Parliament
LISCHKA Andreas	Vienna Hospitals Association
MARSCHANG Sascha	European Public Health Alliance
MORKŪNAITĖ-MIKULĖNIENĖ Radvilė Office	European Parliament
NYGROOS Hanna	Region Västra Götaland
REIDEL Armin	Fresenius Kabi
RIFAI Frank – Sami	Hôpital Privé d'Evry, C2DS
RIVASI Michèle Office	European Parliament
SGARZI Davide	Region Emilia Romagna
STIGH Lena	Jegrelius Institute

USPASKICH Viktor Office	European Parliament
ZAMFIRESCU Dan Office	European Parliament

INTERVENTIONS

Corinne LEPAGE, Member of the European Parliament

Mrs. Corinne Lepage, a French politician and member of the Environment Committee at the European Parliament, opened the discussion by pointing out that patients should not be treated as guinea pigs by being exposed to medical devices that contain harmful chemicals.

This issue is crucial but unfortunately it does not seem on the radar screen of the European decision makers. We need to reinforce the rules before and after the placing on the market and we need an ambitious legislation on this issue.

Anja LEETZ, Executive Director, Health Care Without Harm Europe

HCWH-Europe is an international non-profit organisation that brings together hospitals and healthcare systems, medical associations, health-affected constituencies and environmental and health organisations with a mission to transform the healthcare sector worldwide so that it becomes environmentally and ethically sustainable and no longer a source of harm. Mrs Leetz called for a more ambitious legislative proposal on medical devices that aims to achieve the replacement of phthalates in medical devices, but, beyond that, that also identifies and replaces all harmful substances in medical devices. Mrs Leetz called on hospital systems and the general public to pressure legislators and industry to encourage the production and market uptake of medical devices that do not contain hazardous chemicals, causing no harm to the health of European citizens and the environment.

Strong regulatory leadership that will both raise awareness on this issue amongst healthcare professionals and will push medical device producers to develop more alternatives to PVC, phthalates, and other harmful substances in medical devices is required.

Eline Kristensen AGGERHOLM, Chemicals Officer, Danish Ecological Council

The Danish Ecological Council is a non-profit organisation that promotes sustainable development, where environmental concerns, social justice and human wellbeing are main focal points. Ms. Aggerholm presented the trailer of a documentary produced by the Danish Ecological Council titled "Hazardous Chemicals in our Blood – a documentary of phthalates in medical devices". The Danish Ecological Council is strengthening its efforts to combat the use of phthalates in the medical sector. In the documentary, scientists and paediatricians raised concerns on the

impairment observed in the development of the reproductive system in animals and foetuses when exposed to endocrine disrupting chemicals, like phthalates. One of the interviewees, Danish MEP Dan Jørgensen (S&D), states that medical devices containing harmful substances should be prohibited unless no alternatives are available and "if there is an alternative, the EU Commission should have the power to say: OK – a ban is now in force."

Sami-Frank RIFAI, Managing Director of the Hôpital Privé d'Evry in Paris, and Treasurer of the Comité pour le Développement Durable en Santé (C2DS)

C2DS is a French non-profit organisation with 330 hospital members that for the last seven years has raised awareness among key players in the healthcare sector and promoted the benefits of good practices in managing environmental, human and economic impacts of healthcare activities. Over the years, C2DS has noted a growing demand among member hospitals for phthalates-free medical devices, with many establishments voluntarily deciding to favour "greener" medical devices. In 2010, C2DS started a fight for a legislative proposal that restricted the exposure of vulnerable groups to phthalates in the healthcare sector and finally, in December 2013, France voted a law requiring the phthalate Di(2-ethylhexyl)phthalate (DEHP), present in tubes used in paediatric, neonatology and maternity wards, be banned by 1st July 2015.

The French ban of DEHP is an important first step towards the phasing out of phthalates at European level. In many similar situations, the position of a Member State has lead to a domino effect, influencing other countries to adopt similar legislation. HCWH Europe encourages parliamentarians to be, from now on, even bolder and extend the ban to other phthalates in other medical devices being used beyond neonatology and maternity departments.

Mr. Rifai , as a Hospital Director, couldn't ignore that many substances used in the healthcare sector are harmful. Mrs Rifai further explained how the maternity ward of the Hôpital Privé d'Evry is carrying out an ongoing programme to phase out as many medical devices containing CMRs (substances classified according to the EU as Carcinogenic, Mutagenic or Reprotoxic) as possible. Another example is the Clementville maternity ward in the south of France that adopted a phthalates-free policy in 2010 with an estimated increase of costs of only 5 percent.

Charlotta BRASK, Head of the Environmental Department of the Stockholm County Council

The Stockholm County Council is committed to continuously decreasing its environmental impact by taking up an ambitious Environmental Challenge policy between 2012-2016, focussing on three areas – Climate-Efficiency, Resource-Efficiency and Health-Promoting Environment and setting 16

interim targets in those three areas. The Stockholm County Council's healthcare sector represents 40,000 healthcare visits every day and has a budget of 4.5 billion Euros. One of the targets of the Health-Promoting environmental work is reducing the environmental and health risks of chemical products.

> **By 2016, all chemicals and chemical products that are listed on the County Council's phase-out list of chemicals shall be removed from all County Council's funded activities. The total quantity of phased out substances must be decreased by 80 percent in comparison to 2006. In 2016, all County Council's funded activities shall neither purchase nor procure goods containing substances on the County Council's phase-out list.**

Mrs. Brask presented the chemicals strategy of the Stockholm County Council that has lead to a 90 percent reduction of hazardous chemicals between 2007 and 2011. The chemicals strategy is based on the Stockholm County Council phase-out list that is aligned with the REACH candidate criteria and applied throughout the procurement process. Plasticisers like BBP, DBP and DEHP are among the substances on the phase out list. Furthermore, Mrs. Brask showed how the share of different PVC free and phthalate free products has steadily increased. This result has reinforced the role of a central procurement policy that gives the Council an advantage in dealing with manufacturers. Mrs Brask also emphasised that the healthcare sector has to work together, share criteria and increase the demand for alternatives that minimise exposure to endocrine disrupting chemicals.

Armin REIDEL, Business Unit Manual Blood Processing Director at Fresenius Kabi (Fresenius Medical Care)

The Fresenius Group has business activities in more than 150 countries worldwide and a sales volume of 19.3 billion Euros. Fresenius Medical Care was the first medical company certified by the Nordic Ecoloabel (SWAN) for its PVC-free dialysis bag. Dr Reidel presented the range of DEHP-free alternatives commercialised by Fresenius Medical Care, including systems for bloodline, needles for haemodialysis, and CAPD and APD solutions for peritoneal dialysis. All blood tube systems in the paediatric field are DEHP free. Fresenius Medical Care uses TOTM as an alternative plasticiser or biofine, a non-PVC material that is free from plasticisers. TOTM is being used to replace DEHP because of its low leaching and extraction resistance properties in addition to its high flexibility, elasticity and resilience. Fresenius Kabi is currently performing tests with other plasticisers to identify DEHP alternatives.

Dr Reidel presented also the results of a market research carried out in hospitals and blood banks in Germany and Italy to understand what were the concerns and requirements of health practitioners. The study showed that there was a general lack of information about softeners such as DEHP, more so in Italy than in Germany and more in hospitals than in blood blanks. Most of

the respondents to the survey did not speak about DEHP as an issue of concern but pointed out safety, hygiene, sterility, usage and biocompatibility as their main concerns.

The lack of awareness on the risk of softeners, such as DEHP, by hospital and blood bank managers results in low demand for phthalates free medical devices.

The Fresenius Group continues to have PVC containing products in their portfolio because customers ask for them, due to their low cost.

Lena STIGH, Project Manager of Life+ Project PVCfreeBloodBag, Jegrelius Institute

The Jegrelius Institute works together with consumers, companies and the public sector to stimulate demand and production of non-toxic products. Mrs. Stigh presented the concept and first results of the Life+ Environment project PVCfreeBloodBag that she is managing. The project is a collaboration between industry and the healthcare sector, aimed at demonstrating that it is possible to produce a PVC-free blood bag that fulfils the required specifications, including the CE-labelling in the spirit of REACH. Currently, there are no PVC-free blood bags on the market. The project is focusing on increasing demand; on producing different compounds and a PVC-free blood bag prototype, whilst evaluating and testing its economic feasibility. A PVC- free blood bag, tested and approved, is expected for 2014.

Prof. Dr. Andreas LISCHKA, Former Head of the Children's Hospital "Kinderklinik Glanzing"

Prof Andreas Lischka has been involved for many years in a campaign to phase out PVC in hospitals and in particular in the Children's Clinic Glanzing, which is part of the Vienna Hospitals Association and one of the first to have a PVC-free neonatal intensive care units, with the exception of a limited number of devices for which there are no PVC free alternatives available yet. Prof Lischka started with an overview of the growing scientific evidence that exists on the toxic effects of plasticizers in PVC-containing medical devices, in particular DEHP, pointing at the risks for foetus, newborns and infants. Dr Lischka presented the outcome of the phase out campaign carried out from 2001to 2010 and how the amount of PCV-containing products procured and the waste of PCV containing products used in the neonatal intensive care unit had decreased by 50%. Prof Lischka insisted that PVC products should be avoided, even if the PVC industry argues for the use of different non toxic softeners, because these alternatives in most cases do not offer any guarantee that they are safer than currently offered products.

DEBATE

After each presentation, the floor was open for questions. Some of the questions revealed how little awareness exists on the part of the policy makers on these issues.

All participants agreed that, for any real change to happen, the EU legislation needs to be updated by taking into account the latest science. Reference was also made to REACH, that lists DEHP on the candidate list in order to be controlled as well as other EU legislation that restricts the use of phthalates in toys. The new medical device regulation proposal, therefore, needs to reflect other EU legislation and include the phasing out of phthalates. In addition, it was stated that medical devices should be free not only of phthalates but all hazardous chemicals not to harm vulnerable patients. Finally, it was agreed that increasing the demand for chemicals-free medical devices by healthcare facilities would bring down their price to a competitive level.

GALLERY