Eucomed, working for you

Regulatory Affairs

Medical technology in Europe is a tightly regulated industry. However, effective regulation needs to recognise the impact of the law on the industry that develops the technology. Eucomed provides a constructive interface between the regulators and the regulated, ensuring the best interests of manufacturers are considered when laws are being designed that will govern the placing and maintaining of medical technology on the market in the EU and beyond.

It is Eucomed's Regulatory Affairs mission to fashion a predictable, sustainable and appropriate regulatory environment. We work to:

- Ensure that the technology and innovation which healthcare systems need are available to more patients;
- That competitiveness is encouraged and supported;

Eucomed pursues its regulatory affairs mission through three areas of activity:

1. Forward thinking and planning, building networks and connections and aligning positions;
2. Collaborating with regulators and policymakers;
3. Informing and educating to help shape regulatory policy.

Forward thinking and planning

We provide broad representation, promoting a consensus view of our industry that is orientated towards patient and business needs. By planning for the future, with working groups monitoring regulatory developments at EU and global level, we can anticipate and mitigate against unnecessary regulatory hurdles that may hinder the efficient availability of medical technology. We are constantly striving for a truly harmonized EU market and global alignment. We stimulate inclusive and open discussion across the broad Eucomed membership and the medical technology industry.

Our activities

- Strategy group setting and defining industry positions on key topics;
- Actively tracking and monitoring EU and global developments in many areas, including:
    - Recast of the medical devices directives;
    - EU harmonized standards;
    - Unique Device Identification;
    - Clinical evidence, vigilance and post market surveillance;
    - Patient safety: reprocessing of single-use devices.

Collaborating with regulators and policymakers

We strive for early engagement and the opportunity to input into EU legislation and guidance documents at the initial stages. Eucomed's dedicated government affairs team, drawn from the Commission and European Parliament are confident and comfortable navigating the formal and informal workings of the EU and interacting with EU Commissioners, MEPs, Member States representatives and other stakeholders.

Our activities

- Working with DG SANCO to create a high-level ministerial conference on innovation and the Recast of the medical device directives;
- Access and direct member participation in all Commission, EMA and Notified Bodies committees and working groups, including the Commission's Medical Devices Expert Group;
- Providing expert input to Regulators on specific issues before initiatives are proposed/taken at EU and global level.

Informing and educating

We provide a unique resource to keep you ahead of the curve in regulatory developments. Eucomed also provides a forum for you to connect with and learn from industry peers, and a platform for senior leaders to shape and drive regulatory policy.

Our activities

- Dedicated Strategic Regulatory and Environmental Committees;
- Early dissemination of documents under development at EU and global level, supported by Eucomed guidance documents to members;
- In-house expert advice/guidance on proposed legislative measures;
- A world class internal regulatory capacity that provides insights and expertise;
- Monitoring and reporting on national regulatory requirements and deviations.

About the Eucomed Regulatory Affairs Group

The Regulatory Affairs group consists of experts in regulatory affairs from Eucomed member companies, national associations and the Eucomed secretariat. The Group's priorities are pursued in collaboration with other relevant Eucomed working groups.

If you have suggestions or questions please contact John Brennan, Director Regulatory & Technical Affairs (tel.: +32 2 775 92 32; e-mail: john.brennan@eucomed.org) or Merlin Rietschel, Manager Regulatory and Technical Affairs (tel.: +32 2 775 92 23; e-mail: merlin.rietschel@eucomed.org).