Client-in-Confidence

ERA Technology Limited
Cleeve Road, Leatherhead
Surrey, KT22 7SA, England
T: +44 (0) 1372 367350
F: +44 (0) 1372 367359

Report Title: **Impact of additional RoHS substances on medical devices**

Client: **COCIR, EDMA & EUCOMED**

Client Reference:

Report Number: 2014-0662

Project Number: REG0112001
Report Version: V8.0
Report Issue Date : 23 October 2014
Document Control: Client-in-Confidence

Report written by:

Dr. Paul Goodman
Principal Consultant
Integrity Group

Approved by:

Dr. Chris Robertson
Head of Regulatory Compliance
Integrity Group

## DISCLAIMER

Whilst great care has been taken in the compilation of this report, use of the information therein is entirely at the risk of the client or recipient. It does not constitute legal advice and should not be relied on as such. ERA Technology Ltd. does not accept responsibility or liability for loss or damage occasioned to any person or property acting or refraining from action as a result of any material in this publication.

## DISTRIBUTION LIST

Client
Project File
Information Centre

## DOCUMENT CONTROL

Distribution of this document by the recipient(s) is authorised in accordance with the following commercial restrictive markings:

| | | |
|---|---|---|
| **Client-in-confidence** | : | ERA Technology Ltd provides this document in confidence to the client. The Client may use and copy the document in whole without alteration for its own business purposes including disclosure to third parties. |
| **Commercial-in-confidence** | : | No distribution or disclosure outside of the recipient's organisation is permitted without the prior written permission of ERA Technology Limited. |
| **Distributed-in-confidence** | : | Distribution of the document shall be in accordance with the document distribution list and no further distribution or disclosure shall be allowed without the prior written permission of ERA Technology Limited. |
| **Recipient-in-confidence** | : | ERA Technology Limited distributes this document to the recipient on the condition that no further distribution or disclosure by the recipient shall be allowed. |

For the purpose of these conditions, the recipient's organisation shall not include parent or subsidiary organisations.

Commercial restrictive markings are as contained in page header blocks.

If no restrictive markings are shown, the document may be distributed freely in whole, without alteration, subject to Copyright.

**ERA Technology Limited, Cleeve Road, Leatherhead, Surrey KT22 7SA, UK**
Tel : +44 (0) 1372 367350, Fax: +44 (0) 1372 367359, Web : www.era.co.uk

## Contents

## Summary

The medical device industry is different to other sectors of the electronics industry because its products need to go through a conformity assessment process which involves approval by a Notified Body for higher risk devices, before they can be sold in the EU and in the rest of the world.

When a substitution is required, this may involve redesign, testing for reliability and for patient safety and to obtain the data needed to gain approval in the EU and in the rest of the world. This can take many years especially if the change in design is significant which may occur when a new substance restriction is proposed

This report is an assessment of the impact of the proposed restriction by the RoHS Directive of four phthalates on the medical industry. The report considers the issues with the alternatives that appear to be available, the timescales needed to implement changes and several applications where exemptions will be needed.

More details are given in the appendix of the timescales that were originally adopted for the original six RoHS substances to illustrate the lessons learned by industry from the original RoHS directive. These lessons give an indication of the time that will be needed for additional restrictions. The appendix also describes the specific issues that affect the medical industry which were originally investigated by ERA in its study for the Commission to determine whether it was possible to include categories 8 and 9 in the scope of RoHS. The issues identified during this study are described here because they are relevant to additional RoHS substance restrictions.

Estimated timescales have been made by manufacturers for the time needed for all of the activities required to replace the phthalates and gain approval globally for medical applications and there are eight applications where substitution is not possible before July 2021 and so exemptions would be needed.

# 1. Introduction

The RoHS directive currently restricts six substances in electrical and electronic equipment which has included medical devices since 22 July 2014 and will include in-vitro diagnostic (IVD) medical devices from 22 July 2016.

The RoHS directive recast includes an obligation for the Commission to consider adoption of additional substance restrictions in accordance with Article 6. Article 6 does not specifically

mention a timescale for future restrictions and there is no mention of transition periods. However, article 6.2 includes requirement that substitute reliability is assessed and a socio-economic assessment is carried out and these should influence the time period for any future restrictions taking effect. Other issues such as the availability of substitutes (Article 6.2e) should also influence timescales. However, the main purpose of the RoHS directive is to protect human health and the environment and any measures that are detrimental to either of these, even indirectly, should be avoided. Unintended consequences such as removing life-saving medical products from the EU market or by forcing manufacturers to use different and potentially unsafe alternatives could both harm human health.

The Commission has assessed five additional substances and is considering submitting proposals to restrict four phthalates in types of equipment in categories 1 – 7 and 10 from 22 July 2019 and in category 8, 9 and 11 equipment from 22 July 2021 (one will be banned as a Persistent Organic Pollutant - POP). This would allow medical equipment manufacturers about seven years to comply (from the date of this announcement). Many electronic components without these new restricted substances will not be available immediately and some are likely to be available only shortly before 2019. As a result, medical equipment manufacturers will have only a little more than two years to evaluate these new components, test new designs, carry out clinical trials and obtain re-approval from Medical Device Notified Bodies to allow sales in the EU and approvals from the authorities in other jurisdictions for sale outside of the EU, which takes much longer than in the EU. In some cases, two years will not be enough. In fact the situation could be much worse as requesting and obtaining exemptions can take up to two years which leaves very little time to look for alternatives and write exemption requests once the supplier announces in 2019 that they cannot supply a substitute after all.

COCIR, EDMA and EUCOMED, the trade associations representing the European medical imaging, IVD and medical devices industries, have asked ERA to carry out an assessment of the likely impact of the five additional substance restrictions from July 2021 on the healthcare industry, in particular to consider the timescales that are likely to be needed for full compliance and whether exemptions will be required. This report identifies that the following exemptions will be needed if the compliance deadline for category 8 is July 2021:

- DEHP in ion selective electrodes until July 2025
- DBP in integrated circuits until July 2029[1].

[1] This exemption is needed to allow manufacturers to continue production of current designs after 2019 using ICs that contain DBP to allow them time to develop new replacement products without detrimentally affecting the availability of medical equipment to EU hospitals. It is not intended that these ICs would be used in designs that are developed after 2019

- DEHP, DBP and BBP in flexible cables for connection to moving parts, e.g. ultrasound transducers, defibrillator patient cables, ECG patient contact cables and cables connected to IVD robotic arms until July 2025
- DEHP in tubing used for transport of diagnostic reagents or solutions and patient samples within in vitro diagnostic analysers until July 2026
- DEHP in tubing and associated connectors and valves used for blood that re-enters patients until July 2029
- DEHP in tubing and associated connectors and valves used with fluids for patient contact (e.g. wound irrigation) until July 2025
- DEHP in tubing and associated connectors and valves used with gases for assisting and monitoring breathing and anaesthetics until July 2025

Additional exemptions would be needed if the restriction takes effect before July 2021

The history of the RoHS directive to date is described in the appendix. This also describes the lessons learned by the ERA study carried out for the European Commission into whether inclusion of categories 8 and 9 in the scope of RoHS would be possible. The specific issues of the medical sector identified by this study are unchanged and affect the timescale needed to implement substance substitutions.

## 2. Additional substance restrictions

Five substances have been reviewed for possible restriction. These are four phthalates, which are mainly used as plasticisers, and one flame retardant. All are already regulated by the EU REACH Regulation 1907/2006 and are classified as substances of very high concern (SVHC). Details of these are shown in the table below:

**Table 1. Substance proposed for RoHS restrictions, common uses and existing regulation**

| Name | Example uses in medical devices | REACH SVHC status | REACH and other restrictions |
|---|---|---|---|
| Bis-ethylhexyl phthalate (DEHP) | Very common plasticiser used in PVC (e.g. cable insulation), rubber and other polymers, in adhesives, paints, inks and lacquers. Used in PVC tubing, blood bags, catheters, "O"-rings, etc. | REACH SVHC. Will be subject to authorisation with a sunset date of 21 February 2015 | Restricted in children's products |

| | | | |
|---|---|---|---|
| Dibutyl phthalate (DBP) | Plasticiser used in rubbers, PVA, lacquers and in paint | REACH SVHC. Will be subject to authorisation with a sunset date of 21 February 2015 | Restricted in children's products |
| Di-isobutyl phthalate (DiBP) | Plasticiser with very similar uses as DBP | REACH SVHC. Will be subject to authorisation with a sunset date of 21 February 2015 | |
| Benzyl butyl phthalate (BBP) | Plasticiser used in PVC, rubbers, paints, adhesives | REACH SVHC. Will be subject to authorisation with a sunset date of 21 February 2015 | Restricted in children's products |
| Hexabromocyclododecane (HBCDD) | Flame retardant used mainly in high impact polystyrene (HIPS) | REACH SVHC. Will be<br><br>subject to authorisation<br><br>21 August 2015 | Proposed to be banned globally as a Persistent Organic Pollutant (POP) by Stockholm Convention, proposed from February 1016 |

As HBCDD will be restricted by the POPs Regulation, it is not considered further in this review. The four phthalates are used in a very wide variety of components and parts used in medical devices and IVD including:

- PVC insulation of wire and cables. Some cables need to be very flexible as they make electrical connections to moving parts.
- Flexible PVC mouldings, sheet and film
- PVC tape for electrical insulation
- Some types of rubbers used for parts such as grommets, seals, "O"-rings, etc. Rubber is used as electrical insulation for some types of inductors
- Capacitors, resistors, etc. in flexible insulation, encapsulants and labels
- Flexible adhesives, sealants, potting materials, lacquers, paints and some inks (use in inks is now uncommon). These materials are used in a wide variety of applications.
- PVC tubing for blood, gases and chemicals in a variety of devices including IVD analysers.
- Many others such as in plastic mouldings as a processing aid, etc.

Note that the four phthalates, especially DEHP is also used in many medical devices that have no electrical function such as gloves, blood bags, catheters, feeding tubes and orthodontic retainers. These are not in scope of RoHS unless supplied as a constituent part of a product with an electrical function.

# 3. Assessment of substitutes

There are a large number of plasticisers commercially available, but each has a unique combination of properties, so that drop-in replacements are not likely to exist for most current uses. This means that reformulation of the polymer material is usually needed to obtain suitable performance and properties and this will take a certain amount of time for each application. Furthermore, manufacturers will need to ensure that alternative plasticisers not only provide the required physical properties and long term reliability, but do not pose a health risk to patients. Many of the potential substitutes have hazardous properties, which are discussed below under 5.3.

A potential alternative to plasticisers for some applications is to use flexible polymers that do not need plasticiser additives. Cross-linked polyethylene cable insulation is sometimes used instead of PVC and is popular in tunnels as it does not emit dense toxic and corrosive smoke in fires. However, to achieve the required fire retardancy, high concentrations of mineral flame retardants such as alumina trihydrate must be added and this makes the material much less flexible than PVC and the dimensions are often different (thinner) so in the case of e.g. cables that different connectors need to be identified, tested and used.

Alternative plasticisers include different phthalates, but those with similar molecular weight may have similar toxicity and so should not be used as restrictions on these could be imposed in the future. DiBP is included in the proposed five for this reason as although it is not widely used in electrical and electronic equipment[2], it would be the obvious choice to replace DBP due to its very similar properties. Phthalates can be split into two groups – short alkyl chain which include DBP, DiBP, BBP and DEHP (DBP has a three carbon chain and DEHP has eight) and longer alkyl chain which include DiNP and DiDP which have nine and ten carbon chains respectively. Most of the short alkyl chains are classified as SVHCs as some have been classified as category 1B reproductive toxins so manufacturers should avoid these where possible. Long alkyl chain phthalates are not classified as category 1B reproductive toxins, but their properties are sufficiently different to make their use as substitutes difficult or in some applications impossible.

There are many other types of plasticisers, but most are newer substances with much less research on toxicity available. The current view is that some are safer than DEHP, DBP and BBP, but more research is needed on many and some may not be safe to use. Recently, a non-phthalate plasticiser; TOTM and bis(2-ethylhexyl) adipate were added to the Community rolling action plan (CoRap) and two other non-phthalate plasticisers; 1,2-Cyclohexane dicarboxylic acid diisononyl ester (DINCH) and diethylhexylterephthalate (DEHTP) are under scrutiny as possible

[2] Oeko report on additional RoHS substances

endocrine disruptors. It will not be straightforward to identify substitutes that are safe, will not be restricted in some way in the future and will meet all essential technical requirements.

A further complication is matching properties of alternatives to the phthalates. Important characteristics include:

- Viscosity at use temperatures and at the plastics forming temperature, e.g. during injection moulding as plasticisers can also be used as processing aids in many types of polymer
- Vapour pressure at use temperature (this usually needs to be very low for long lifetimes) and also at plastics forming temperature (not too high)

These characteristics are closely related as plasticisers with low viscosity are the most effective at making the polymer flexible, but tend to have a relatively low vapour pressure at use temperatures so that they evaporate over time and the material becomes brittle and inflexible. Higher molecular weight materials have higher vapour pressure, but are more viscous and so can be more difficult to process. Other important properties are:

- Inertness with other ingredients of the plastic formulation
- It must plasticise the polymer sufficiently (to make it flexible) and the plasticised plastic must be stable (i.e. the plasticiser must not separate to leave brittle hard polymer)
- Flexibility of plasticised material (some plasticisers are added only to aid forming and do not plasticise at ambient)
- Water absorption; this is very important for electrical insulation as moisture affects electrical resistivity. If this decreases, it can affect the function of circuits or even cause catastrophic failure due to arcing. Some alternative polymers to PVC have higher water absorption properties that can cause failures due to a process called "water-treeing" which causes electrical discharge.
- Very low toxicity – not always easy to determine, especially with newer substances.
- Low migration rate into fluids, e.g. when used for tubing, etc. and into skin when used in materials that have human contact such as patient tables.
- Compatibility with coatings – Tubing that is used for blood is coated internally with heparin to stop clotting. Some plasticisers interfere with the heparin coating so that clotting occurs which blocks the tube. Heparin also inhibits migration of DEHP into blood and so needs to also be able to inhibit migration of other plasticisers[3].

[3] "Opinion on Medical Devices Containing DEHP Plasticised PVC; Neonates and Other Groups Possibly at Risk from DEHP Toxicity", Adopted by The Scientific Committee on Medicinal Products and Medical Devices On 26 September 2002. Doc.SANCO/SCMPMD/2002/0010 Final

As direct drop-in replacements will rarely exist and medical equipment manufacturers cannot substitute materials without first ensuring that patent safety and equipment performance are not negatively affected, extensive testing, validation and sometimes also clinical trials must be carried out. These require significant amounts of employee time and will occupy significant calendar time. These issues are discussed under appendix 1 of this report.

## 3.1 Alternative plasticisers

About 50 to 100 plasticisers are commercially available including phthalates. However, these are not universally suitable and for each specific application, there may be relatively few that plasticise the material and provide the required properties. Many are not benign and have hazard properties that affect humans and the environment. The main types, known hazards and use limits are as follows:

**Table 2. Known hazards and limitations of uses of potential substitute plasticisers**

| Type / example | Hazards | Limitations on use |
|---|---|---|
| Alternative phthalates such as di-isononylphthalate (DiNP) This is used as a substitute for DEHP | Shorter alkyl chain phthalates such as dipentyl phthalate and 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (proposed for addition to REACH Annex XIV are category 1B reproductive toxins (same as DEHP). Longer chain phthalates do not have this classification. Dinonyl phthalate has no hazard classification according to the ECHA classification and labelling inventory[4], although it is restricted in children's product by REACH. Recently listed by California Proposition 65 | Several other phthalates are already classified as SVHCs and some are proposed for inclusion in Annex XIV so will require authorisation for use. DiNP is the most commonly used substitute for DEHP but is not suitable for replacement of DBP or BBP which are shorter alkyl chain phthalates |

[4] http://echa.europa.eu/regulations/clp/cl-inventory

| | | |
|---|---|---|
| Adipates such as diethylhexyl phthalate (DEHA) and tridecyl adipate | DEHA is a reproductive toxin[5] and tridecyl adipate is a suspect PBT[6]. The Danish EPA study[7] identified a risk to the environment and classified it as very toxic. | Can be used in PVC but higher molecular weight adipates may be incompatible with polymers. More volatile than phthalates and shows poor polymer fusion properties |
| Benzoate esters such as dipropylene glycol benzoate | Danish EPA study found insufficient data to assess risk | May be used as a substitute for BBP but plastisols have poor storage properties |
| Sebacates such as diethylhexyl sebacate (DOS) and azelates such as diethylhexyl azelate (DOZ) | Di-isodecyl azelate is a suspect PBT[6]. DOZ is included in the CORAP list. The Danish EPA study determined that DOS poses a risk to humans from exposure via the environment | Have 10-fold higher vapour pressure than DEHP. High cost so uses have been limited, therefore field reliability data is very limited. |
| Citrates such as triethyl citrate | Low toxicity so are used in food contact applications, but the Danish EPA study concluded that acetyl tributyl citrate is "harmful" | Poor "permanency", high volatility cause fogging and high level of "extraction" so uses are limited |
| Epoxy esters such as epoxidised soya bean oil (ESBO) | The Danish EPA study concluded that ESBO is "toxic" | Develops incompatibility with PVC during aging leading to migration (out to the surface) and development of sticky surfaces. This is promoted by sunlight. |
| Phosphate esters such as trixylyl phosphate (TXP) and tris-ethylhexyl phosphate | TXP is a category 1B reproductive toxin and SVHC. Tris-ethylhexyl phosphate is classified as an irritant and | Few limitations and also act as fire retardants. Limitation is with toxicity |

[5] http://www.ncbi.nlm.nih.gov

[6] From CORAP evaluation

[7] "Environmental and Health Assessment of Alternatives to Phthalates and to flexible PVC", Carried out by COWI for the Danish EPA, 2001.

| | | |
|---|---|---|
| | was classified by the Danish EPA study as harmful. | |
| Polyester plasticisers | | Do not aid processability of polymers, e.g. during extrusion or injection moulding. |
| Terephthalates such as diethylhexyl terephthalate (DEHTP) | TEHTP is being assessed as a possible endocrine disruptor | Lacks permanence properties |
| Cyclohexane dicarboxylates such as di-isononyl cyclohexane dicarboxylate (DINCH) | Reproductive toxin. Being evaluated as a possible endocrine disruptor | Higher volatility and less compatible with PVC than DEHP. Also needs a higher fusion and processing temperature |
| Triglycerides | | Very limited availability |
| Trimellitates such as trioctyl trimellitate (TOTM) | TOTM is a suspect PBT. The Danish EPA study found that TETM is Tri-2-ethylhexyl trimellitate is harmful. Another study found evidence of reproductive toxicity[5]. | Compounding and processing are difficult due to high viscosity and poor fusion properties |
| Glycerol acetylated esters | | Made from castor oil (a natural product from the castor oil plant) so availability is very limited |

An issue with the newer plasticisers is that they have not yet been as comprehensively tested as DEHP, DBP and BBP. Therefore there must be some uncertainty over their health and environmental hazards. Some, such as DINCH, have only very recently been suspected of having endocrine disrupting properties. Manufacturers will want to replace the four phthalates with substitutes that are safer and will not be restricted in the future but because of the reasons explained above, this is not straightforward and will take time and effort to make this choice.

The properties of alternative plasticisers differ from DEHP, BBP and DBP which can affect the stability of products in two ways. Plasticisers with higher vapour pressure will evaporate more rapidly so that the plastics become harder and more brittle so that failure due to cracking becomes increasing likely. This becomes a critical issue for products which need to perform over a longer time period, in some cases 20 or even 30 years.[8] Migration out of the bulk material to the surface is also a problem as the substance can be absorbed by users of the equipment and by patients. Migration can be measured in many ways (fluid composition, temperature, time, etc.), so data from one publication can rarely be compared with others. Therefore, relative estimates are usually only possible and these are suitable only for the type of fluid used for the test. Migration rates into fats are very different to aqueous solutions and some substitutes that have much lower migration rates than DEHP into water have similar or higher migration rates into oils and fats[9]. A illustrative selection of published data is given below.

**Table 3. Vapour pressure and relative migration rate data for plasticisers**

| **Plasticiser** | **Vapour pressure*** | **Migration potential[5, 7]** |
|---|---|---|
| DEHP (for comparison) | 3.4 x $10^{-5}$ Pa at 25°C | - |
| Di-isononyl phthalate | 6 x $10^{-5}$ Pa at 20°C | Research inconclusive[10] |
| DEHA | 0.011 Pa (relatively high) | One of the highest rates. Considerably higher than DBP |
| DOS | 1.46 x $10^{-4}$ Pa, 1.3 x $10^{-5}$ Pa | Considerably higher than phthalates |
| DOZ | 5.1 x $10^{-4}$ Pa | - |
| DINCH | 1.4 x 10-4 Pa (at 50°C, from | Low (eight-fold lower than |

[8] The typical life of a new IVD instrument within a given laboratory is 5 to 7 years, at which time the laboratory will often upgrade its system for a newer or different model. Given that the instrumentation is usually designed to operate much longer, when it is removed from the laboratory, it is typically refurbished and placed into another lab. Clinical laboratory blood analysers, medical optics lab analysers, blood bank analysers and point of care handheld bedside analysers are examples of IVDs which may be allotted typical lifetimes (ranging upwards from 7 years) however may last far longer when refurbished. Refurbished devices can be out in the field for 15-20 years (and there are some concrete examples of well-maintained instrumentation in the field already 30 years). Apheresis equipment, cell savers, electrosurgical generators, ventilators and patient monitoring devices are examples of medical devices which are allotted typical life spans of more than 5 years. The real life time is often longer and in many cases extends to 15-20 years or longer. Many devices are sold as used devices to a second or third customer.

[9] SCENIHR opinion on the safety of medical devices containing DEHP plasticized pvc or other plasticizers on neonates and other groups possibly at risk, 2008

[10] http://www.verbraucherrat.at/content/02-projekte/03-chemische-gefahren/01-weichmacher-im-spielzeug/phthalates2.pdf

| | | |
|---|---|---|
| | BASF datasheet) | DEHP[5]) |
| TETM | 5.25 x $10^{-10}$ Pa (very low) | Double that of DEHP |
| Acetyl tributyl citrate (ATBC) | 6.1 x $10^{-4}$ Pa | High |
| Dipropyleneglycol dibenzoate | 6.2 x $10^{-5}$ Pa | - |
| Diethylhexyl terephthalate (DEHT)[11] | 2.86 x $10^{-3}$ Pa | - |

* Where two values are quoted, these are from two different sources of data and indicate that values depend on test variables such as polymer composition.

Note that flexible polymers such as PPE do not contain liquid plasticisers and so will have extremely low vapour pressure and migration rates. However, their properties are not suitable for all applications.

## 3.2 Alternative flexible polymers

Alternative flexible polymers include:

- Polyethylene – the physical properties are not the same as PVC and if flame retarded with inorganic substances such as alumina trihydrate, this is considerably stiffer
- Silicone – already used in some medical applications but research has shown that it degrades and fails due to lipid uptake[5].
- Ethylene vinyl acetate (EVA)
- Thermoplastic elastomers such as polyurethane which has some medical applications
- Rubbers

The advantages of PVC include:

- Ease of fabrication, e.g. by solvent and heat welding (not possible with several alternatives)
- Mechanical properties, it has good flexibility and does not "kink"
- Barrier performance

Any alternative polymer must give the same or better performance and have no negative toxicity effects. For most applications, durability will be important to ensure that medical

[11] http://www.cpsc.gov/PageFiles/126546/phthalsub.pdf

equipment does not fail when it is needed for treatment of patients. Processability and properties can be significant limitations for alternative polymers

# 4. Uses by the medical industry and need for temporary exemptions

## 4.1 Integrated Circuit (IC) packages

Materials declarations from a few IC suppliers state that DBP is used as a constituent of the die attach material (usually for flip-chip devices). Die attach materials are a mixture of adhesive and silver metal particles. The silver conducts heat away from the die and is about 75% of the die attach material. Example materials declaration state that about 0.2 – 0.3% DBP is added to the die attach material with 0.001 to 0.002mg of DBP being in each component. The amount used is present at a very low concentration of each device, but is added for a specific purpose and is used at ca. 1% of the adhesive (excluding silver particles). Various die attach adhesive types are used with epoxy resins being common when silver is added. These epoxy resins are quite hard and brittle and as they have a much larger coefficient of thermal expansion than silicon, there is a risk that temperature changes will place strain on the silicon die causing it to crack. The epoxy resin is given some flexibility by addition of DBP so reducing strain on the die.

DBP is a very low viscosity plasticiser and replacing it with an alternative plasticiser will require full reformulation of the die attach materials and reliability testing of the IC package. As this will involve a significant cost to the IC manufacturer, they are likely to make older types with few sales obsolete rather than invest in alternative materials. This will be a problem for medical device manufacturers, because many of the circuits they use contain unusual types of IC and often these are older types. During 2005 – 2006, a short time prior to the original RoHS deadline, IC manufactures announced which ICs would become obsolete with no RoHS compliant versions available. This is likely to occur again a short time before additional restrictions take effect (proposed for July 2019). This will give medical equipment manufacturers only two years to redesign circuitry, write new software for the new devices, carry out reliability assessment, clinical trials if needed and apply for MDD or IVDD approval. This type of work will take much more than 2 years and medical equipment manufacturers have estimated that this could typically take up to 10 years for the most safety critical and complex medical devices, with up to 7 years likely to be needed for many types of medical device. As a result, there will be insufficient time for manufacturers to have compliant and approved medical devices by a 2021 deadline. The only way that medical devices that contain these components could continue to comply is if there is an exemption that allows continued use of these components in designs of medical device that were available in the EU before July 2019. The up to 10 year period to replace these ICs will start from the date when the supplier announces that they will not produce a RoHS compliant version, which could happen shortly before the RoHS deadline for categories 1 – 7 & 10 of July 2019.

For some types of equipment such as ultrasound systems, changing integrated circuits or any other components could detrimentally affect image quality. Ultrasound manufacturers have previously found that components in power supplies as well as on the main printed circuit boards (PCBs) can affect image quality and so extensive requalification of any new designs is needed. Changing components in IVD analysers also requires extensive testing to ensure that the accuracy of test results is unaffected.

### 4.1.1 Implications on healthcare in the EU

Medical devices need to be very reliable because serious harm to patients can occur if the equipment unexpectedly stops working. Medical device manufacturers therefore carry out extensive testing for durability and reliability before placing new products on the market. As this work requires a significant effort and takes a lot of time, there is a tendency to use older designs of printed circuit boards that have proven to be very reliable for many years in new products. As a result, the ICs on these boards are often older types that are likely to become obsolete instead of the IC manufacturer replacing DBP with an alternative plasticiser. Newer ICs are not simply 'plug and play' in a device. The medical device manufacturer would need to redesign the PCB, write new software and thoroughly test the new designs for each device type affected. This work would be required in addition to the on-going new product development that all medical manufacturers need to carry out.

Unless an exemption is granted, manufacturers would be forced to stop selling many current medical technologies that use non-RoHS compliant ICs in the EU because there would be insufficient time to redesign and adapt these products befor a 2021 deadline.

Currently the number of medical devices and IVDs using older types of ICs containing DBP and is unknown, but several manufacturers have commented that a significant range of products would be impacted. Making a diverse range of products obsolete in the EU before there are alternative products available to replace them would have a significant impact on the EU's healthcare system, which relies on a steady supply of medical technologies to meet its diagnostic and therapeutic needs.

There is therefore a good socioeconomic reason to allow sufficient time for manufacturers to continue supplying older designs until new products to replace those products can be developed tested and approved.

## 4.2 Wire and cable insulation

Whereas general wire and cable insulation will not need longer than a July 2021 compliance deadline, some specialised cables as well as flexible cables attached to moving parts, will require longer. This is described below.

Plasticised PVC is a common insulation material used for electrical wire and cables because it is inert to most environments likely to occur in medical applications and remains flexible for many decades. There are several types of use conditions that will be considered here:

- Electrical connections to and within electrical equipment. These include mains power cables and wire used to make connections inside electrical equipment where no movement is required. This is probably the least demanding wire / cable application where substitutes and will be available from wire and cable suppliers for evaluation the soonest.
- Wire and cable used where these are connected to moving parts of equipment, so that long term flexibility is needed without imposing strain on the parts that they connect. This is a more demanding application as flexibility at least as good as currently used materials is needed, as described below.
- High frequency, high voltage cables such as are used in CT
- MRI applications where plasticisers can affect image quality
- Ultrasound applications where flexibility can affect image quality

Simple PVC insulated wire that is used to construct electrical equipment, mains power cords, etc. is already being substituted by cable manufacturers due to the inclusion of DEHP in the REACH SVHC candidate list. They often make these changes without informing customers[12], however, this is a concern to medical equipment manufacturers as they are required to carry out impact assessments before any changes are made.

Some medical devices, such as clinical laboratory blood analysers, use large quantities of insulated wiring. Estimates of 1.5 miles have been calculated by one manufacturer and some use three times this length or more.

The large wire content is necessitated by the large number of assemblies contained within the analyser. Examples include cooling and heating assemblies, sensors to detect open and closed doors, motors and metering devices. All of these must be connected to the main circuit board which controls their functions.

Some medical equipment manufacturers would prefer to avoid PVC if at all possible, partly because this is increasingly a customer preference. Selection of an alternative plasticiser is not straightforward as some are classified as hazardous and some are suspected of having hazard classifications as discussed in section 3.1. Many substitutes have not been fully tested and so may be found in the future to have hazard classifications that deter their use, e.g. if they turn out to be a PBT or endocrine disruptor.

[12] Information from a UK electrical components distributor.

However, using alternative polymers for electrical insulation is not always straightforward and the safety and reliability will need to be proven before any substitute can be used. Alternative polymers that are available for wire and cable insulation include PPE (polyphenylene ether), PPO (polyphenylene oxide), polyethylene (PE), various fluorinated polymers, EPDM (Ethylene Propylene Diene Monomer) rubber and others. All have advantages and disadvantages. PVC may not always be the best performing material, but manufacturers have many years of experience and reliability data so are able to use it and know that medical devices will be safe and reliable. The table below gives some of the advantages and disadvantages of common insulation materials

| Insulation | Advantages | Disadvantages |
|---|---|---|
| PVC | Durable, excellent moisture resistance. Can be recycled | Max operating temp. 70 - 105°C (not usually a problem). High dielectric loss (only an issue with high frequencies) |
| Polyethylene (PE) | Low dielectric loss and high initial dielectric strength | Relatively stiff and inflexible. Moisture sensitive causing water treeing under high voltage and breaks down at high temperature |
| Cross-linked Polyethylene (XLPE) | XLPE has low dielectric loss but higher than PE. Max operating temp. 90 - 110°C and has better ageing characteristics. Good resistance to cracking | Relatively stiff and inflexible. Medium resistance to water treeing |
| EPR (ethylene propylene rubber) | More flexible than PE and XLPE and lower thermal expansion | Medium to high dielectric loss. Poor tear resistance and easily damaged due to its softness |
| Polyurethane | Tough and flexible, even at low temperature. Good water and chemical resistance | Poor electrical properties so suitable only for outer cable jackets |
| EPDM | -55 to +150°C range, good flexibility and good dielectric strength | |
| Fluoropolymers | Several types available. Very flexible, thermally stable and | FEP has poor cut through resistance, Susceptible to cold flow when stressed (bent) over tight radius or when laced |

| | | |
|---|---|---|
| | chemical resistant | too tightly, emits toxic and corrosive gases in fires |

Another issue that can arise is that some polymer insulated wires are available with different insulation thickness to that of PVC. For example, Alpha-Ecowire uses PPE insulation but the diameter of the insulation of 0.81mm$^2$ wire is 1.4 mm for PPE compared to 2.57 for PVC. The manufacture claims that the reason why thinner insulation can be used is its superior dielectric strength, however the cost of PPE is higher than PVC and so may also be a consideration. This diameter difference means that the equipment manufacturer may also need to replace their connectors to types that can be used with the thinner insulation.

Availability of certain styles of connectors is proving problematic. Implementation of PVC replacements will prove futile without the availability of workable connectors. Additionally, new connectors will also have to be validated. Due to the thinner insulation, pin crimping may not be as durable. The pins could slip out over time, which is especially worrisome given the long lifetimes of medical devices.

### 4.2.1 Electrical connections to and within electrical equipment

Replacing the insulation of wire used for low frequency wiring looms inside equipment and for mains cables will be relatively straightforward and in some cases may have occurred without the knowledge of equipment manufacturers. Under these relatively undemanding conditions, alternative plasticisers should give satisfactory performance, although to comply with the medical device directive, manufacturers are required to carry out risk assessments to ensure that this does not affect patient safety before any changes are made. Compliance with a July 2021 deadline is not expected to be an issue unless unforeseen circumstances occur.

### 4.2.2 Flexible cables attached to moving parts

Flexible cables are used to make connections to moving parts of medical equipment, such as those that connect to robotic arms in IVD analysers, X-ray imaging equipment where the X-ray tube is moved to suitable locations, etc. Very flexible cables are also needed for connections to ultrasound transducers and cables that connect patients to defibrillators and to echo-cardiogram (ECG) equipment. Other examples include cables that connect to SpO2 sensors, temperature probes, fetal scalp electrodes, cardiac output probes, TCpO2 probes IUP (intrauterine pregnancy) cables, etc. that are attached to patients. Cables for these applications need to remain very flexible for their lifetime and in many cases also need to withstand sterilisation either with chemicals or heat.

Flexibility is given to PVC by the plasticiser which can be present at relatively high concentrations. The plasticiser must be fully compatible with the PVC and make it flexible. Some plasticisers in PVC are unstable and migrate out, others do not give flexibility. Many of the alternative plasticisers have higher viscosity than DEHP so give inferior flexibility. As shown above in Table 2 and Table 3, many substitutes are not hazard-free, some are more volatile than DEHP and so will give shorter lifetimes and some have higher migration rates which may be unacceptable where the cables are in contact with patients' skin or are frequently handled by hospital staff. As a result, selection of a suitable alternative will be far from simple.

Long term flexibility can be important for the reliability of connections between the wire and connectors. Where solder connections are used, cyclic stress due to repeated movements can cause fatigue cracking and the rate at which this occurs depends on the stress level. Stiffer, less flexible insulation will increase this stress level. If the wire is attached to a plug-in connector, there is a risk from a failure mechanism called "fretting". Fretting is where the surfaces of connectors rub against each other due to sideways movement which could be caused by the moving parts of the medical device transferring this movement to the connector by too stiff insulated wire. As the sideways movement occurs, the metal surface is damaged. With base metals such as tin, every time the air formed oxide is disrupted and clean metal is exposed, more oxide forms until there is enough electrically insulating oxide to cause an open circuit. With precious metal coatings such as gold, this is rubbed off to reveal the base metal which behaves as described above.

Identification of a suitable alternative insulation for cables used to attach to moving parts will involve extensive testing to simulate the repeated movement. This cannot however be very greatly accelerated because the ability to move without changes in flexibility can change over 10 – 20 years due to volatilisation and migration of plasticisers. Volatilisation is dependent on its vapour pressure (usually data is available), but prediction of migration rates is very difficult as it depends on many variables, as discussed above. Therefore, simulation of a 10 – 20 year lifetime requires testing, typically with 20 million movements carried out over a period of several years. As a result an estimated worst case substitution period of up to 10 years has been predicted (by 2025), which includes identification of suitable materials, redesign of equipment if needed, reliability testing, biocompatibility if patient contact occurs, testing of equipment for effects on accuracy of results, ultrasound image quality (see section 4.2.5), etc. and global approvals.

### 4.2.3 Computer Tomography

Computed Tomography (CT) gives 3-dimensional X-ray images from multiple X-ray images. The X-ray source and detector are mounted on a ring that circulates rapidly around the patient.

Cables are required to pass high voltage power to the X-ray source and collect digital data from the detectors. This circuitry is used in a very demanding environment that can experience high g-forces, vibration and the high voltage cables can experience temperatures of 60 to over 100°C.

- There are many potential alternative cable insulation materials to DEHP-PVC and so the first task is to determine which of these will be suitable, reliable and not contain substances that are restricted or become obsolete in the future.
- Once a material is selected, trials to construct the complex cable assemblies will need to be carried out and the assemblies tested for reliability.
- If they are satisfactory at this stage then assessment in CT machines will be carried and long term reliability trials carried out.
- If trials in CT are satisfactory, the manufacturer will at least need to carry out a risk assessment and in some cases will also need to apply to a Notified Body for re-approval under the Medical evices Directive.

This work has been predicted to take many years and although some types of cable could be replaced before the proposed deadline, for others, it is predicted that this will not be possible and at least over six years will be needed. If the first choice of material proves to be unsuitable, or if any unforeseen issues occur, which is likely with very complex designs of cable assembly, manufacturers have predicted that this will take more than 5 years and so they could not meet a deadline of July 2019 but should be able to comply by July 2021, unless unforeseen circumstances occur. A CT scanner will not comply with RoHS until all of its constituent cables and other parts comply with RoHS.

Example timelines for CT cable substitution as well as many other applications are provided in an appendix.

### 4.2.4 MRI applications

Before any new materials can be used in MRI scanners, they must be tested to ensure that:

MR signal

- All materials (including wires and cables) used in or near the imaging volume of MRI scanners are required to not exceed a certain level of electromagnetic response in the frequency range of interest for MR imaging during and after exposure to electromagnetic excitation by MR transmit signals.

High voltage spikes

- Any material used within the MRI exam room shall be evaluated for potential built up of electrostatic energy that could release during imaging to an extent hampering MR imaging (spikes) as this distorts images.

Once a suitable material is identified, the procedural steps described above for CT cable assemblies needs to be carried out. Therefore the total timescale will be longer than for CT and meeting a deadline of July 2019 is not achievable, but MRI may be able to comply by July 2021, unless unforeseen circumstances occur.

### 4.2.5 Ultrasound transducer cables

Cables that connect to the transducer are the most critical part of the ultrasound system. The performance of the cable insulation could affect image quality and so alternatives need to be fully evaluated including with trials with patients. The reason why cables are so important for image quality is that medical ultrasound transducers are very complex designs with multiple transducer elements, each have its own electrical cable. Any stresses induced by cables affect the performance in unpredictable ways which in turn causes image distortion that makes diagnosis difficult or impossible. Durability of cables is also important so flexibility must not increase as this could cause stresses leading to distortion. Because of these additional requirements, manufacturers estimate that even without unforeseen problems, the timescale needed will be more than eight years (i.e. by end of 2022) and could be much longer with 10 years being a more realistic estimate.

## 4.3 Tubing

Tubing is very widely used in medical devices, for example:

- IVD analysers to transfer reagents, body fluids, blood, etc.
- Gases in respiratory support equipment and for anaesthesia. With these the flexibility of the tubing is critical for accurate gas pressure measurement and control
- Dialysis and other equipment for handling and treating blood that is transferred to patients
- Drug and fluids dosing equipment; where very accurate liquid flow rates are often needed
- Wound irrigation (transfer of wash fluid to open wound to remove bine debris, etc.). Must be sterilisable and not contaminate the sterile wound irrigation fluid.

PVC tubing sold separately would not be in scope of RoHS, whereas when the same tubing is installed in electrical equipment it must comply (the exception to this is tubing sold as a consumable, i.e. which is only used once before incineration). This could create a safety issue if

users of medical devices replace tubing with a different grade that has slightly different dimensions or flexibility as this could cause leaks or affect accuracy of analysers. This is not likely to occur with professional healthcare providers but is more likely with equipment used by non-professionals.

Essential properties of tubing and specific parameters that are required may be technology specific and as there are a very large number of applications, a lot of work will be required to identify, test and gain approval for substitutes. In recent years, concerns have been expressed over DEHP in medical tubing although a clear risk to patients has not been proven. Due to these concerns however, medical equipment manufacturers have considered alternatives, but in most cases have continued to use DEHP plasticised PVC because of its proven reliability and the considerable difficulty in finding replacements.

One essential requirement of tubing where the gases or fluids contact with patients is that they must be disinfected or sterilised. Hospitals use various methods including heat, chemicals and radiation and so tubing needs to withstand all of those methods that might be used. Ability to sterilise is a limitation for some materials, for example, tests by one medical equipment manufacturer showed that an alkylacetate plasticised PVC turns brown and becomes brittle when radiation sterilised.

Issues of replacements are considered as follows:

### 4.3.1 Suitability for human blood that re-enters patients' bodies

Tubing is used to transfer blood in many medical procedures including dialysis, transfusions, extra-corporeal membrane oxygenation, blood recovery and autotransfusion systems (used during surgery to collect, clean and then return a patient's blood), etc. However, most tubing is used only once and most equipment is not supplied with tubing, which is sourced by hospitals for use with their equipment. There are only a few medical devices where blood contact may occur and which have an electrical function so are in scope of RoHS. Therefore the following is applicable only to those very few applications.

As mentioned above, tubing used for blood is coated internally with heparin to stop clotting. Some plasticisers interfere with the heparin coating so that clotting occurs in the tube causing a blockage. Heparin coatings also have an additional benefit of inhibiting migration of DEHP into blood and this property is needed also with alternative plasticisers[3]. When a medical device is modified, such as by substitution of a plasticiser in PVC tubing, the manufacturer must at least carry out a risk assessment to show that there is no increased risk to patients. This is required by the Medical Devices Directives. However, one problem with carrying out a risk assessment of alternative plasticisers is that although some "No Observed Adverse Effect Levels" (NOAEL) or Lowest Observed Adverse Effect Levels (LOAEL) data is available for DEHP and some alternatives (note that most are not hazard-free), there is no data on the exposure levels of

alternatives and so it may not be possible or will at least be difficult to assess the risk from an alternative plasticiser to patients[5].

Another reason for using DEHP stabilised PVC for blood is that this material has a relatively high oxygen permeability which gives good blood platelet stability that is difficult to reproduce with alternative materials[3]. Another benefit found with DEHP plasticiser is that red blood cells stored in contact with DEHP-PVC show less hemolysis (damage to cells) than without DEHP[13]. Because of these issues, it is very difficult to replace PVC for tubing and other materials (taps, valves, etc.) used for blood contact.

Currently, in the EU only DEHP-PVC is approved for tubing used for blood that enters patients' bodies so manufacturers would not be permitted to use alternatives until these are approved. Approval would require very stringent and lengthy testing. Furthermore, as manufacturers make only one version of each medical device for sale globally, the tubing must also be approved in all other countries where it is used. For example, in the USA, there are US Pharmacopea (USP) designations for medical tubing which has six levels. Where circulating blood is involved for prolonged periods, Class VI is required and only DEHP plasticised PVC is approved. Different types of medical tubing are advertised including PVC with different plasticisers and also made with alternative polymers, but these are Class IV or lower (and PVC is needed for blood as described above). Very stringent testing is needed before a material can be approved for medical use in the EU or for US Class VI applications. Medical device manufacturers' experience has found that at least two years would be needed before an alternative could be approved for use due to the lengthy test and approval requirements in non-EU countries.

### 4.3.2 IVD analysis where one tube may be used for a wide variety of fluids

In-vitro diagnostics analysers are complex automated equipment that are able to analyse a very wide variety of materials such as blood and other body fluids for bacteria, viruses (such as Hepatitus C), cancers, drugs, etc. Manufacturers that provide comprehensive clinical laboratory testing will offer a full menu, e.g. 100 or more assays (e.g. infectious immunology tests, detection of drugs of abuse, establishing blood glucose levels etc.). A variety of analytical techniques may be used such as spectroscopy and chemiluminescence, both of which are very sensitive to low concentrations and both can be affected by trace contamination. Chemiluminescence is used to detect or measure many of the analytes (or markers) and relies on the emission of light from a chemical reaction. The emitted light level is measured to determine the concentration of the material of interest. This can be an extremely sensitive

[13] G. Rock, et al, Incorporation of plasticizer into red cells during storage, Transfusion, Vol. 24, No 6, 1984 and R. S. Labow, et al, The effect of the plasticizer DEHP on red cell deformability, Blood, Vol. 70, No 1, 1987.

technique, but the results are affected by a wide variety of contaminants. Heavy metals for example must be present at low part per million level, as higher levels are known to interfere with the chemiluminescence signal. Contamination from organic substances that desorb from tubing into reagents can also affect accuracy as the IVD tests which can be affected by extremely small amounts of contamination. Contamination issues are partly dependent on the design of the analyser and the analysis method. For example, if a solution of an enzyme is pumped through tubing, it must not interact with substances on the tubing surface as this will affect test result accuracy.

Luminescence techniques are selected by manufacturers as the detection systems of choice where these are suitable due to their extreme sensitivity which allows detection of molecules at the pmol (picomolar) level. This however makes the tests very sensitive to anything that can perturb the reaction rates and manufacturers' development and validation procedures have to include studies to ensure that the tests perform consistently at these very low levels. All changes to materials such as the types of tubing used, that could affect the performance of the luminescence reaction need to be comprehensively tested.

The tubing in IVD analysers is used to transfer both reagents and wash solutions. Each of the 100+ tests carried out by one analyser requires different reagents and the test results will be affected to some extent by different impurities. Replacing tubing that is used currently will require the following:

- Identification of an alternative that will have suitable physical properties for use in the analyser and is not likely to cause contamination
- As it is impossible to be certain whether the alternative tubing will affect accuracy, most of the tests carried out by the analyser will need to be validated using the full range of test materials and at all of the likely concentrations that need to be analysed.
- Some polymers adsorb and desorb materials and so it is also necessary to carry out sequences of different tests to make sure that one test does not affect the next. Of course, with e.g. 100 analysis procedures, there will be a very large number of sequences to evaluate.
- Some types of tube will deteriorate and this could affect test results and so longer term durability trials will be needed to determine when tubing should be changed and to ensure that test results are not affected by tube aging
- If any of the above shows that a choice is unsuitable, the entire process will need to be repeated.

The time required for the above procedures will be lengthy and will be needed for each model of analyser on the market as each carries out analysis in slightly different ways (different tests run on different technology platforms). It was for these reasons that the RoHS directive 2011/65/EU allowed two additional years for IVD medical devices than for medical devices. The

timescale required will need to be similar to that allowed by the original RoHS directive which was 10 years from the date when it became clear that IVD would be in scope of RoHS as a result from the 2006 ERA study until 2016 when these enter scope. Therefore, replacement of tubing will not be possible until 2026, 11 years after the date when the Commission intend to publish proposals to restrict the phthalates by RoHS.

### 4.3.3 Tubing for gases

Several medical devices are used for gases and with some, accurate pressure measurement and control is essential. Gas permeability is also important for some applications. For example, tubing that is connected to CO2 sensors must be impervious to CO2 to obtain accurate CO2 measurements in patients' exhaled breath.

Some examples include:

- Central apnea, Bradycardia, Tachycardia, and Oxygen saturation. These are life support devices that are used to continuously monitor breathing, typically of young children and infants. The monitoring equipment provides audible and visual alarms to alert carers, typically parents, when the infant or child experiences a cessation of breathing (central apnea), bradycardic event (low heart rate), tachycardiac event (high heart rate), or a decrease in oxygen saturation. These alarms are necessary for caregivers to respond to these events and provide proper care.
- Obstructive sleep apnoea is a medical condition where the walls of the throat relax and narrow during sleep, interrupting normal breathing. This can cause partial or complete blockage of airflow. The main effect is to cause tiredness due to constantly being woken up. Medical devices are used to provide a continuous supply of compressed air to treat the condition. These use tubing and some designs have heaters in the walls of the tube to warm the air.
- Ventilators of various designs are used to assist breathing for a variety of medical conditions. These devices provide either total ventilatory support or augment patient breathing in treatment of respiratory insufficiency. Failure of these devices can result in respiratory failure followed by death. Some are only used within hospitals and others are used in homes, outdoors, and in transit (e.g. ambulances). These pass air or oxygen into the lungs and it is important to control the gas flow and gas pressure. For this, the tubing must be sufficiently flexible to be comfortable for the patient and stay in place, but must be sufficiently rigid for accurate pressure control. Some models involve triggering the ventilator to deliver air or oxygen to the patient which requires very accurate pressure measurement and so any change in the performance of the tube could have a detrimental effect on the function of the ventilator
- Anaesthesia machines include several tubes for accurate flow control of air, anaesthetics and other gases. These need to accurately control gases by volume and pressure.

In conclusion, tubing used for gases often needs to have very specific properties and so the time needed to identify substitutes could be lengthy, in particular where there is patient contact.

### 4.3.4 Timescale for tubing substitution

The length of time needed to comply with substance restrictions will depend on the application. This is because patient contact requires additional safeguards, testing and trials. Tubing used for low pressure gases, e.g. to operate pneumatics are the simplest to substitute because there is no patient contact and contamination of gases is not an issue. Tubing used for blood, especially with lengthy contact periods and the blood passes into patients is the most critical and extensive testing and trials plus authorisation is needed, although most medical tubing used for blood is a consumable and new equipment such as dialysers are supplied without blood-contact tubing. The estimated timescales for the main types of uses for tubing are shown in the table below. A relatively recent requirement in the USA from the FDA is that tubing for fluids for patient contact and tubing for gases breathed by patients are required to be tested for stability in use. This requires real-time stability testing which can take up to five years as accelerated testing is not permitted. This greatly adds to the development cycle time especially if the first choice of material fails this test or after five years it is discovered that the original choice of plasticiser is more hazardous than originally thought (this has already occurred as discussed in section 3). Therefore, as a worst case up to 10 years may be required for these applications.

| **Main procedural stages** | **No patient contact and no contamination issues** | **Patient contact with fluids that pass through tubing** | **Tubing for gases breathed by patients** | **IVD analyser tubing where contact with many reagents occurs and high purity is essential** | **Extended blood contact** |
|---|---|---|---|---|---|
| Identification of substitute | 3 months | 3 months | 3 months | 6 months | 6 months |
| Biocompatibility assessment of tubing material | Not required | 6 months | 6 months | Not applicable | 1 - 2 years |
| Redesign | 3 – 6 months | Up to 1 year | Up to 1 year | Up to 1 year | Up to 1 year |

| | | | | | |
|---|---|---|---|---|---|
| equipment | | | | | |
| Reliability testing of materials, sub-assemblies and of complete equipment | 6 months | Up to 10 years | | 2 – 4 years | 2 years |
| Validation of procedures using new tubing | Not required | Not required | Not required | 1 to 2 years | Not required |
| Clinical trials | Not required | Depends on application, 1 year is typical if needed | Depends on application, 1 year is typical if needed | Not required | 2 years |
| Approvals for medical device legislation globally* | 1 year | Up to 2 years | Up to 2 years | 2 years | 2 years |
| Member State approval for Blood Directive[14] | Not applicable | Not applicable | Not applicable, | Not applicable | Up to an additional 3 years |
| Changes to documents, risk assessment, processes and production process | 3 months | 3 months | 3 months | Ca. 12 months | Ca. 12 months |
| **Total time needed (worst case)**** | **2,5 years** | **10years** | **10 years** | **Up to 11 years** | **Up to 14 years** |

* In the EU, Notified Bodies typically require up to 6 months between submission of data and issue of approval. Gaining approval in some non-EU countries takes much longer with some countries requiring additional testing. Two years is fairly typical but it is not uncommon for this to take up to 4 years in some countries. Medical devices are not sold in large numbers so the manufacturer usually cannot make one version for the EU and a different version for other

[14] Where blood is collected, there is additional national requirements that takes 2 – 3 years due to Directive 2002/98/EC

countries and so they have great difficulty changing their production line over to the new version until approval is gained globally.

** The total elapsed time needed will depend on many criteria. Worst case assumes; the most complex designs, there is a very high patient safety risk and that R&D is not straightforward. However, an important issue is the number of products and the number of parts that need to be changed by an individual manufacturer. The number of engineers available to each manufacturer is limited so a high workload can lengthen the timescale for substitution.

## 4.4 Ion selective electrodes

IVD analysis systems which use ion selective electrodes are intended for point of care (Emergency Department, ICU, Neonatal ICU, OR) or laboratory testing of blood gases, electrolytes, metabolites, total hemoglobin, and hemoglobin derivatives in arterial and venous whole blood samples. The systems are also intended to be used for the measurement of dialysate and pleural fluids.

This type of point of care testing allows for a shorter time to obtain test results, which enables faster therapeutic intervention as compared to traditional laboratory testing. More timely (quicker) intervention yields improved patient outcome. This is a different technique to the chemiluminescence and spectroscopic analysers described above and is used where results are needed very quickly.

### DEHP in ion selective electrode exemption

Several manufacturers of IVD equipment use membrane based ion selective electrodes that contain DEHP which is used as an ion transport medium (not as a plasticiser). The membranes contain an ionophore (the recognition element), polymer matrix, plasticizer and organic lipophilic salt. When exposed to a solution containing ions of interest a potential is developed at the membrane sample interface that is measured as a difference against a reference electrode. This potential difference is proportional to a specific ion's activity (i.e. its concentration). In body fluids, blood, etc. there are many ions and so each type of IVD ion selective electrode is designed to measure one specific type of ion. This is not straightforward and relies on the use of membranes that selectively bind the ion of interest. Without this selectivity, Na+, K+ and other cations would give similar responses and could not be differentiated. The selectivity and more importantly the clinical performance of these sensors are governed by the specific molecular structures and ratios of the membrane components. A change to a different plasticizer (even to a similar phthalate) will change the sensor selectivity, performance and clinical result. Therefore, no drop-in plasticizer exists.

Some manufacturers design their ion selective electrode modules so that they can analyse for an ion in several different types of fluid, for example in blood, pleural fluid, dialysate, etc. Each electrode must give accurate measurements in all of the types of fluids for which they are designed to operate, and changing a constituent of the membrane, will affect the analysis parameters in each type of fluid in a different way making substitution especially difficult. As electrode membrane compositions are specific for each ion, all of the electrodes that currently contain DEHP will need to be reformulated.

One example IVD analyser measures pH, pCO2 (bicarbonate ion concentration), pO2, Na+, K+, Ca2+, Cl-, glucose, lactate, tHb (total haemoglobin), haemoglobin fractions (oxyhemoglobin (O2Hb), deoxyhemoglobin (HHb), carboxyhemoglobin (COhb), methemoglobin (MetHb) ) and Neonatal total Bilirubin. These are measured in a variety of fluids including pleural fluid, blood and dialysate. One type of analyser uses ion selective electrodes that contain DEHP to measure K+, Na+, bicarbonate ion concentration (pCO2) and pH and this design of IVD analyser has a unique combination of performance parameters and functions. Some of these functions and characteristics are available with competitors' analysers but a few are unique to this one analyser. Ion selective electrodes are installed in special cartridges that also contain reagents. These cartridges give advantages to hospital workers in that they are easy to use and maintain so that a maximum number of analyses can be carried out each day. Each manufacturer makes its own design of cartridge that they are specific to their own analysers. Each cartridge is compatible only with one type of analyser for which it is designed and so it is not possible to use ion selective electrodes from one manufacturer in a different manufacturer's analyser.

Some of the unique characteristics of this example analyser are:

- Optical full CO-oximetry measurement on whole blood and not on a hemolyzed sample (faster and simpler analysis, as explained above).
- Sample types of whole blood as well as pleural fluid and dialysate fluid samples can be analysed.
- Glucose measurements which incorporate correction for interfering electrochemical substances in blood (exogenous and endogenous) via a separate, dedicated electrochemical electrode.
- Lactate measurements which incorporate correction for interfering electrochemical substances in blood (exogenous and endogenous) via a separate, dedicated electrochemical electrode.
- Automatic system detection of interference on ionized sodium results from quaternary ammonium salts.
- Maintenance free system requiring only a yearly filter change.
- Measurement cartridge available for testing 20 min after installation.
- Integrated bar code scanner.

- Optional integrated, manual ampoule breaker.
- Design minimises biohazard to operators. This includes the ion selective electrodes which become bio-hazards from use and so are incinerated and are excluded from the WEEE directive.

Other manufacturers' analysers also use ion selective electrodes with DEHP and these designs also have (different) unique combinations of performance and functions. Replacement of DEHP in these products will be equally difficult to the design as described above. Ion selective electrodes from one manufacturer cannot be used in analysers from a different manufacturer as each has to be specifically designed to operate with the unique algorithms and analysis procedures used by each analyser.

### Quantity of DEHP used in the EU for ion selective electrodes

The design and sales of IVD ion selective electrodes is proprietary so the total amount of DEHP used in this application is not known. However one manufacturer has estimated that they place less than 340 grams DEHP onto the EU market for this application annually.

### Timescale for substitution

- Reformulate types of sensors that use DEHP,
- develop new algorithms for each new sensor formulation,
- develop new manufacture processes and release criteria,
- establish new quality control values for production,
- establish new external proficiency sample bench marks for testing,
- verify and validate performance (over use life and shelf life) with all types of analytes,
- develop, validate and release new software,
- repeat all shipping studies.

Assuming that this work is not limited by the availability of suitable engineers and no steps need to be repeated due to unsuitable results, this technical development is likely to take, of the order of, 5 years. However, currently, IVD medical device manufacturers are still working on compliance with the RoHS recast directive to replace the original six substances and this work will not be complete until a short time before July 2016. Diverting more resources from new product development is not an option as this will prevent potential improvements in patient care because newer products are more sensitive, faster and cheaper to operate. More importantly, having additional engineers will not significantly reduce timescales as many of the activities must be carried out sequentially by individuals. Based on these constraints and taking into account that RoHS substitution is always found by manufacturers to take longer than they expect, a time period of 7 – 8 years is more realistic.

Once this work is completed, the manufacturer would then be required to gain re-approval under the IVD - Directive (CE mark) and also gain approval in all other countries where they

are sold (as only one design will be made for the global market), including the USA, Japan and China (which has an exceptionally lengthy re-approval process). The regulatory path is of the order of 2 years.

Total time to implement the change is at least 7 years and may be up to 10 years.

## 4.5 Labels

Plasticised plastic labels are used on components such as electrolytic capacitors and also on medical devices to provide mandatory information required by the medical device directives. It is essential that contact details are visible on medical devices in case hospital workers experience difficulties and need to seek advice. In some circumstances, obtaining this information quickly could have serious safety implication, for example if the equipment is needed in an emergency. Another use of the phthalates is in flexible adhesives and so flexible adhesive labels made of materials other than PVC could also be affected.

## 4.6 Capacitors and resistors

Materials declarations of many types of capacitors indicate that DEHP and DBP were quite commonly used until recently. However, information from some component manufacturers indicates that DEHP and DBP were replaced in 2011 and 2012 probably due to these being added to the REACH Candidate List. These substances are used as plasticisers in encapsulation polymers (mainly as a process aid) and the flexible plastic wrap labels of electrolytic capacitors. These materials are also used on some types of resistors. It is very likely most of these standard passive components will be available after 2019 without the four phthalates and so medical device manufacturers will have no choice but to use them and an exemption will be unnecessary, unless early obsolescence of components occurs as described in section 4.1.

The performance of replacement components in some types of medical device is very critical as this can affect image quality from ultrasound and possibly also from MRI and CT.

## 4.7 Other uses

### 4.7.1 Mouldings

Flexible PVC mouldings have many diverse uses from bellows for protecting ultrasound cables without restricting movement, to patient table covers that can be sterilised and do not harm patients. Time will be needed to evaluate the available DEHP-free PVC alternatives.

One older application is for the tanks used to hold chemicals in automated X-ray film developers. The tanks must be resistant to alkaline developer chemicals at pH 10 – 11 and for acidic fixing solution at pH ca. 3. Many materials are not sufficiently resistant to these chemicals so substitution would not be straightforward. This is a declining market so the manufacturer will

not invest in time or resources to find an alternative material for these tanks as this would not be economically viable. As a result manufacturer would be forced to stop selling this equipment in the EU market when the restriction takes effect although they do expect sales after July 2021. If these machines are not available, this would prevent hospitals from carrying out X-ray examination using film based X-ray equipment as they are unable to develop their films if their old developer machine cannot be replaced. Sealants, paints, inks, etc.

From review of safety data sheets, it appears that a small proportion of these materials contain plasticisers to give flexibility. Where these are used in a medical devices the substitute material needs to be evaluated to ensure that it does not negatively affect reliability. This is especially important for materials used on printed circuit boards (PCB) as these tend to have a larger thermal coefficient of expansion than the PCB so induces stress that can damage bonds and components if flexibility is lost. When added to paints and lacquers to ensure flexibility, these are important to prevent delamination due to the coating becoming brittle over time. If coatings peel of, corrosion can occur resulting in premature failure.

# 5. Discussion

Substitution of DEHP, DBP, DiBP and BBP in many cases will be technically feasible but often this will not be straightforward. The first difficulty (after identification of the phthalate) is selection of a substitute that:

- Has suitable performance and properties (including over the lifetime of the device)
- Is safer in terms of hazard classification and risk to human health and the environment, and;
- Will not in the future be restricted

For the reasons explained in section 3, this is far from straightforward. There are no drop-in replacements as all have different properties, an additional major concern is that some of the substances that a few years ago were thought to have no hazard classification are now suspected as being possible PBTs or endocrine disruptors.

In many medical device applications, the performance of the plasticised material or the component containing the phthalate could be very significantly affected in a way that could affect patient safety and so extensive testing is needed before it can be used. In other cases, the restriction will cause component suppliers to make older components obsolete and use of alternatives will require new PCB designs and often also new software. All of the activities required by the Medical Devices Directives can take a long time, especially as unforeseen results are likely which cause delays or having to repeat activities. Several illustrative timescale charts are included in the appendix to show the activities required, how long each takes

(minimum and maximum timescales) as well as the effect of unsatisfactory results at certain stages.

Several types of medical technology are described here where no alternatives are currently known and so exemptions would be justified based on the criteria of Article 5.1a. These are:

- Very flexible cables used to connect moving parts, such as robotic arms, to ultrasound transducers, ECG and defibrillators.
- Tubing (including connectors) for blood that re-enters the patient
- Tubing (including connectors) for IVD analysers
- Tubing (including connectors) for gases or fluids that come into contact with patient
- Ion selective electrodes
- Integrated circuits

If potential substitutes exist but there is insufficient evidence on the long term reliability of a material in medical technology, it should not be considered as a viable substitute. This situation occurs with all of the above applications..

It is worth considering that if medical device manufacturers do not have sufficient time to comply with new restrictions, manufacturers will have to stop sales in the EU. This would negatively harm patients in the EU. Negative human health effects are an acceptable criteria for granting exemptions.

Replacement labels, simple cables and passive components should be possible within a 5 years' transition if no unforeseen issues occur. However, it should be noted that IVD medical device manufacturers will not have completed substitution of the original six RoHS substances until July 2016 and so they will have less resources available for phthalate substitution before this date.

# 6. Conclusions and time needed for applications

The results of this review show that the time needed for substitution varies greatly for some applications. The following table gives an indication of the time required (from least to most time required) assuming that substitution is not straightforward and that work has to be repeated due to poor results. This is realistic as research can never be guaranteed to identify a suitable alternative without encountering problems. The timescales below are explained either in the applicable parts of section 4 or in the appendix, part B.

| Uses of phthalate and applications | Estimated date when substitutes will be available and medical devices approved |
|---|---|

| | **for sale or it is known that an exemption will be required** |
|---|---|
| Off-the-shelf passive components | Many have already been replaced by suppliers |
| Simple cables and wiring | Most have already been replaced by suppliers |
| Plastic parts and sealants | End of 2019 |
| X-ray equipment cables | 2021 |
| General purpose cables | By 2020 |
| Tubing – pneumatic, vacuum – non patient contact | Should be possible before July 2021 |
| CT cables | By mid-2021 |
| MRI cables | By end of 2021 |
| Integrated circuits which contain DBP plasticisers in die attach material[15]. | 2029 |
| Flexible cables for connection to moving parts; such as ultrasound transducers, defibrillator patient cables such as for SpO2 sensors, temperature probes, fetal scalp electrodes, cardiac output probes, TCpO2 probes IUP (intrauterine pregnancy) cables, etc., cables that connect to X-ray sources that are moved to precise positions around patients, ECG cables and cables connected to IVD instrument robotic arms | Mid - end 2025 |
| Ion selective electrodes | 2025 |
| Tubing and associated connectors and valves used with fluids for patient contact (e.g. | Should be possible by July 2025 |

[15] This exemption is needed only for models of medical devices that are designed before 2019. This will allow manufacturers sufficient time to replace these older models by new products, including time for reliability testing and gaining approvals using newer ICs that do not contain DBP

| | |
|---|---|
| wound irrigation) | |
| Tubing and associated connectors and valves used with gases for assisting and monitoring breathing and anaesthetics | Should be possible by July 2025 |
| DEHP in tubing used for transport of diagnostic reagents or solutions and patient samples within in vitro diagnostic instrumentation | By 2026 |
| Tubing and associated connectors and valves for blood that re-enters patients | By 2029 |
| Developer trays for X-ray film machines | July 2021 |

The following exemptions will be needed if the compliance deadline for category 8 is July 2021:

- DEHP in ion selective electrodes until July 2025
- DBP in integrated circuits until July 2029
- DEHP, DBP and BBP in flexible cables for connection to moving parts, e.g. ultrasound transducers, defibrillator patient cables, ECG patient contact cables and cables connected to IVD robotic arms until July 2025
- DEHP in tubing used for transport of diagnostic reagents or solutions and patient samples within in vitro diagnostic analysers until July 2026
- DEHP in tubing and associated connectors and valves used for blood that re-enters patients until July 2029
- DEHP in tubing and associated connectors and valves used with fluids for patient contact (e.g. wound irrigation) until July 2025
- DEHP in tubing and associated connectors and valves used with gases for assisting and monitoring breathing and anaesthetics until July 2025

If the compliance deadline is earlier, for example July 2019, the following exemptions will also be required:

- X-ray equipment cables
- General purpose cables
- CT cables

The suggested expiry dates listed above are based on the technical issues and required activities that are described in this report and reflect the time needed to comply. Exemptions in Annex VI of the RoHS Directive have validity periods of up to seven years from the date that the equipment enters scope of RoHS. Seven years from July 2014 (for MDD) or July 2016 (for IVDD) will be before the above dates, but seven years beyond July 2021 is enough for most of the above applications.

It is worth mentioning that the quantities of the four phthalates used in these applications are relatively small in comparison with global production. The major uses in passive components, PVC cable and wire and most sealants, adhesives, etc. have already been phased out. Most medical PVC tubing is not in scope of RoHS as it is purchased and used by hospitals and most medical devices are supplied either without tubing attached or with replaceable tubing. The remaining uses are very specialised and so represent relatively small quantities. DBP is believed to be used in only a very small proportion of ICs. It is only used in types of IC that generate heat and so need silver loaded die attach material, whereas most ICs do not need to be heat conductors. X-ray imaging with film is now relatively uncommon in the EU and declining so that the film developer machine manufacturers do not expect many sales in the future.

# Appendix:

## A. Results of ERA Review and lessons learned regarding timescale needed for substitution

The RoHS directive was first considered by the EU about 18 years ago. Directive 2002/95/EC was adopted in January 2002 and the restrictions took effect in August 2006. However, at that time, medical devices were excluded from its scope due to concerns over the safety and reliability of RoHS compliant medical devices.

In 2006, ERA was awarded a contract from the European Commission to determine if it would be possible to include medical devices (and monitoring and control instruments) in the scope of a recast RoHS directive. After a very detailed review, ERA concluded that inclusion in scope was possible, but manufacturers needed sufficient time and a number of exemptions. This study was completed in mid-2006 and recommended that restrictions were imposed after at least six years to allow medical device manufacturers sufficient time to comply and an additional two years (so 8 years from 2006) for IVD equipment. The recast RoHS directive 2011/65/EU allowed even more time so that restrictions did not take effect until 2014 and 2016 respectively which was 8 years after the ERA review for medical devices and 10 years for IVD. This has been sufficient time for medical device redesign as compliant medical devices are now being produced. This has also been sufficient time to identify all uses of the six substances, determine if reliable alternatives exist and where none are available to request and be granted exemptions before the 2014 deadline. All of these activities could not have been done in less time as many products were not fully compliant and approved for sale in the EU until a short time (< 1 year and some < 6 months) before July 2014. The timescale is shown below:

| Year | Regulatory activities | Industry activity |
|---|---|---|
| **1998** | RoHS first proposed | |
| **1999** | | |
| **2000** | | |
| **2001** | | |
| **2002** | RoHS directive adopted, but excluded category 8 | Industry initiated R&D to identify substitutes |
| **2003** | | |
| **2004** | | Some RoHS compliant components begin to become available |
| **2005** | | Most components comply by end of 2005 |
| **2006** | Restrictions enter force. ERA review carried out | Most manufacturers had difficulty complying by RoHS deadline |
| **2007** | | |
| **2008** | | |
| **2009** | Recast proposed by EC | Medical device manufacturers already working on compliance with RoHS |
| **2010** | | |
| **2011** | Recast adopted | Exemptions for medical devices requested |
| **2012** | | More exemptions for medical devices requested |
| **2013** | | |
| **2014** | Restrictions enter force for medical devices | Medical devices comply by July |
| **2015** | | |
| **2016** | Restrictions enter force for IVD medical devices | |

The 2006 review by ERA for the Commission was carried out to answer one question: "Is it possible to include categories 8 and 9 in the scope of the RoHS Directive"? The answer was yes, but time and exemptions were needed to comply. This study did not consider the possibility of additional substance restrictions because in 2006, none had been considered or proposed and so the conclusions were based solely on the original six RoHS restricted substances. However the timescales agreed subsequently (22 July 2014 and 2016) have been challenging for medical device manufacturers who have managed to comply only a short time before the 2014 deadline. IVD medical device manufacturers are still working on compliance. These timescales therefore should be an indication of what will be needed for additional RoHS restrictions if the substitution of the substances are as technically difficult as the original RoHS

six. As with the first six RoHS substances replacement of the four phthalates will be relatively easy in some applications, but very difficult in others. This is described below.

### Resource limitation

It was described in ERA's report on the possibility of including categories 8 and 9 in the scope of the RoHS directive, that one limitation on the time required to comply is the availability of suitable engineers with the experience and expertise to carry out the work to redesign and assess compliant versions of medical devices. The pool of engineers available globally is limited and so the medical industry cannot shorten the timescale by employing more engineers. If one manufacturer recruits at the expense of a competitor, their competitor's timescales will lengthen.

### Conflict with new medical devices development

The medical sector is in one way completely different to other types of electrical equipment. Medical devices are used to cure illness and save lives and so manufacturers are constantly carrying out research into products with better performance that will improve patients' chances of being diagnosed correctly and of being cured. The engineers who develop new products would be the same engineers that have the necessary expertise to design and develop RoHS compliant versions by replacing substances. These would need to be diverted to RoHS compliance in order to shorten the time needed to comply with substance restrictions as far as is feasible. This can be achieved only however only at the expensive of developing fewer new products and so having to comply with RoHS could harm human health in the longer term due to diverting resources and this may also indirectly result in increased healthcare costs.

Currently, healthcare costs in the EU are increasing due to an increasing and aging population. There is a need to reduce treatment costs and manufactures are responding by research into new types of medical devices. More sensitive MRI and CT, for example detect illness earlier which improves survival rates, but also makes treatment easier and therefore at lower overall cost. Another fairly recent example is the gamma knife used for treatment of tumours and cancer. Tumours can be destroyed by a single treatment with the gamma knife, whereas traditional treatments require many separate radiotherapy sessions, which have a much higher cost to healthcare providers. Therefore, there is a realistic need for medical equipment manufacturers to continue to invest in new products and there needs to be a balance between investment in new products and investment in RoHS compliance. The ERA report recommended that manufacturers be allowed sufficient time to allow for both activities to be carried out.

### Timescale for achieving compliance

There will however be a limit to how quickly the activities required for compliance can be carried out, irrespective of the number of employees available. Redesign times cannot be

accelerated by more people as the design of each product or module is often carried out by a single design expert or at most a relatively small team. The time required for reliability testing cannot be shortened if the results are to be realistic and represent real life conditions.

- Accelerated testing, such as by temperature and humidity cycling, vibration, etc., is carried out by using more severe conditions than are experienced in real life. But the larger the difference between test conditions and life conditions, the less reliable are the results and they can be meaningless if conditions are too severe.
- For some applications, clinical trials may be required. This can be very time consuming as first recruits need to be found for the trials and this can take several years for rare illnesses and many months for relatively common conditions. The trials themselves can take several years although this depends on the type of treatment.
- When re-approval by a Notified Body is required for the Medical Devices Directive, this process will take up to 6 months. Approval in non-EU countries often takes much longer than the EU (i.e. from two years to up to four years for some countries). Manufacturers do not want to stop producing the older version until approvals are gained in all countries where they will be sold as usually, there is only one version of each product sold globally in the EU and outside of the EU.

**Workload of medical equipment manufacturers and time needed to comply with new restrictions**

The first stage to comply will be to identify where the five substances are used and once this is known, alternative materials and components will need to be sourced. Once these are available, they will be assessed in medical equipment and performance and reliability testing can begin. Each of these three steps will take time to carry out. Moreover, each step cannot begin until certain preceding actions are completed as described here. Further delays will occur when no suitable alternative component is available so that equipment has to be redesigned. This is very time-consuming and expensive and has been a common cause of older medical products becoming obsolete rather than being modified to comply with RoHS by July 2014. It may seem to be a benefit to stop selling older models if new designs provide better healthcare, but this is not always the case. Older models are often cheaper and provide the required performance. Healthcare providers' budgets are always limited so if they are no longer able to buy these older, cheaper products, they would be able to buy fewer new, but more expensive alternatives.

**Identification of current uses**

When RoHS was adopted in 2002, industry was unaware of the substances present in the parts and components that they used. It took a great deal of time and effort to find information on RoHS substances and as a result most component manufacturers were not able to supply compliant components until less than one year before the compliance deadline. This was

especially difficult for plastics that were sourced from Asia. Supply chains are complex with many different suppliers of raw materials feeding into supply lines so that not only finding out which substances are present but also ensuring that the RoHS substances were not used was especially difficult. This difficulty will inevitably be repeated if the phthalates are restricted.

To some extent, finding information on the five substances should be slightly easier as they have been REACH SVHCs for several years. This has meant that if they are present at >0.1% by weight of an article, the supplier should inform the recipient. However, experience of European manufacturers and importers is that their suppliers are very reluctant to provide SVHC data. It is quite common for an importer to manage to obtain a definitive response for less than 50% of the parts that he imports. A possible reason might be that the supplier does not know and they have difficulty finding an answer. However, another reason may be that the SVHC is present but the supplier does not understand REACH and incorrectly assumes that they are restricted and so they will not admit to their presence.

Another limitation of REACH SVHC data is that the 0.1% concentration limit is not the same as for RoHS. The REACH SVHC limit is for articles, whereas the RoHS limit is for homogeneous materials. It will be quite common for phthalates to be present in materials at >0.1% (such as in an adhesive), but at <0.1% of the article. This situation will occur for example when they are present in inks, adhesives, paint or in lacquers and so the REACH SVHC data will indicate that the substance is absent, whereas one of the constituent materials of the article may have >0.1% so will not comply with RoHS. In effect therefore, industry will need to start obtaining information on parts they use now and previous experience showed that the original six RoHS substances in 2002 and REACH SVHCs, so this will take at least 2 years to complete.

**Sourcing alternatives**

Medical equipment manufacturers do not manufacture plastics or electrical components and rely on a large number of suppliers for that parts and materials that they use to construct their products.

All equipment is constructed from a very large variety of components. Most are not unique to the medical sector and so compliant versions will be needed by July 2019. This is less than five years from now and a great deal of work will be needed to determine if any of the substances are used, reformulate and test materials and construct and test components before these can be supplied to customers. When RoHS was adopted in 2002, industry had more than four years to comply, but compliant components were not widely available until less than one year before July 2006. If this timescale is repeated, then compliant components will not be available until only a short time before July 2019.

Many medical devices are constructed from sub-assemblies built by suppliers and these suppliers will have the same issues as discussed above in finding out if any of the five

substances are present. As a result, these sub-assemblies (e.g. power supplies) will not be available until uses are identified, alternatives are available and new designs are constructed and tested. As sub-assembly suppliers will not be able to obtain compliant components before the beginning of 2017, compliant sub-assemblies may not be available to medical equipment manufacturers until at least a year later, in 2018. At this time, the medical equipment manufacture can start evaluating the new sub-assemblies but testing, gaining re-approval etc., may not be complete by July 2019.

Medical device manufacturers are in the process of identifying uses of the four phthalates. One has discovered that up to 50% of their very large number of PCBs contain at least one of the four phthalates and this is in applications other than as IC die attach. Changing a material such as an adhesive or sealant on a PCB will require work to ensure that the alternative does not affect reliability or safety. This is time consuming and where a manufacturer has several thousand PCBs to change, due to limited numbers of engineers this will take many years to complete.

# B. Implementation timescales

Six illustrative example timescales have been estimated and are provided below. These show the main steps required to make substitutions, how long they might take and if they need to be carried out sequentially or can be carried out simultaneously.

Substitution requires many steps to be carried out. The flowchart shown below includes all steps that might be required and is used to estimate the following six timescales. The flowchart shows what is likely to be expected from a typical substitution of a phthalate in a medical device.

The following flowchart represents a simplified process for substitution of phthalates in medical devices. To determine the time required a general scenario has been developed on the basis of the experience with RoHS process gathered so far:

- The first alternative selected fails the test at component level, therefore a new one has to be selected and evaluated.
- The new component fails the tests at system level, therefore redesign is required.

Redesign is limited to the component or system without the need to look for a third alternative. This is not unlikely to occur.