COCIR
Brussels, Belgium

Medical Equipment SRI

Investigation on Methodological Approaches to include Ecodesign Requirements on the use of Hazardous Chemicals in the COCIR SRI.

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1 INTRODUCTION

Medical devices placed on the EU market must comply with both the Medical Devices Regulation (MDR) 2017/745/EU and the Restriction of the use of certain Hazardous Substances (RoHS) Directive 2011/65/EU and its amendments. Both include substance restrictions but the approaches used are very different.

The medical industry has complied with the RoHS Directive since 2014 and report that this is very costly financially as well as administratively in terms of time occupied by employees who would otherwise be developing new medical technology. Category 8 was included in scope of RoHS after a study carried out by ERA Technology Ltd. (now RINA Consulting Ltd.) in 2005/6 for the European Commission with the aim to determine whether inclusion was possible. Determination as to whether inclusion would be overall beneficial was outside the prescribed scope of this study although an impact assessment was carried out by the Commission[1] which estimated costs that far outweighed any benefits.

The MDR Annex I section 10.4 requires substitution of carcinogens, reproductive toxins and mutagens (CMR) of category 1A and 1B as well as endocrine disrupting (ED) substances, of which the EU has two classifications, 1 and 2, unless the manufacturer can show that the use of the substance is justified from a benefit – risk analysis. The scope of these requirements is limited to materials that come into contact directly with patients or in contact with solids, fluids or gases that are administered or re-administered to patients.

RoHS is different and restricts currently 6 types of substances increasing to 10 substances from July 2021. Restrictions apply to all homogeneous materials used in electrical equipment including medical devices unless the use is permitted by an exemption. Exemptions are granted only on the basis of three criteria: that substitution is scientifically and technically impractical; if reliability cannot be assured; or if the overall health, safety and environmental impact of the RoHS substance is less negative than the overall health, safety and environmental impact of substitutes.

At the same time companies have to comply with requirements on substances from legislation worldwide and with specific black-lists coming from clients or purchasing organizations, although EU legislation is usually the most comprehensive.

COCIR has established a self-regulation initiative (SRI) and this includes the eco-design of certain types of medical imaging devices. COCIR is considering to extend the SRI to the management of hazardous chemicals as a voluntary approach to foster substitution of hazardous substances using as a basis the MDR approach and applying it also to devices, parts of materials that are not in contact with the body COCIR has asked RINA to carry out an investigation to determine how this might be achieved.

2 Identification of substances (CMRs and EDs)

The COCIR SRI intends to address a single substance every year, identified as relevant, and in case of multiple applications of that substance, only a few applications will be addressed. Given the high number of hazardous substances used in MDs, the selection of relevant ones is a first critical step. CMR (1A and 1B) and ED substances are good candidates (although RoHS can and does restrict substances with other classifications).

The MDR defines CMRs using the definitions from the REACH Regulation (1907/2006), but does not provide a list of substances. EDs are also defined by the REACH Regulation although these can also be as defined by delegated acts to the Biocidal Products regulation (528/2012), although none have so far been published. Therefore manufacturers need to identify CMRs and EDs themselves.

2.1 CMRs

There are various lists published but the definitive one that should be used is the ECHA Classification and Labelling Inventory (C&L I). This lists the hazard classifications of all hazardous substances used in the EU. Some classifications are determined by the EU as harmonized classifications, which must be used by all manufacturers,

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[1] http://ec.europa.eu/environment/waste/weee/pdf/ia_report.pdf

importers and distributors; these are the most reliable. There are also classifications submitted with REACH registration dossiers and from REACH notifications from industry, some of which may not be correct. Harmonised classifications are reliable. REACH registration classifications are determined by manufacturers based on testing and so should be correct whereas notification classifications are the least reliable as no evidence is required.

It is possible to search the C&L I by hazard classification and for category 1A and 1B CMRs. Six separate searches are needed (searching for 1A and 1B carcinogens together identifies only those substances which have been classified as both 1A and 1B, not 1A or 1B only). Search results can be downloaded as Excel spreadsheets[2].

Classification	Number listed
Carcinogen 1A	1,059 substances, of which 336 are harmonised classifications
Carcinogen 1B	1,707 substances, of which 692 are harmonised classifications
Mutagen 1A	232 substances, of which none are harmonised classifications
Mutagen 1B	900 substances, of which 429 are harmonised classifications
Reproductive Toxin 1A	692 substances, of which 27 are harmonised classifications
Reproductive Toxin 1B	1,572 substances, of which 232 are harmonised classifications

There are therefore a very large number of category 1A and 1B CMRs and the list is still growing. However, lists of each of the six classifications include many duplicates as many substances are carcinogens and also reproductive toxins, etc. If duplicates are excluded, there are about 4,400 CMRs in the ECHA database. The MDR however requires manufacturers to consider only those substances that have harmonised classifications as CMRs, which is a shorter list, with about 1,200 substances classified as CMR 1A and 1B.

The actual list of substances that need to be considered is, however, a very much shorter list as those substances that do not occur in medical devices can be excluded. This would exclude substances used only in processes that are not present in the medical device as well as substances with specific uses that are not medical device uses, such as pharmaceuticals, petrochemicals and herbicides. RoHS restricted substances could also be excluded (unless exempted) and also substances that will occur only as trace impurities such as the polycyclic aromatic hydrocarbons.

One option for COCIR members is to use the California Proposition 65 list of substances that may occur in Medical Devices. This said, it must be treated with caution as:

- California Proposition 65 does not use the 0.1% concentration limit, so many substances can be excluded, such as the polycyclic aromatic hydrocarbon compounds which are usually present at <0.02%.
- California Proposition 65 includes some category 2 CMRs such as antimony oxide.
- California Proposition 65 includes only carcinogens and reproductive toxins. Substances that are mutagens or EDs but not carcinogens and reproductive toxins are not included.
- California Proposition 65 does not include all of the CMR substances listed in the ECHA C&L I.

A more reliable approach would be to select applicable substances from the total list of about 4,400 CMRs to generate a suitable shorter list.

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[2] Searched on 15th January 2018. Note that substances are frequently added so the current totals may be higher.

2.2 EDs

As stated above, there is no single up-to-date list of category 1 and 2 EDs as defined by the EU. Also, it is not possible to obtain this information from the C&L I. However, various lists do exist which could at least initially be used by medical device manufacturers. These include:

- The European Commission funded a study in 2000 carried out by BKH to assess 564 substances proposed by various organisations[3]. This study produced several lists which are available from the ECs website. It includes a list of 146 substances with endocrine disruption classifications of 1 to 3 (3 = not an ED) and specifically human EDs and wildlife EDs. These lists are now out of date as a lot of research has been carried out since this study was completed and more EDs identified.
- The Danish Government has published a list of 194 substances that it regards as category 1 ED substances. This particular list was published in 2010[4].
- The REACH Candidate List of Substances of Very High Concern (SVHCs). There are only five human endocrine disrupting substances that are classified as SVHCs in the REACH Candidate List (BPA, DiBP. BBP, DEHP and DBP). There are nine wildlife endocrine disruptors that are SVHCs, but these may not be relevant to the MDR Annex I section 10.4 requirements.

The USA is screening 109 substances for endocrine disrupting properties but has not yet published a list. Japan has published a list of 67 suspected endocrine disruptors, but most are not yet confirmed.

To date, all substances classified as EDs by the EU are also CMRs and a list of CMR and EDs is the same as a list of CMRs only.

2.3 Applicable substances

Although there are a very large number of substances that are classified as CMRs or EDs, most can be discounted as they would never occur in medical devices at >0.1% (either by weight of the device or in homogeneous materials). A large proportion are used only as process chemicals, many are petrochemical intermediates and a significant number are used only as agricultural biocide or medicinal drugs.

RINA estimates that there are about 4,400 unique CMRs and EDs although only about 1,200 CMRS 1A and 1B with harmonised classifications, however of these less than 200 and probably less than 100, could occur in medical devices. These substances would include:

- Flame retardants
- Plasticisers
- Polymer stabilisers
- Polymerisation catalysts (although most are <0.1%)
- UV absorbers
- Anti-oxidants
- Pigments
- Resins with unreacted monomer impurities (but usually at <0.1%)
- Beryllium alloys for springs
- Lead added to alloys as a machining aid (RoHS exempt).

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[3] http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm

[4] http://eng.mst.dk/chemicals/chemicals-in-products/endocrine-disruptors/the-eu-list-of-potential-endocrine-disruptors/

2.3.1 Substance selection process:

This procedure would need to be agreed as it will not be feasible for COCIR members to consider many substances simultaneously.

One option is to consider requests from clients as guidance, for instance:

- http://saferchemicals.org/get-the-facts/business-case-studies/kaiser-permanente-case-study-using-safer-chemicals-in-products-supports-preventive-health-care/
- https://noharm-uscanada.org/saferchemicals

Other issues may necessitate some substances being prioritised such as proposed additional RoHS restrictions. This is considered in more detail here.

2.3.2 Future RoHS restrictions

Unlike the MDR, future RoHS substances could be those with classifications other than CMR category 1A and 1B or EDs. The most recently announced study of potential RoHS substance restrictions includes antimony oxide which is a category 2 carcinogen and tetrabromobisphenol A which is classified as aquatic acute and chronic category 1 but is not classified as being harmful to humans.

For a substance to be restricted by the RoHS Directive, it is necessary only for the EU to comply with Article 1 which states:

"…restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE"

Article 6 defines the procedure for adding substances to Annex II, but does not limit the Commission's or the EU's ability to restrict additional substances. It is not necessary to prove that an uncontrollable risk exists (unlike REACH restrictions) and it is not even necessary for suitable alternatives to exist.

As part of the last recast review, the Commission awarded a contract to the Austrian UBA to consider additional RoHS substance restrictions and to propose a suitable methodology. Unfortunately, this study was unsatisfactory in many respects. Some of the suggestions and contributions from industry appeared to have been largely ignored and the resultant priority list of substances included many that are never present in electrical and electronic equipment. Attempts to refine the methodology were subsequently started by the Commission but have not been completed. Therefore, the methodology is as defined in Article 6 of the Directive. Member State proposals need to provide the information listed in Article 6.2 (although this gives no indication of the level of evidence required). The Commission need to consider the issues in Article 6.1, but in practice none of these are barriers to further restrictions. Article 6.1 does state that to achieve the aim of Article 1, the Commission must take account of the precautionary principle and carry out a review, based on a thorough assessment and during that review, the Commission shall consult interested parties. This highlights several points:

- Precautionary principal – often misunderstood and incorrectly used. This should be interpreted that a ban is justified if there is clear evidence of harm although not proven and that substitution would eliminate this possible harm. It is wrong to use this principal only because a substance is hazardous and it is essential to consider whether substitutes are safer as the precautionary principal applies to these substances as well as the ones being considered for restriction. If a ban would not protect health and the environment, then perhaps alternative measures should be considered, as is the approach used by REACH.
- A review, based on a thorough assessment – typically the Commission would ask consultants to do this. Unfortunately, both previous additional RoHS substance studies have been poorly carried out with very unsatisfactory results that the Commission could not use. The first in 2007 by Oeko ignored substitutes and industry suggestions and the consultants did not appear to understand chemistry (as they proposed many process chemicals) or electrical equipment. The more recent UBA study had similar issues. The

next review will be by Oeko again so it will be of great concern to industry that this is carried out as an unbiased scientific study that does not aim to rubber stamp proposed restrictions that are not justified.

- Consultation with stakeholders are standard for EC studies. Although this is an opportunity to provide data and comments, there will also be comments from NGOs and Member States that are not always scientifically based. Furthermore, from previous experience, the consultants may ignore information that does not fit with their preconceptions. Industry clearly must be co-ordinated and proactive to have a chance of exerting any influence and should be prepared to lobby the Commission, MEPs and Member States as well as providing detailed stakeholder contributions to avoid undesirable outcomes.

The UBA methodology, in principal considered the quantity of exposure and the minimum amounts that cause harm (such as NOAEL, see section 3.1.2), but does not actively obtain reliable data on exposure levels (unless in publications). This essential data may be available from monitoring industrial WEEE recycling sites, and so would necessitate collaboration with EU industry. The impact of the four RoHS restricted phthalates on human health from electrical and electronic equipment was determined by UBA using many separate assumptions that in combination was unjustified and resulted in conclusions that were too inaccurate to be able to determine whether restrictions were necessary or not. The environmental harm was not considered despite a previous – and much more comprehensive – EU impact assessment concluding that a risk to the environment may occur, although this was from all uses, not just electrical and electronic equipment, and so a REACH restriction would be needed to eliminate this risk if it cannot be adequately controlled. The EU impact assessment did not identify a risk of harm to humans, which is why the four phthalates are not banned in the EU except in children's products.

3 METHODOLOGIES FOR ASSESSMENT OF EXPOSURE/RISK FOR HUMAN HEALTH AND ENVIRONMENT

"Risk" as applied to exposure to hazardous substances is determined from both the quantity to which humans or the environment are exposed and also the minimum quantity that is known to cause harm. Before going any further, it worthwhile explaining these variables.

3.1 Level of Risk

Risk is the likelihood that a hazardous substance will cause harm to humans or the environment. If no harm is possible, then there is no risk. However if there is a possibility of harm then there is a risk, although the risk may be negligible depending on the exposure level and minimum amount that has been found to cause harm.

3.1.1 Exposure levels

Exposure levels from hazardous substances ideally need to be measured for an accurate estimate of risk. However, it is necessary to consider exposure to:

- Workers
- Humans via the environment
- Humans as consumers/equipment users
- The environment.

Workers: Measurement of exposure by workers in factories is probably the easiest as methods have been developed to analyse the air that they breath as well as monitoring blood and urine to calculate the level of exposure, for example as mg/day or by airborne concentration as ppm or mg/m^3. Maximum workplace exposure limits exist in EU States for many hazardous substances and so exposure levels are often measured to ensure compliance. Health screening may also be carried out but does not directly measure exposure levels.

Consumers: Exposure by the public is more difficult to measure. EU citizens may be exposed to a substance from multiple sources and these will vary depending on location, i.e. if the person lives near to a factory, in a city or in a rural location and whether they use products in the home that contain the substance. This results in huge variation in likely exposure levels although regulators should consider the worst case situations to protect all EU citizens.

Methods commonly used to measure levels of exposure include:

- Simulated exposure by laboratory testing of products in artificial sweat (for dermal exposure) or artificial saliva for products that are placed in the mouth.
- Exposure to substance in containers used for food is measured using simulated food materials
- Exposure from food by analysis of a wide variety of food types. Food may be contaminated with substances arising from air, soil or water-borne contaminant.
- Air concentrations, such as in rooms can be measured. This can analyse for particulates as well as vapours.
- Drinking water analysis

Consumer exposure can be measured as the total from all sources. EU REACH restrictions may be adopted if the level of exposure exceeds known safe levels and this cannot be controlled by other methods. Therefore, if the proportion of total exposure due to a substance from one type of product exceeds the known safe level, then there is a proven risk, a restriction would be justified and should be effective. However, if a type of product provides only a small percentage of the total exposure from a substance and the health risk is due to this substance from other sources, then alternative measures are needed to be effective.

Environment: Exposure to the environment will depend on the chemical and physical properties of the substance. Emissions can be to air (as fumes), water (from waste water disposal) or land (disposal of solid waste). However this is more complex as air emissions can be deposited onto land and into water when they are washed down by rain. Also, substances in land (i.e. soil) can be washed into water supplies by rain. Some substances are very stable, i.e. persistent and so decompose in the environment very slowly and levels can then gradually build up, however most substances will react in some way. Many organic substances biodegrade in water and so may disappear altogether after a fairly short period so that the concentration in water can be very low or negligible.

Biodegradation or chemical reaction can however convert one hazardous substance into different hazardous substances that may pose a different risk. For example, the RoHS -restricted flame retardant decabromodiphenyl ether (deca-BDE) is classified as being persistent but is not classified as being toxic by most notifiers[5]. Research has shown that it degrades very slowly in the environment to other polybrominated diphenyl ethers (such as hexa-BDE) and these substances are classified as being category 1 aquatic toxins and are also toxic to humans. However, these substances degrade (to safe by-products) much more quickly than deca-BDE and so the concentrations of, for example, hexa-BDE that are reached at any time will be extremely small as decomposition is faster than formation so levels of exposure are correspondingly very small.

Chemical analysis of water (rivers, lakes, sea, etc.), soil and river sediments can be carried out and many standard methods have been published. Concentrations in air in chimney emissions and in air downwind of chimneys close to factories can be and are routinely measured, but the concentrations of most industrial chemicals in the general environment will usually be too low to be measurable. Some substances in air are regularly measured, though, such as NOx, SO_2 and, particulates, but most of these have multiple sources (vehicles as well as factories and power stations) and it can be difficult to estimate the proportion from one specific source.

Exposure estimation: The only reliable method to determine exposure is by measurement. This can be expensive to carry out though. There are impact assessments published for some hazardous substances as well as research papers that describe publications of measured exposure levels and it may be possible to use this data to estimate exposure levels. It is necessary to take account of the test conditions for the published work and compensate for any differences with the conditions of exposure from the use of a medical device. This can make a large difference as, for example, the area of material that contains the substance, ambient temperature, air flow, etc. all will affect atmospheric concentrations. As the COCIR SRI deals with potentially all hazardous substances including those

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[5] See ECHA C&L I

where contact is not involved, overall exposure during mining, production, manufacturing and recycling need to be considered, although exposure during the use phase may be excluded in most cases. For exposure during other life phases, COCIR should compare exposure due to substances in medical devices with the total production per year of the chemicals for other applications.

3.1.2 Minimum amounts that cause harm

This information is usually obtained from testing. Animal tests such as with rats are commonly used as well as with other animals that more closely correspond to human physiology as sometimes mice and rat data does not correspond to the effect on humans. This is useful as it gives quantitative data and can show what is the smallest amount that could cause harm.

Medical health data for groups of people exposed to a substance is also used but has limitations. Firstly, the exact exposure level may not be known, only the likely range of exposure. For some substances, exposure may be from multiple sources. However, human population data is useful for assessing data for groups of workers that are exposed to levels higher than the general population. This data is used to determine safe workplace exposure levels as well as minimum amounts that can cause harm.

Minimum levels that cause harm are published in several formats, such as the following examples:

- No Observable Adverse Effect Levels (NOAEL) for human health effects.
- No Observable Effect Levels (NOEL) for human health effects.
- Lowest Observable Adverse Effect Levels (LOAEL) for human health effects.
- LC50 = Acute environmental toxicity: lethal concentration that kills 50% of test population, qualified by species and exposure route.
- LD50= Acute environmental toxicity: lethal dose that kills 50% of test population, qualified by species and exposure route.
- NOEC = Chronic environmental toxicity: No Observable Effect Concentration (used for environmental organisms).
- LOEC = Chronic environmental toxicity: Lowest Observable Effect Concentration (used for environmental organisms).
- PNEC = Predicted No Effect Concentration, which is estimated from test data such as LC50 and NOEC values.

Different values will be available for each hazard classification, i.e. cancer from inhalation will be different to cancer from dermal contact. Usually, the lowest exposure level value for any human health hazard is used and also the lowest values for all environmental hazards.

Useful published data exists for the most commonly used hazardous substances, but may not exist for less common substances. For example, comprehensive data exists for DEHP, but much less data is available for di-heptyl-phthalate because it is much less widely used. However, it seems likely that the toxicity of DEHP, which has 8-carbon alkyl chains will be similar to diheptyl phthalate which has 7-carbon alkyl chains. The minimum amounts that cause harm will not be the same though. A much smaller amount of DEHP (a category 1B reproductive toxin) can cause reproductive toxicity than the minimum amount of the very similar DiNP (9-carbon alkyl chains), which does not meet the criteria to be classified as a reproductive toxin, although it does exhibit some reproductive toxicity.

Methods have, however, been developed to estimate hazard classification and minimum amounts that cause harm, which are known as QSAR (quantitative structure-activity relationships) modelling. A QSAR toolbox is available from the European Chemical Agency and is intended for industry and governments to use[6]. This has been developed for REACH registration, but could also be used for benefit-risk analysis. Unfortunately this has limitations

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[6] https://echa.europa.eu/support/oecd-qsar-toolbox

and can only be used if reliable data is available for more than one similar substance so that trends in properties can be used for accurate predictions.

Impact assessments of hazardous substances usually allow a margin for error as there is typically some uncertainty over the minimum level known to cause harm, especially if QSAR modelling has to be used. It is common practice to use a margin of 10, 100 or even 1000 times to allow for errors[7].

There are many data sources for these types of information. One source that collects data from multiple sources has been established by the EU Joint Research Centre accessed via the ChemAgora[8] web portal. This includes data from EU, US, Australian, Japanese and other government websites that collect data of quantities that could cause harm.

4 SUBSTITUTE EVALUATION

The MDR requires that all potential substitutes should be evaluated and all aspects of substitution should be considered using a risk-benefit analysis. Exemptions from the RoHS Directive can be justified based only on three criteria (see section 1). These are compared below.

Criteria	MDR	RoHS
Substitution is scientifically or technically impractical	Would mean that no alternatives exist	This is acceptable as justification for an exemption.
Reliability is not assured	This should justify continued use of the substance	This is acceptable as justification for an exemption.
Overall health, safety and environmental impact of alternatives are more negative than the overall impact of the substance	This would need to be proven by a risk-benefit analysis	This is acceptable as justification for an exemption but an independently reviewed life cycle assessment is required.
Socio-economic assessment	Can be considered as part of the risk-benefit analysis	Can only be considered as a secondary justification and is used to determine validity period of exemptions.
Impact on innovation	Can be considered as part of the risk-benefit analysis	Can only be considered as a secondary justification and is used to determine validity period of exemptions.
Availability	Can be considered as part of the risk-benefit analysis	Can only be considered as a secondary justification and is used to determine validity period of exemptions.

Substitutes can be alternative materials or design, but they must meet performance and reliability requirements. This usually means that the substitute must have at least the same performance and be no less reliable on the basis that inferior performance would be less able to diagnose conditions and inferior reliability increases the risk

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[7] California Proposition 65 requires a 1000 fold margin for published NOEL values to determine if warnings need to be given

[8] http://chemagora.jrc.ec.europa.eu/chemagora/idSearch

to patients if equipment is unexpectedly unavailable. However, the MDR goes further as it requires a risk-benefit analysis and so, in principle, an increased risk if outweighed by increased benefit may be acceptable.

Substitution is usually considered stepwise:

- The first question is whether an alternative substance can be used because, if a suitable drop-in replacement exists, then this would be the simplest option to investigate further. Usually, however, no drop-in replacement exists and all substitute materials are slightly different. There may be one or more substances that meet all of the essential technical criteria required for the material or none, but some could be overall good enough to provide acceptable performance and reliability.
- If there are more than one alternatives identified, these should be prioritised so that effort is expended initially with the most promising one or two candidates. Reliability and performance will need to be assessed by testing and, if necessary, by clinical trials.
- If no alternative materials exist or the performance or reliability of apparent substitute materials is unacceptable, then alternative designs need to be considered. These would include, for example, redesign of printed circuit boards using different electronic components or changing the dimensions of the equipment to incorporate larger but lower density counterweights. Redesign is usually more costly than identification of substitute materials and so may not be considered if substitute materials exist that are acceptable.
- Life cycle health and environmental impact is sometimes considered by medical equipment manufacturers because eco-design principals often improve manufacturability, ease of repair, recycling and refurbishment and avoidance of hazardous waste disposal costs. Overall eco-design can improve profitability, which is why it is used, but it can also have benefits for the global environment, for example, reduced energy consumption / CO2 emissions. The medical sector already encourages eco-design on a life cycle basis, which includes avoiding and replacing hazardous substances, with standard EN 60601-1-9:2007 “Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design”.
- All equipment manufacturers consider costs – of R&D, substitution, new equipment and return on investment. Expenditure is usually prioritised such that mandatory compliance with legislation and health and safety of employees are both essential and so must come before new product development. However, one option for manufacturers is to phase out a product instead of substitution if the return on investment is too small and the same investment in new products will generate better returns. This approach can however have a negative impact on healthcare. Hospitals do not always need the state-of-the-art equipment and older models tend to be lower priced. All hospitals have limited budgets and so if prices were to increase overall as old designs were forced to be obsolete due to new substance restrictions, then the hospitals would be able to buy less new equipment and they would have to use older equipment for longer. It is well known that as equipment becomes older, it can become less accurate and less reliable. Both can result in a negative health impact[10].
- Sometimes substitution is unavoidable. For example, if RoHS were to add a new substance restriction this would affect all existing products as well as new designs. R&D would be needed to replace the substance and the time and effort expended will inevitably be at the expense of new product development, not only because funds are limited, but also because there are only a limited number of trained engineers[10].
- Another cost consideration is as follows. With medical devices, unlike most other types of equipment, new products can result in improvements in health (due to better and faster diagnosis and treatments) and so a benefit-risk analysis should take this into account. This might mean not investing in substitutes if the overall risk-benefit analysis shows that the overall risk-benefit of a new product is superior to that from substitution. The financial cost of substitution does however have indirect impacts which are difficult to quantify, but are no less real. If a manufacturer were forced to delay the development of a superior performance medical device that would improve the health of patients, due to diverting expenditure onto substitution, then this will delay launch of new products which could have an indirect negative impact on health. RoHS exemption based on overall health impacts however must be justified using a comparative quantitative life cycle assessment (LCA), but this is often difficult to prove because:
    - It is almost impossible to quantify in monetary or other terms the health benefits from new technology. Historical trends may not be useful because health is affected by so many variables,

such as the types of food eaten, health care expenditure per capita, average age of population, affluence and education and new medicines as well as the potential benefits of new equipment. Predicting the future benefits is therefore almost impossible in monetary terms although there clearly would be benefits if diagnosis could be made sooner and treatments were more effective. If on average patients recovered sooner then there are reduced costs to hospitals, but it is not possible to quantify these benefits as a direct result of a new type of medical device, even though there clearly are such benefits.

- The benefits of substitution of a hazardous substance for different substances are often unclear. There has been some research to determine the health costs of some hazardous substances (including lead and cadmium), but these are only intended to be from air emissions and landfill at end of life. Production impacts are not taken into account but can be much more significant when this occurs in countries with poor environmental controls compared with the EU where end of life is strongly regulated and, at least as far as medical devices are concerned, equipment is recycled safely. Another limitation is that several researchers have made these calculations using different approaches and obtained a very wide range of results. Finally, a third issue is that data for most substitutes does not exist so a like-for-like comparison is usually not possible.

Life cycle assessments are too time consuming and in many cases uncertain to be any value for this SRI and so an approach based on risk-benefit analysis as used for the MDR may be more suitable. This would consider:

- Substance restrictions are imposed to protect health and the environment and the so the impact on these from the substance specifically used in medical devices should be assessed as one criteria.
- Actions proposed to minimise harm to health and the environment
- Impact of industry trends (which may reduce the impact)
- Positive and negative impacts of possible substitutes if any exist.

The aim of the SRI would be to reduce the negative health and the environmental impacts of the selected hazardous substance either by substitution or by other means, unless no harm is believed to occur or substitution is not technically possible.

5 MARKET TRENDS

All industry sectors are affected by trends in the use of hazardous substances and their replacement. High reliability sectors such as medical devices and aerospace use relatively small numbers of electronic and electrical components and materials compared to consumer electronics, IT or telecom. Manufacturers and also large distributors often have green procurement policies that either match global substance restrictions or go further with restrictions that are not required by global legislation. This imposes pressure on suppliers that can result in them making components, parts and materials obsolete when the quantities sold makes continued supply uneconomic.

5.1 Impact of REACH

The REACH Regulation 1907/2006 also encourages hazardous substances to be phased out. When Substances of Very High Concern (SVHCs) are added to the Candidate List, many manufacturers endeavour to replace SVHCs to avoid having to provide REACH Article 33 information to customers, which they believe, in some cases correctly due to green procurement policies, will discourage further sales. For example, when DEHP was added to the Candidate List in October 2008, many wire and cable manufacturers began to replace this substance as a plasticiser with substitutes and, by 2012, most US and European wire and cable manufacturers had replaced DEHP in their products although DEHP-plasticised cables are still made by some Asian manufacturers. This change has occurred even though REACH Article 33 is an information requirement, not a restriction.

A similar trend has occurred with DBP which was also added to the Candidate List in October 2008. This was widely used as a plasticiser in adhesives that were used to seal or encapsulate various types of capacitor and other electronic components. By 2011, many component manufacturers had replaced DBP. 4,4'-methylenedianiline (MDA) is an epoxy resin hardener which was one of the first SVHCs in October 2008. Cured resins do not contain

MDA, but many epoxy resin manufacturers stopped production of formulations that contain MDA when it was added to the Candidate List. This is a common trend, when substances become SVHCs, if substitution is possible then manufacturers aim to replace the SVHCs within a few years. This is probably an intended effect from the REACH Regulation and may in many cases be sufficient with no further action being necessary.

REACH also adopts restrictions listed in Annex XVII as well as requiring authorisation of the use of chemicals listed in Annex XIV after sunset dates. Authorisation applies only to uses of chemicals in the EU and not to imported articles where the substance is incorporated outside of the EU. However both restrictions (even partial ones, such as in tyres only or in toys only) and authorisation strongly discourage both manufacture of these substances globally as well as supply to the EU and can result in them becoming obsolete.

5.2 Impact of RoHS

RoHS restrictions are known to affect industry sectors that are excluded from this legislation.

Most electronic components are sold to sectors in scope of RoHS and it is not usually economically viable to make special non-RoHS compliant versions for other sectors as the numbers sold are usually too small. The military and aerospace equipment sectors are very concerned that its products are required to be very reliable and have long lifetimes and so avoid substitution wherever possible as this creates uncertainty and requires extensive and costly reliability and performance testing as well as re-qualification or re-approvals. However, these sectors and others that are excluded from RoHS usually have no choice but to buy components that are commercially available which will usually be RoHS compliant versions. Military equipment was at one time able to make its own non-compliant components, but cost restraints now mean that only Commercial-Off-The-Shelf (COTS) components are now widely used and these are usually and unavoidably RoHS compliant.

RoHS therefore forces manufacturers of equipment outside of the scope of RoHS to use RoHS compliant components. Some have made life-time buys to delay having to substitute, but this is always only a temporary measure because, as components age, they become more difficult to solder so that eventually they are not usable.

RoHS has also affected industry sectors outside of the scope of RoHS by encouraging full RoHS compliance. This is sometimes required by customers. For example, it is UK Ministry of Defence policy that military equipment should be RoHS compliant where this is possible even though no legal restrictions apply. Some aircraft manufacturers are aiming to make new models RoHS compliant and are increasingly using lead-free solders.

A large proportion of equipment manufacture in out-of-scope sectors is carried out by subcontractors. It is common for printed circuit boards to be assembled by specialist companies and most of these will also have customers in sectors in scope of RoHS. They will want to avoid the risk of non-compliance that can occur by cross-contamination if two separate processes, one with lead-free solders (and only compliant parts) and one with lead-based solders (and some non-compliant parts) are carried out and so increasingly they will operate only one lead-free production process. The few sub-contractors that operate lead solder lines now charge a premium over those that only provide lead-free and this trend has forced many manufacturers of equipment that is excluded from RoHS to switch their products to RoHS compliant designs.

Note that RoHS restrictions can be adopted if a substance is hazardous. An uncontrollable risk does not need to be proven, unlike for REACH restrictions.

5.3 Global trends

The EU is clearly the global leader in substance restriction legislation, but many other countries are following the EU with their own legislation.

Countries including South Korea, China, India, UAE, Taiwan, Singapore and Vietnam have legislation based on EU RoHS and Russia will have its own RoHS legislation from March 2018 and others are planning RoHS legislation. Some US States have substance restrictions, notably California which has very limited RoHS legislation as well as California Proposition 65 which although is only an information requirement, it discourages the use of a very large number of substances classified as carcinogens and reproductive toxins.

In the past, the manufacture of components and materials that contain RoHS substances was widespread as these could be used in products that were not sold in the EU. However, as restrictions have spread to other countries,

these have had to be phased out and replaced with RoHS compliant versions. As a result, the global supply of components, parts and materials that do not comply with RoHS is gradually becoming more difficult.

6 TIME NEEDED FOR SUBSTITUTION

Medical device manufacturers already have experience with substitution when category 8 was included in the scope of RoHS. The time needed was very varied as it depended on the materials to be replaced, the applications and types of equipment. Work had started by many companies by 2005 and many were not fully compliant with modified medical devices approved globally until 2014, a period of at least nine years. This was possible, however, only by allowing the use of some of the RoHS substance by granting many new exemptions.

COCIR has previously estimated the time required to replace the RoHS restricted phthalates in various applications. A flow chart that shows the multiple steps required is as follows:

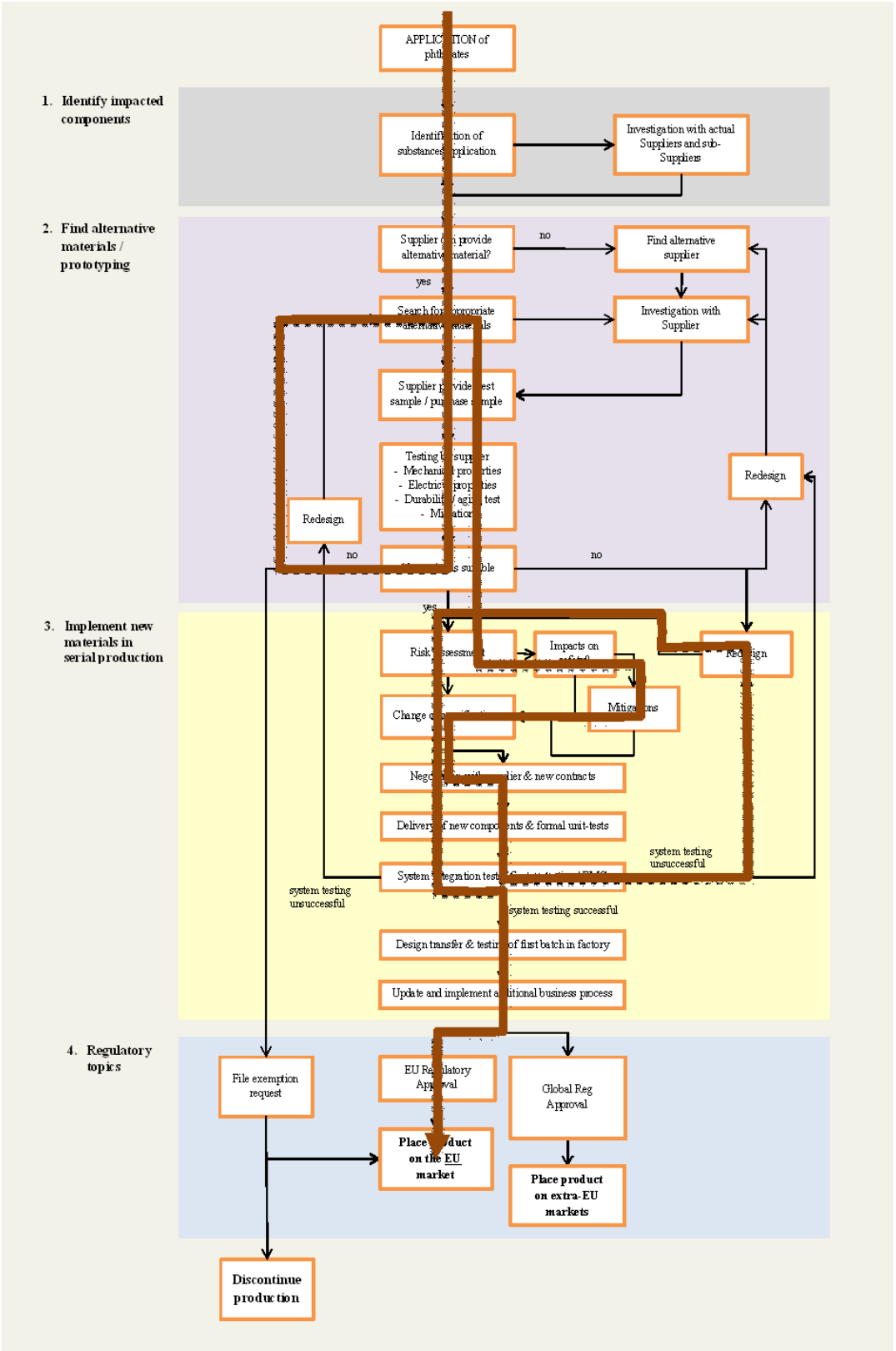

Figure 1. Phthalate substitution flowchart

The estimated timescale ranged from about 5 years as a best case, where no difficulties were encountered and a drop-in replacement is available to a worst case of at least eight years for some types of product. Timescales will be lengthened if a potential substitute is found and early tests seem encouraging but when evaluated in trials, it is shown to be unacceptable, then the process will need to start all over again. If this happens more than once, then the timescale could be well over 10 years.

7 IMPACT ON INNOVATION

Medical device manufacturers aim to develop innovative new diagnostic equipment and treatment techniques that give better treatment outcomes for patients. This can for example be earlier diagnosis, faster cures, less invasive treatments and a cure instead of long term management of conditions. Improved outcomes result in improved health of EU citizens.

Medical device manufacturers are the same as any other equipment manufacturer in needing to balance benefits to shareholders, legislative compliance and investment in new products.

Medical device manufacturers' first priority is to ensure that their products and processes comply with legislation and that their employees work in a safe environment. Financing regulatory compliance is essential and be prioritised over new product development. The medical sector is highly competitive and medical practitioners continuously need better medical diagnosis and treatments. Also, the EU has a growing and aging population placing greater demands on health service providers, usually without the availability of increased funding. This results in the medical sector having to invest a relatively high proportion of its profits on new products to both remain competitive and satisfy medical demands. COCIR estimates that R&D spending on the medical imaging and health ICTs sector represents up to 8% of sales volume[9].

Compliance with legislation always has a financial cost and, for some legislation, this cost can be relatively large and can have a negative impact on innovation. For example, the cost of RoHS compliance was estimated to be about 1% of turnover per year during the period when designs were changed to convert products to comply and then an ongoing cost of about 0.1% of turnover[10]. This estimate was made by the consumer and IT sectors and is probably lower than the actual costs to the medical sector whose products can be very complex and must be very reliable. Some transition cost estimates were as high as 4% of turnover. Also, clinical trials and approval costs will be incurred and so the compliance cost of RoHS for the medical sector was probably about 2% of turnover per year. This cost was for RoHS only and medical equipment also has costs to comply with REACH, all other applicable legislation and now also the MDR substance requirements.

The high financial cost of compliance with substance restriction legislation may however not have significant benefits to human health or the environment due to the relatively small quantities (e.g. lead in X-ray tube bearings use less than 50 grams of lead per year) of these substances that are used compared with other industry sectors and as most medical devices and all imaging equipment is used by professionals and has a relatively high scrap value, these will be collected for recycling at end of life and this is required by EU legislation to be carried out safely.

The high financial cost of compliance inevitably reduces the funds that are available for investment in new designs and new treatments which will negatively impact on future health of patients world-wide, not only in the EU. If a medical device manufacturer could invest 4% of turnover in innovative new technology development, but new substance restrictions cost 1% of turnover, then investment will have to decrease by 25% and development of new life saving technologies will take longer to be commercialised. As a result of this delay, some patients could be ill for longer resulting in higher costs to hospitals and also some may die unnecessarily[11].

With the RoHS Directive, manufacturers must continuously carry out research into substitutes for exempt applications, even if prospects of finding substitutes appear to be small or negligible. This is because all exemptions are intended to be temporary and it is not acceptable to do nothing and assume that exemptions will be renewed automatically. This type of research since 2011 has already identified many substitutes for RoHS substance

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[9] http://www.cocir.org/our-industry.html

[10] http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

[11] This is a logical assumption, but is difficult to substantiate as no evidence is available.

applications and so many Annex III and IV exemptions can expire, however, those that remain are those that it has not yet been possible to substitute as it is more difficult or seem to be impossible to find substitutes. Research on these will therefore be costly but with little chance of success and so no actual benefits are likely to arise from this expenditure, whereas investment of these funds in new product development would give health benefits.

8 RISK/BENEFIT ANALYSIS OF USE OF THE SUBSTANCE

Although it is not currently known what approach the European Commission will propose for the MDR risk-benefit analysis, these are typically ratios of quantified risks and benefits. These are commonly used for medical research and to determine if the risk-benefit ratio is sufficiently favourable to allow trials with human patients. These are also used to determine, for example, whether vaccination would be beneficial overall. Medical risk-benefit analysis is not normally used to assess alternative hazardous substances and so a new methodology would need to be determined. Medical risk-benefit analyses are much more straightforward to carry out than one for a hazardous substance. For example, a hypothetical[12] risk-benefit analysis to determine whether to carry out a vaccination would compare the following two options:

	Vaccinate	Do not vaccinate
Cost of vaccination program	€50 million	€0
Cost of treating people suffering from side effects from vaccination	€500,000	€0
Cost of treating unvaccinated ill people	€250,00 (usually a small proportion refuse vaccination)	€75 million
Number of people with targeted illness	100	10,000
Number of deaths from targeted illness	2	200

It is clear from this hypothetical example scenario that vaccination has a lower cost and greater benefit than not vaccinating, but these analyses are not always so clear.

Typically risk-benefit analyses compare doing nothing, such as not banning or substituting a substance with an action such as a new restriction or substitution. Risks are probability ratios or fractions (e.g. 1/1,000) and the benefits need to be quantified in some way, such as in financial terms. Both are very difficult to calculate for a risk-benefit ratio that analyses a hazardous substance.

8.1 Risks

As far as medical risk-benefit analysis is concerned, risk means probability of harm. Factors to be considered may include:

- Probability that the substance will harm a patient when the medical device is used. This will depend on the level of exposure and the minimum amount known to cause harm.
- Probability of harm to the patient if the hazardous substance in the medical device has been replaced with a substitute. This will also depend on the level of exposure from the substitute and the minimum amount known to cause harm as well as if substitution potentially poses any other risks of harm, such as due to inferior reliability, inferior accuracy, etc.

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[12] Created by RINA to show how these analyses are interpreted

- Probability that the hazardous substance will cause harm to a) human health and b) the environment during mining /refining, manufacture, use and end of life phases.
- Probability that the substitute to the hazardous substance will cause harm to a) human health and b) the environment during mining /refining, manufacture, use and end of life phases.
- If the substance is replaced and so less R&D on new medical technology is carried out what is the probability that this will affect 1) financial cost of operations (by hospitals); 2) likelihood of disease spread; 3) likelihood of complications with or without operations; 4) life expectancy; 5) overall state of health; 6) alternative treatments for his disease; 7) illness will be detected sooner, etc.

8.2 Benefit

There may be many different benefits that need to be considered but defining these in financial terms may be difficult or impossible. Benefits could include:

- Not using a hazardous substance may reduce ill health and environmental damage from the substance in some or all life cycle phases.
- If a hazardous substance is not used, then a substitute material or design will be used instead. This may have a different negative health and environmental impact than the substance it replaces. Comparative life cycle assessments of two alternative materials often show that for some impacts one has a less negative impact and for different impacts, the other has less negative impacts[13]. Therefore overall, neither would appear to be superior. This is mainly because it is very difficult to compare different life cycle impacts as they are not equivalent.
- Increased funds for new medical technology resulting from not substituting could affect: 1) financial cost of operations in hospitals (e.g. take less time, local versus general anaesthetic, shorter recovery time, fewer side effects, less infection, etc.); 2) likelihood of disease spread; 3) likelihood of complications with or without operations; 4) life expectancy; 5) overall state of health; 6) alternative treatments for his disease; 7) illness will be detected sooner, etc. in a positive way.
- There may be higher or lower costs and other benefits from not using the hazardous substance including:
    - Cost of R&D
    - Cost of new equipment
    - Cost of trials and gaining approval
    - Higher material costs
    - Lower waste disposal costs (e.g. if less hazardous substances are used)
    - Reduced ill health from less exposure to hazardous substance. Some estimated financial costs (in €/kg) have been published for air and land emissions of a few substances, but estimates vary considerably.
    - Reduced environmental costs from less exposure to hazardous substance. Difficult or impossible to quantify in financial terms
    - Health and environmental costs of exposure to substitute substance
    - Socio-economic costs and benefits (some can be financially costed, others are qualitative only).
- If the substance is replaced and so there is less R&D spending on new medical technology, there will be a cost impact on 1) financial cost of operations (e.g. these are more, more complex and costly, etc.); 2) likelihood of disease spread (e.g. due to later detection); 3) likelihood of complications with or without operations; 4) life expectancy; 5) overall state of health; 6) alternative treatments for disease; 7) not detecting illness sooner, etc.

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[13] This was the conclusion from the US EPA's LCA comparing lead and lead-free solders.

Guidance on risk-benefit analysis is awaited but Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). An extract of their terms of reference are[14]:

2. Terms of reference
The Scientific Committee is requested to provide guidelines on the benefit-risk assessment of the presence, in the medical devices specified below, of phthalates which have one or more of the following properties: carcinogenic, mutagenic, toxic to reproduction or endocrine-disrupting, according to the criteria outlined in the previous section.
The devices covered, or those parts thereof of those materials used therein, are those which:

- are invasive and come into direct contact with the human body,
- (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body.

The guidelines shall include guidance on how, for an individual device, to:

- analyse and estimate potential patient or user exposure to the substance,
- analyse possible alternative substances, materials, designs, or medical treatments,
- to justify why possible substance and/or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product, including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials.

In addition, the Scientific Committee is requested to

- identify any relevant knowledge gap; and
- to give consideration to what extent of new evidence would be deemed appropriate to justify an update of these guidelines before the maximum period of five years.

9 FUTURE OUTLOOK - DISCUSSION

Today in 2018, all medical devices are RoHS compliant, however the medical industry still has obligations and associated costs to replace RoHS substances in exempt applications and eliminate additional RoHS restricted substances. Manufacturers are already working to replace the four phthalates pending restriction in 2021, but more restrictions are likely to be adopted in the future. In addition, medical device manufacturers also have to comply with the new substance obligations of the MDR.

Although the MDR obligations are not a ban, it only covers patient contact materials and it requires substitution only when replacement is technically possible and benefits of substitution outweigh risk. This might be a better overall alternative approach in the future for new RoHS substance restrictions and for dealing with exemptions. This report has explored the various issues that influence the use of substances that may be considered for restriction as well as substitution issues and risk-benefit analysis.

RoHS restrictions clearly have a significant financial cost and this reduces funding available for new medical device development which in turn has a negative impact on human health. As the medical sector is believed to comprise less than 1% of the electronics industry, industry trends will inevitably result in regulated substances being phased out within the medical sector where this is technically possible anyway. If future new RoHS substance restrictions were not to apply to medical devices, it is likely that their use would decline by almost as much as if the new restrictions were mandatory due to market obsolescence. The most likely circumstances where they would continue to be used would probably be justifiable as RoHS exemptions.

The impact of future restricted substances and exempt uses of hazardous substances in electrical medical equipment that is in scope of RoHS on human health and the environment is likely to be small at most. This is because the quantities of substances used by the medical industry are relatively very small in comparison with all other industries and also because the medical industry will be affected by industry trends that cause the

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[14] https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_009.pdf

obsolescence of regulated substances. Industry sectors such as aerospace that are excluded from RoHS are already significantly impacted and having to substitute where technically feasible.

The aim of RoHS and REACH is the protection of human health and the environment and so if this is achieved by a combination of market trends and voluntarily replacing hazardous substances where technically possible, then Member States and manufacturers can both benefit from reduced enforcement and compliance costs respectively. Reduced compliance costs will also increase the funding that could be available for new medical technology, potentially quite significantly. Earlier diagnosis and better, simpler treatments can potentially also reduced healthcare costs of Member State governments[15].

A potential disadvantage for the medical sector is that cost-benefit analysis for the comparison of use of a hazardous substance with all possible technically viable and reliable substitutes will be complex to carry out. Clearly, the decision to continue using a substance is justified if there are no technically viable, reliable alternatives, but often there are many options that may need to be considered. Take, for example, fire retardants. There are currently over 70 commercially available and so if the one that is currently used is a CMR, then a large number of potential substitutes exist. However, despite this situation, if the CMR flame retardant can be proven to pose no risk to health or the environment, a risk-benefit analysis would show no benefit in substitution but a negative impact due to the costs incurred. This is very different to RoHS where identification of a hazard is enough to justify a restriction, even if there is no evidence that it causes harm.

Risk-benefit analyses, as part of an SRI, would be simpler to carry out if an average overall benefit to EU health per unit of investment is known. Investment in new medical technology is intended to develop new techniques that:

- Save lives from fatal disease
- Diagnose illness earlier so that patients are more likely to survive, live longer, treatments are less invasive and less costly
- Reduce treatments costs (shorter hospital stays, need for less resources, etc.)
- Etc.

The types benefits achieved from each investment in a new medical device will be very variable. Sometimes, results will be disappointing with few benefits whereas some developments have very dramatic benefits. It has not previously been possible to show an overall improvement in EU health due to new medical devices over a period of time because so many other variables have an influence (improved food, medicines, exercise, etc.). Therefore a different approach is needed to calculate the health benefit from financial investment, for example as an overall health benefit per €1million invested averaged for all significant new developments in the last 20 years. If COCIR members review their most significant new technologies to calculate benefits such as lives saved, hospital cost reductions, etc., per €1 million invested and these figures could be averaged to obtain a single figure that can be used for the medical imaging sector SRI's cost benefit analyses.

So if a cost benefit analysis is needed to determine whether to substitute a hazardous substance, the cost of substitution would reduce that amount of new product investment funding available which would result in a negative impact on future health benefits. The size of reduced health benefits can be calculated from the SRI overall average. This "cost" would be compared with the "benefits" of replacing a hazardous substance to clearly show whether substitution benefits outweigh investment benefits.

The advantage of this approach for the medical sector is that the costs and benefits of substitution versus continued investment can be directly compared to determine which would be the superior option overall. Medical devices are different to most other types of equipment in scope of the RoHS Directive. Investment in new models of electronic equipment (TVs, washing machines, computers, etc.) does not benefit the health of EU citizens unlike medical devices. Therefore, it should be reasonable to consider medical equipment substance restrictions much more broadly taking into account the health benefits from investment and innovation.

For a voluntary risk-benefit approach to be accepted, the European Commission and Member States may expect to be convinced that the methodology used is able to prove that there would be no or negligible harm incurred by

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[15] Treatment can be quicker and easier if illness is diagnosed earlier. New techniques such as keyhole surgery allow faster recovery times and shorter stays in hospital. Both result in cost savings.

humans or the environment from continued use of a substance. However, this may be difficult to prove or require additional measures in factories world-wide that cannot be proven to be achievable, especially at end of life of the equipment when this occurs outside of the EU.

In practice, situations will be more complex as few substances are completely benign including those not classified as being hazardous. Medical cost-benefit analyses compare costs, illness and deaths for two scenarios, in situations where there usually are illness and deaths with both options. If this approach is used for RoHS substitution of hazardous substances, will all Member States accept a legislation change from a substance ban to an alternative approach that may allow its continued use? Politically, this will be difficult to achieve. However, a cost-benefit analysis is the correct approach as its aim is to result in overall improved human health and a healthier environment, i.e. less illness, deaths and environmental harm.

10 CONCLUSIONS

The options for an SRI for medical imaging equipment to manage hazardous substances as an alternative to future RoHS restrictions has been investigated. The medical sector has many years of experience with RoHS and fully understands the high cost that has been incurred which inevitably has reduced investment funding available for new medical devices.

If medical devices were outside of scope of RoHS, substitution of RoHS restricted substances would still occur because of market trends. The only circumstances where this would not occur is when substitution is technically difficult or impossible to achieve. The Medical Devices Regulation has introduced a new requirement for invasive and patient contact materials where any CMR 1A or 1B and ED substances should be substituted unless it can be shown by a cost benefit analysis to be unnecessary. This approach has advantages over RoHS as the health benefits from medical device investment should be taken into account before deciding on whether substitution is beneficial overall.

Medical device manufacturers are familiar with cost benefit analyses but these need to be adapted for hazardous substance substitution. It will be necessary to be able to quantify the benefits from investment so that this can be compared with any benefits from substitution. If the benefits of substitution are far smaller than the overall health benefits from the same funds being used in new medical device development, then clearly substitution would not be justified or necessary. Only if substitution benefits are significant compared to investment benefits should this be pursued.

The SRI needs to be a group initiative that is recognized by the EU. An example of a pre-existing medical voluntary initiative is “Health Care Without Harm”[16], which has a much broader scope than medical imaging equipment. The aims of the SRI need to be clearly defined and agreed so that companies in the SRI are recognized as having a co-ordinated policy to reduce the use of hazardous substances.

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[16] https://noharm-uscanada.org/documents/healthy-business-strategies-transforming-toxic-chemical-economy

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