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## Practical application of REACH Article 33 to very complex objects

Dear Mr Lefèvre,

As the European trade association of the medical technology industries, MedTech Europe represents manufacturers of *in vitro* diagnostic medical devices and medical devices in Europe. The innovative medical technologies made available by our members often consist of very complex objects. For those *in vitro* diagnostic medical devices and medical devices, the application of REACH Article 33 on information on substances in articles presents a considerable challenge.

We understand that ECHA, the Commission and Member States are willing to evaluate proposals for a practical implementation of the Article 33 requirements. In that regard, MedTech Europe would like to express its support for the approach proposed to you by COCIR ("*COCIR discussion paper on practical application of Article 33 to very complex objects*") on 8 January 2018.

MedTech Europe is convinced that:

- The minimum information to be communicated is only the SVHC name.
- Further information on the SVHC is only required if needed to allow safe use of the article.
- Identification of the component containing the SVHC is only required if such information is needed to allow safe use of the article.
- Possible exposure is the most relevant criterion for the risk assessment to identify/exclude such need for further details.
- The level of detail regarding SVHC information formally communicated for complex *in vitro* diagnostic medical devices or medical devices must not distract recipients/users from relevant safety instructions according to the *In Vitro* Diagnostic Medical Devices and Medical Devices Directives/Regulations.

We would like to stress that this approach is fully compliant with the legal text of REACH Article 33 and the related Judgment of the European Court of Justice of 10 September 2015.

We would highly appreciate your feedback on this very important matter.

### MedTech Europe

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I remain at your availability for discussing this in person or providing further information.

With kind regards,



**Oliver Bisazza**

*Director Regulations & Industrial Policy*