Several issues are covered in this second review
1. Product groups to be included (cat 8 & 9)
2. Substances banned
3. Technical Changes
4. Issues on definitions
5. Issues on implementation

For each of these issues the Commission has generated a set of different options for a possible solution. Eucomed has expressed its view on each of these options for the above five issues.

I. PRODUCT GROUPS TO BE INCLUDED [ARTICLE 6 OF RoHS] CATEGORIES 8 and 9

1. Continue excluding one or both categories altogether

   **Eucomed:** If the European Commission decides to adopt this option it will be acceptable for us.

   It should be noted that the actual volume of Medical equipment makes up a very small proportion of the overall electrical appliance industry and the tonnage of the RoHS banned substances is also low. The volume is less than 0.25% of the total 12 million tonnes of EEE sold annually in Europe.

2. Continue excluding one or both categories altogether and encourage eco-design

   **Eucomed:** We already encourage Eco–design within the Industry. For example there has been an Environmental Focus Group within Eucomed since 1994 which has kept members up to date on environmental matters and promoted environmental good practice to members.

   In addition medical devices already have to satisfy much environmental legislation – Packaging & Packaging Waste Directive, WEEE Directive, REACH Regulation all of which influence the design of our medical devices. More Directives will follow, eg. EuP, Batteries…
The WEEE Directive already has a requirement relating to Eco–design in Article 4 Product Design (related to domestic products only) and Article 7 Recovery point 4.

Eucomed strongly supports life cycle thinking and the environmental design objectives behind the RoHS, WEEE and EuP Directives. There are many ways that companies are dealing with these environmental issues and indeed the industry sector has voluntarily created the new International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment.

The IEC 60601-1-9 environmental design standard was published in July 2007 and enables medical device design teams to:

- Use a Risk management based approach to evaluation & design.
- Identify and prioritize the significant environmental aspects of the product across all of its life cycle phases.
- For significant environmental aspects, establish and document environmental design targets to reduce adverse environmental aspects.
- During the product conception and design specification phases, consider innovative emerging or alternative design technologies and/or solutions that can significantly reduce adverse environmental aspects.
- Assess the actual environmental performance of the final prototype against the environmental design targets. Any deviations from the targets must be documented for consideration in future designs.
- Identify the types and mass of packaging material(s) and, in the absence of local laws, the appropriate method for returning, recycling or disposal of the packaging materials.
- In the documentation accompanying the product, provide instructions for minimizing the product’s environmental aspects during normal use and disposal at the end of life.
- List substances and materials that can be recovered and recycled from the product.

Eucomed has extensive experience in reducing the life cycle environmental impacts of its products while maintaining safety and performance, minimizing harm and advancing healthcare performance.

Examples include:

- Filmless X-ray systems
- Voluntary take-back systems (in advance of and parrell to the WEEE Directive) including refurbishment of used equipment and reuse of components
- Established procedures for risk analysis of use of hazardous substances
- Hazardous substance replacement where possible
- Extensive implementation and use of ISO 14001 and EMAS Environmental Management Systems

We would agree that an Eco-design approach gives more flexibility to the manufacturers to reduce the environmental burden. However the developed Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment should remain a
voluntary standard and left to the decision of the manufacturer. If authorities do not consider the published standard as robust enough to legitimate exemption from RoHS, the industry is not in favour of a mandatory compliance to this standard (for example through harmonization under the 3 directives applicable for Medical Technology).

Finally many medical technological solutions require the use of hazardous substances, whether to improve the performance or reliability of devices, or provide effective patient protection. Eucomed feels that the use of hazardous substances in medical devices should be permitted provided that their use can be justified after a risk benefit analysis.

3. Include them both from the beginning (probably around 2012 taking into account time necessary for co-decision and accomplishing transposition of revised RoHS in all MS)

Eucomed: It will be difficult within this time scale to confirm the reliability performance required for all medical devices, potentially forcing the removal of products from the market due to the increased/unknown risk associated with replacement of component parts.

Eucomed requires higher level of reliability assurance than for consumer products.

Accurate high level reliability data is the key factor and it will also be a requirement of the (MDD) Notified Body. This essential requirement for high level reliability data should be included in the revised Directive.

Medical technology should be phased into the RoHS, based on risks, with the following dates of inclusion:

- MD**’s in 2014 (* with the exclusion of the MD’s included in the last category)
- IVD’s in 2016
- AIDM’s and MD’s with life supporting applications (such as external pacemakers, defibrillators, perfusion systems etc.) no date; to be reviewed at next RoHS revision

4. Include both categories but with a deferred deadline (e.g. 2014)

Eucomed: Eucomed believes that the earliest date that medical devices (Directive 93/42/EEC) could be included in the RoHS Directive is 2014.

However appropriate and accurate reliability data must be available by 2012 if we need to be compliant by 2014.

This sector includes a very wide range of products mainly aimed at hospitals but also used by general practitioners and in some cases consumers themselves. Some are relatively simple products but others are some of the most complex and safety critical electronic products available, including CT scanners, PET and MRI. Medical Devices are often unique for the complexity due to the number of parts with extreme operation conditions, often compared to the aerospace products, in terms of g-forces, mechanical shocks, vibrations ionizing radiation and chemical stresses.
A small number of medical device manufacturers producing simple, less safety critical products have already introduced RoHS compliant versions. In many cases, these products have a relatively short life time (less than 5 years) and so concerns over adequate field reliability data for long-term use of lead-free soldering is not an issue. In other cases, the products are used in non-safety critical applications. It must also be pointed out that there are cases where there are no alternative technical solutions, like replacing lead for shielding.

Large complex products may take up to 7 years to design (usually by refining and modifying equipment from previous models) and can contain over 100,000 component parts and cost several millions of Euros. These products are safety critical and have an anticipated service life considerably in excess of 10 years.

There is as yet no field data to confirm the reliability of lead-free equipment which is expected to operate for 10 or more years and where thermal cycling occurs. To avoid conflicts between the RoHS Directive and the medical devices Directives it is essential to ensure that adequate field data is available to validate the laboratory data from accelerated testing. Adequate field data should be available by 2012 and then evaluated before lead-free solder is used for medical devices. This will take time.

It can take up to 18 months to test and validate complex products in order to prepare the technical file for review by the (MDD) Notified Body. The length of time to gain approval from a Notified Body can take up to one year. In the mean time, the RoHS compliant version can not be sold in the EU.

Medical technology should phase in into the RoHS, based on risks, with the earlier mentioned dates of inclusion.

5. Include both from the beginning with the exemptions proposed by ERA (tables 71&72: depending on the adoption date, table 72 exemptions may be redundant)

Eucomed: We have concerns regarding Table 72, in particular the date 2012. It should be 2014. See 4 above.

Eucomed is concerned that the Commission is proposing to put our difficulties in implementing the inclusion of our complex products into the RoHS scope ahead of the benefits of this sector.

The burden on the TAC cannot be an argument to implement generic legislation that can potentially cause risks to patients. With this argument intrinsically the Commission admits medical technology products are complex and show a wide variability. If the nature of the products leads to a more complex approach to exemptions of the RoHS scope, so be it, and it should not be neglected by making generic legislation.
Therefore Eucomed will be very supportive of a specific science based risk management process for the exemptions of the RoHS scope. This should be a process that reflects the complexity of the products and the approval mechanisms of its vertical legislation.

6. Include both with exemptions (tables 71&72) and deferred deadlines and general exemption for lead in solders (p.230&246-248)

Eucomed: The only change is that medical devices should be included from 2014.

7. Differentiate between consumer/industrial equipment for cat.9 (maximum deadline for industrial equipment: 2018)

Eucomed: No comment.

8. Differentiate for In Vitro Diagnostics (IVD) (2016) and Active Implanted Medical Devices (AIMD) (permanent exclusion or exemption until 2020) (p.230)

Eucomed: We strongly support this option for the following reasons:

In-vitro Medical Devices Directive (98/79/EC):

In-vitro diagnostics (IVD) equipment has fundamental differences from equipment covered by the Medical Devices Directive (Directive 93/42/EEC). An additional level of complexity compared to other electro-medical devices is caused by the several facts which all are crucial for the analytical result:

- Interaction of the equipment with a large number of chemical and biochemical reagents, run on the instruments for detecting all different clinical parameters.
- The requirement for strict temperature control of the reagents throughout the analytical processes
- Dosing and handling of patients samples and reagents
- Validation of the whole analytical process for all reagents- this can include hundreds of different reagents just on one large IVD medical devices system, as a single instrument may test multiple parameters for example infectious diseases, oncology and therapeutic drugs analysis or integrated serum (blood) analysis.

New products (which are typically developed every 10 years or so) may be quite different in their external appearance but internally changes can be relatively small. The lifetime of the core parts of an existing design can be from 10 – 20 years, and in some case extend beyond 20 years. Because these complex products must be very accurate and reliable, only fully tested components and circuit designs are utilised. As a result, new products commonly contain circuit designs with associated software that was developed 20 or 30 years previously.
To continue production of IVD equipment, manufacturers are forced to make life-time-buys of obsolete (non-RoHS compliant) components. It is even possible that an obsolete component will be included in the design of a new product – this would never occur in most other parts of the electronics industry.

For new products designs test and validation can take between 3 – 8 years; 3 years for ‘small simple’ instruments and up to 8 years for automated large IVD analysers, and in some cases even longer is required. The validation process alone typically takes about 1.5 years because each IVD instrument is used to carry out a large number of different tests and each one must be validated after any modifications are made, and before the data is available to demonstrate safety and performance. This adds to the complexity and time taken for validation.

There simply are not enough trained engineers in the IVD sector to convert all existing product designs to RoHS compliant versions at the same time, and to prepare the technical files for review and approval. The length of time to gain approval from a relevant Notified Body can be up to one year. In the mean time, the RoHS compliant version cannot be sold in the EU.

The IVD industry has already started a conversion process to RoHS compliant product, reviewing their current designs and implementing RoHS compliance as a design input criteria. The impetus for this change comes from the industry’s desire to meet its environmental obligations and in order to adapt to changes in the electronic component supply industry due to the current RoHS Directive. It has been estimated that 90% of the components used in IVD instruments will be RoHS compliant by 2012, notably in small simple instruments, and it is estimated by manufacturers that some of the small and less complex instruments will achieve 100% compliance at his date also. However, it needs to be stressed that the conversion process is so complex that not all of the IVD instruments will be RoHS compliant until 2016.

In view of this, the medical device industry believes that the earliest date that in-vitro Medical Devices (Directive 98/79/EC) should be included in the RoHS Directive is 2016.

Active Implanted Medical Device (Directive 90/385/EEC):

Active implanted medical devices (A IMD) include heart pacemakers, defibrillators and insulin pumps. These are the most safety critical medical devices are unexpected failure can lead to death or serious injury. Hence the design cycle for new products is very long and most design modifications in new products are incremental changes to existing designs which are known to be very reliable. Typically, the time from concept to clinical trials is 6 to 8 years.

The reliability requirements for A IMD devices are very high. Field reliability data is required in order to obtain approval by a relevant Notified Body so that these products can be sold in Europe. For A IMD products, field reliability data are normally based on field data from

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1 Information from EDMA inquiry to members
October 2007
existing but very similar products. However, there will be no field data from lead-free versions of similar products for many years.

Until AIMD manufacturers can guarantee the reliability of lead-free solders from field reliability data such as this, it will be very difficult to obtain approval from the Notified Body so that these products can be sold in the EU.

In view of this, the medical device industry believes that Active Implanted Medical Devices (Directive 90/385/EEC) should be excluded for the foreseeable future from the RoHS Directive. The earliest date that inclusion of AIMD devices could be considered is 2020.

Medical technology industries truly think the differentiated inclusion into RoHS of medical equipment is the only way forward to ensure the reliability of their products. The suggestion that RoHS like legislation is “likely” to include these products is a claim without evidence and the contrary is true. There is no RoHS legislation (China, South Korea, Japan and California) that is going beyond the scope in the one in the EU. For the typical products of the medical industry all eyes in the world are on “Brussels”.

Medical Devices with life supporting applications:

Malfunctioning of Medical Devices with direct life supporting applications, would have a direct effect, possibly phatal, on the patient. Products in this category are external products that have similar functions as Active Implantable Medical Devices (AIMD’s), such as external pacemakers and external defibrillators or other products that support the patient directly, where any malfunctioning will put the patient directly at risk (perfusion systems, heart lung machines, etc).

II. SUBSTANCES COVERED [ARTICLE 6 OF ROHS]

1. Not add any new justified substances under RoHS and deal with them under REACH

Eucomed: We support this option as REACH already applies to Medical Devices and this Regulation will identify ‘substances of very high concern’ and their use will be both Authorized and may be Restricted.

REACH registration will include all uses of a particular substance including EEE and provides a wider perspective.

This is a better approach than RoHS Directive which imposes a ban on certain substances, but can allow exemptions.

2. Add new substances but only for certain categories of EEE in the scope of RoHS
**Eucomed**: All new substances should be handled under REACH and RoHS should not be expanded.

We are not clear how the new substances and the certain categories would be selected and it would still need the ability to have exemptions, if this option was adopted.

3. **Add new substances for all EEE, in the scope of RoHS but with exempted applications**

**Eucomed**: All new substances should be handled under REACH and RoHS should not be expanded. However if this option was adopted an efficient exemption process will be needed.

4. **Add new substances for all EEE without exemptions at a deferred date**

**Eucomed**: We are not in favour of the extension of RoHS with other substances, since REACH will deal with Substances of Very High Concern.

5. **Add new justified substances under RoHS only if substitutes already available and fully investigated**

**Eucomed**: We are not in favour of the extension of RoHS with other substances, since REACH will deal with Substances of Very High Concern.

6. **Link inclusion of substances at a given deadline (e.g 2014) with the results of a report on the efficiency of waste (WEEE) management for removing HS from the waste stream**

**Eucomed**: We are not in favour of the extension of RoHS with other substances, since REACH will deal with Substances of Very High Concern.

It is the duty of the manufacturer, under “Duty of Care of Waste” and WEEE Directive Article 10 Information for users, to make available information on any hazardous substance in their equipment which maybe present at end of life of the equipment

7. **Not add any new substances but introduce labelling requirements (for example certain phthalates for certain Medical Devices)**

**Eucomed**: We are not in favour of the extension of RoHS with other substances, since REACH will deal with Substances of Very High Concern. Specifically Article 33 will deal with information in the supply chain on Substances of Very High Concern.
Labelling for phthalates is already in the new MDD, so it should not be a requirement in the revised RoHS.

8. Not add any new substances but introduce obligation for easy removability of parts containing HS

**Eucomed:** This requirement is already outlined in WEEE Directive Article 4 Product Design.

In many Member States the hazardous WEEE is collected and treated separately – fridges, TVs, fluorescent lamps.

### III. TECHNICAL CHANGES TO THE SCOPE OF THE DIRECTIVE

1. Separate WEEE from RoHS scope

**Eucomed:** The two directives should be separated.

There is confusion between the two directives and their application to Medical Devices.

WEEE concerns end of life and waste management and the responsibilities of both manufacturers and end users.

RoHS focuses on design of equipment and the banning the use of certain substances which can be dangerous if present in landfills. The design is the responsibility of the manufacturer, plus the duty of informing the final user of the benefits of the design including compliance to legislation, environmental good practice etc.

2. Include explicitly spare parts & components

**Eucomed:** Spare parts for use with devices placed on the market before the entry into force of RoHS should be specifically excluded from RoHS in order to maintain devices in working order.

The problem arises in adding spare parts or refurbishing non RoHS compliant equipment – this will normally require non compliant parts/components. This situation could arise over many years, particularly if the performance is also improved at each maintenance/refurbishment stage.

This would impose unreasonable costs on the manufacturer and user. Older but functioning equipment would have to be replaced for no logical reason.

Further emphasizing the service parts issue with “Not having the ability to service non RoHS compliant product designs could leave equipment unusable, which could increase the overall waste.”
If the equipment is RoHS compliant then it is expected any supporting spare parts/components will also be RoHS compliant.

3. Insert in RoHS clause similar to WEEE Art 2.1 (excluding equipment which is part of another type of equipment that does not fall within the scope)

Eucomed: This WEEE clause is already causing confusion and if adopted is going to create much more confusion and so there is a need to define it with enough accuracy.

Initially we would request for more examples to clarify the situation. For example is a motorized wheel chair or motorized hospital trolley a ‘transport vehicle’?

4. Insert in RoHS clause similar to WEEE Art 2.3 (excluding equipment which is intended for specifically military purposes)

Eucomed: No comment, except medical devices are used for military purposes and some are specifically designed for this environment.

5. Clarify status of consumables

Eucomed: It does need clarification.

Consumables will often be supplied ‘with the equipment’ and the end user installs the consumable before use. This should not come under RoHS

Many consumables have no electrical components so why should they be considered as part of RoHS?

Only consumables in the product when placed on the market that have electrical/electronic components should be considered as RoHS.

Consumables are also included in WEEE if present in equipment at end of life.

The scope of RoHS is electrical equipment, consumables must be excluded, otherwise the scope expands exponentially, and conflicts with other directives.

All “non-electrical” consumables will be captured under REACH

6. Assess the need for including explicitly fixed installations

Eucomed: Fixed installation is causing confusion and further clarification would be helpful for WEEE.
In case of RoHS which is directed at design, it should not matter if the installation is fixed or not - the equipment is functional when purchased in both situations.

7. Assess the need for maintaining a general exemption for LSIT (large-scale stationary industrial tools)

Eucomed: Again much confusion which needs clarification.

Also difference between the design requirements of RoHS & waste management (WEEE).

It is expected this equipment would be RoHS compliant.

This type of equipment also tends to be a large and heavy ‘one off’ and when replaced or removed at end of life needs special treatment usually agreed between supplier & user.

8. Extend scope to cover all EEE

Eucomed: No comment.

9. Add more specialized product categories in an indicative annex

Eucomed: We would not support this option.

The annex 1B list is not particularly helpful as it does contain some medical procedures not medical equipment. It also has a final ‘catch all’ – other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability.

10. "Repair as produced" principle: exclude parts for repairing and for the reuse of products lawfully placed on the market

Eucomed: We fully support the principle of “Repair as produced”, to exempt parts for repairing and refurbishment for reuse of products lawfully placed on the market before RoHS implementation.

For medical devices this is crucial, since only those parts which have been validated before for use within the medical device can be used for repair and refurbishment of the device. Not allowing the use of the validated although non-RoHS compliant parts and components would in effect prevent the reconditioning of the devices for subsequent reuse. This would have a detrimental effect on the environment and contravene the RoHS objectives.

IV. DEFINITIONS
1. **Insert new definition for "placing on the market"**

   **Eucomed:** We support the definition of ‘placing on the market’ as described in the guidance for the New Approach Directive (Blue Book).

2. **Insert new definitions for the economic operators (such as manufacturer, distributor, importer)**

   **Eucomed:** We will be uncomfortable with any changes to definitions that conflict or are at odds with the definitions given in the MD directives.

3. **Insert definition for "fixed installations"**

   **Eucomed:** This is more a WEEE concern.

   It is expected all equipment would be RoHS compliant before it made into a ‘fixed installation’.

4. **Add descriptive definitions for each product category (specifically proposed for cat.8&9 by ERA study)**

   **Eucomed:** This is not necessary and adding further descriptive definitions could lead to more confusion and recategorisation of products.

5. **Include a comitology procedure to update the list of illustrative examples thereby clarifying the status of ‘grey area’ products (see Art 19 of the Packaging and Packaging Waste Directive)**

   **Eucomed:** It would be helpful to have more examples and also agreement across all the Member States.

6. **Insert definition for "homogeneous material" and the MCVs of the Commission decision**

   **Eucomed:** These two topics should be reviewed in light of the REACH Regulation and the conditions that could apply in the use of certain ‘substances of very high concern’.

7. **Insert definition for "spare parts"**

   **Eucomed:** Definition of a spare part:
The RoHS Directive and EC FAQ do not provide a definition of a spare part. However, we provide the following as suggestion:

“any item intended to replace a defective or worn out item, upgrade a device or replaced as part of a planned replacement schedule for a piece of apparatus, equipment or system previously placed and put into service on the market”

This definition from the EMC Directive can form the basis of a definition of a spare part for the purposes of the RoHS Directive, but further discussions may be necessary when ‘systems’ are involved.

Amendments to Article 2.3:
Article 2.3 of the RoHS Directive excludes spare parts for the repair or refurbishment of equipment placed on the market before 1 July 2006. The EC has stated in its FAQ that this extends to spare parts for upgrading equipment because one of the aims of the WEEE and RoHS Directives is to extend the life of products for as long as possible and to avoid waste.

If Medical Devices are included in the scope of the RoHS Directive then Article 2.3 will need to be amended to reflect that the date from which Category 8 products will be required to comply is different to the date of 1 July 2006 for Categories 1 to 7 and 10.

The wording of Article also needs to be changed to take account of temporary exemptions.

This is illustrated by the temporary exemption for lead in solders. Under this exemption, a server put onto the market in 2008 may use lead solders. Common industry practice is to manufacture spare parts (e.g. circuit boards) at the same time as the original equipment and using the same materials, particularly as some components may not be available several years later. However, if this exemption were to end in 2011, for example, and the server subsequently develops a fault, it could not legally be repaired with the (leaded) spare part made in 2008 because the current Article 2.3 only allows the use of spare parts for the repair of equipment put onto the market before 1 July 2006.

Design of Spare Parts:
Re-design of spare parts to comply with RoHS directive, while the unit itself is not compliant has implications on design verification and validation of the product to ensure it remains safe and meets its clinical performance. Hence, the exclusion of the spare parts must continue for at-least 15 years (average product life) from the inclusion of the medical devices in the RoHS directive.

V. FACILITATING IMPLEMENTATION

Va Enforcement of the RoHS Directive

1. Introduce market surveillance mechanisms

Eucomed: We would welcome a ‘common’ approach to market operation surveillance with clear statements on the actual mechanism and respective responsibilities.
2. Include conformity assessment (CA) procedures (sub options: self declaration or third party verification) (suggested also in the "Enforcement Guide", prepared by the informal network, see above)

**Eucomed:** Clarification across Europe on documentation requirements for compliance and declaration of conformity would be welcome. In particular the need for regular technical analysis of components, subassemblies and EEE for RoHS banned substances – there can be very large numbers of components & associated suppliers.

We want consistency of application across the Member States.

Mandatory conformity should be discussed in far more detail.

3. Introduce marking to demonstrate RoHS compliance

**Eucomed:** We are all ready using the CE mark on our product which is part of the conformity process. We consider that no additional marking is necessary,

4. Introduce common procedures for withdrawing non-compliant products from the market and for administrative cooperation

**Eucomed:** It would be helpful, particularly if manufacturers of similar equipment to that which is being withdrawn, were allowed some time to evaluate their own equipment as this particular range of equipment would be under the spotlight by end users.

Many products could be withdrawn due to non compliance of one or more component. A list of such components would be helpful.

5. Use of (international) standards; elaboration of material data bases and material declaration formats

**Eucomed:** The development of standards for testing for RoHS banned substances should be encouraged by the Commission.

In addition ‘supplier’ trade associations should be strongly encouraged to develop ‘standard’ material data bases and material declaration formats so only one set of data generated for use by all the actors in the supply chain.

6. Insert obligation for MS to collect and make available data
Eucomed: We consider that it would be helpful to institute regular ‘review projects’ to analyse both the true cost of compliance to RoHS Directive and the resulting environmental benefits from the reduction of certain substances.

7. Insert review clause with or without progress criteria/indicators

Eucomed: Given that Medical Devices may no longer be exempt it could be beneficial to monitor the progress and benefits for their introduction into RoHS compliance.

8. Introduce stakeholder forum

Eucomed: Stakeholder forums can be helpful in identifying related issues to a given proposal, but can often be too wide ranging. There needs to be focus on a few issues and once completed disband that particular stakeholder group.

9. Introduce implementation-related provisions already existing in WEEE, such as EEE producer traceability requirements (Art. 11(2)), producer register (Art.12(1)), information for users and treatment facilities (Art.10&11(1))

Eucomed: Medical Devices already have CE mark plus labelling giving company details, etc.

Vb. Mechanism for exemptions

1. No more exemptions, but reduce scope of the Directive (in terms of EEE or HS covered).

Eucomed: The current system of granting exemption is long and many have yet to be assessed. However the exemption process is still required. It is very important to have an exemption process for critical medical equipment.

2. Remove additional requirement for stakeholder consultation (art.5.2 of RoHS)

Eucomed: This process is acceptable and the only requirement would be the right to comment on the final consultancy proposal to the Commission so that the Commission & other stakeholders have a final opportunity to understand and evaluate our concerns.

3. Exemptions to be granted only for new technologies or only for new equipment

Eucomed: It would be difficult to define the ‘rules’ for such an approach.
It is important that the exemption should be firmly based on the benefits to society of the equipment and this should apply to existing and future equipment.

4. Industry and not public authorities to assume the burden of proof and cost

_Eucomed:_ There must be one or two overriding reasons why an exemption is requested – usually associated with enhanced product performance and or significant cost reductions.

It is these specific vital benefits that should be first reviewed before more detailed analysis of the equipment etc.

5. Manufacturers to provide substitution plan when requesting exemptions

_Eucomed:_ At the time there are often no ‘equivalent’ substitutions, thus there is no substitution plan yet.

However all exemptions are under review and it is possible substitutions can be introduced at some later stage.

6. Establish standard format for providing info on requested exemptions

_Eucomed:_ This would be helpful. We would suggest this could be phased – series of hurdles. The first would be to identify and agree key benefits and their significance.

7. Introduce cost/broader sustainability criteria for granting exemptions

_Eucomed:_ These are important criteria and could be included in the important few key benefits.

8. Introduce other criteria for granting exemptions

_Eucomed:_ Would concentrate on fundamental benefits and then if necessary at next stage include some of these criteria if appropriate.

9. Exemption requests to be submitted directly to the TAC

_Eucomed:_ Not sure the TAC member would always have the necessary knowledge and experience to present the case for an exemption in an area as specialised as the Medical Device Industry.