Eucomed
Medical Technology

WHITE PAPER
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Transparency and Disclosure

Interactions between Industry and Healthcare Professionals (HCP)

Contents

Transparency: White Paper

I. Introduction

According to Transparency International (TI), transparency is defined as a characteristic of governments, companies, organizations and individuals being open in the clear disclosure of information, rules, plans, processes and actions[1]. As such, transparency is one of the core principles of the Eucomed Code of Ethical Business Practice guiding Eucomed members in their interactions with Healthcare Professionals (HCPs).

Improvements in the clinical care of patients are rooted in the interaction between HCPs and medical technology (MedTech) companies. HCPs (which include entities such as hospitals) are a source of innovation and creativity during the development of innovative medical devices and therefore an essential part of the R&D process. HCPs are also the prime users of technologies and play an instrumental role in the successful access to patients of innovative medical devices throughout Europe and beyond. This is because MedTech companies are legally required to provide HCPs with appropriate instruction, education, training, service and technical support to ensure delivery of safe and effective medical technology and care to patients. In all these interactions, transparency is a crucial element ensuring that these are appropriate and beyond criticism in view of any conflict of interest.

Recently, different stakeholders have been calling for another kind of transparency aimed at the disclosure of the financial information. Such financial transparency or disclosure covers reporting requirements on payments and transfers of value from the companies to HCPs. Different European countries (e.g. France, Slovakia), but also other countries across the globe (e.g. USA, Australia, Japan etc.) have initiated discussions on the issue and some countries are in the process or have already adopted some specific disclosure requirements imposed onto companies and HCPs.

These requirements often differ in terms of thresholds, types of interactions covered, persons involved, level of detail, publication place and frequency as well as implementation periods etc.

Eucomed strongly supports transparency as a broad principle to be conformed to by all stakeholders and in particular applying to companies' interactions with HCPs. Eucomed also understands the developments that lead to these new legal requirements of *financial transparency*. However, whether designed as a self-regulatory scheme [option preferred by the industry] or as a legal scheme,

[1] Anti-Corruption Plain Language Guide by Transparency International, July 2009: http://www.transparency.org/publications/publications/other/plain_language_guide

Eucomed believes that financial transparency should be constructed considering the following **important caveats**:

- Remain proportionate to the objective sought and effectively achieve its purpose, without *de facto* rendering the cooperation between HCPs and medical technology companies impossible by imposing unnecessarily burdensome reporting requirements. This means that:
  - Disclosed information should be limited to information that is helpful to the public, in particular patients in their decision-making process and be made available in a meaningful and easily-understood format that provides the appropriate context for patient education.
  - Disclosed information should be limited to information which is valuable to decision-making purchasing decisions, recommending or/and paying for medical devices.
  - Disclosed information should also aim at being as material as possible.
- Not compromise personal and/or proprietary information, i.e. infringe on the rights and sensitivities of the Healthcare Professionals[2].
- Not needlessly burden companies with heavy and costly internal processes, considering also the time and resource necessary for companies to implement data collection systems, as such specific reporting can be disproportionately laborious to implement internally.

In this White Paper, Eucomed sets out, mainly to support its national member associations, the principles, and major issues related to such transparency as well as its recommendations as to the reasonable, minimum arrangements for a national framework for disclosures, including the safeguards to be built in to be effective, practical and acceptable for all stakeholders, including industry.

[2] Financial transparency cannot be isolated from data privacy laws and regulations. Indeed, the privacy rights must be respected by anyone, in this case particularly MedTech companies, collecting, processing and ultimately publishing personal data of individual HCPs. Data protection rules lay down a series of strict rights and duties in relation to personal data when it is collected and processed (e.g. reinforcement of rights of data subjects, situations where explicit consent is required, prior impact assessment applicable to health data processing operations). It is therefore important to organise prior to any implantation of a national framework for disclosure of payments, a thorough "privacy scrutiny/review" by the local Data Protection Authority, which should give its opinion in terms of consent, process of potential review and further validation.
Given that the EU data privacy framework is under review for the moment, this privacy scrutiny will have to be re-assessed in light of the upcoming new rules. This will avoid contradiction in legal requirements for companies.

II. Transparency in the Eucomed Code of Ethical Business Practice

Strong ethical standards are critical to ensuring appropriate collaboration between the medical technology industry and physicians, and more broadly Healthcare Professionals (HCPs). This is why Eucomed has been actively promoting transparency requirements in our Eucomed Code of Ethical Business Practices (hereinafter the "Eucomed Code")[3], supporting appropriate disclosure of industry/HCPs relationships, such as the following:

- Prior written notification to the hospital administration or HCP's employer (or other locally-designated body) with full disclosure of scope and purpose (e.g. specification of services) is required whenever a Member Company engages a HCP as a consultant or whenever a Member Company makes a financial contribution to the HCP's medical training/education.
- If a Eucomed member provides financial support to an individual HCP who is part of the conference faculty, the Eucomed member should request the faculty HCP to declare that he/she is the recipient of such a sponsorship from a member company at the time he/she delivers a presentation at the conference.

In some countries, such as France, Belgium, Greece or the Czech Republic, specific additional legal requirements already govern the transparency of interactions between industry and HCPs (e.g. prior authorization systems, which may also evaluate the reasonable level of the remuneration).

[3] The Eucomed requirements apply in the absence of local regulations or national ethical codes and must hence be applied together with the other already existing legal and regulatory requirements.

III. *Financial Transparency*: Disclosure of Payments and Transfers of Value

In addition to the important caveats mentioned above, Eucomed would like to emphasize the importance, in particular in times of economic crisis, of balancing the costs versus the benefits of any additional disclosure scheme. Medical technology innovation plays a vital role in the improvement of the quality of care, as well as in the efficacy and sustainability of healthcare systems. Policies need to ensure that governments do not suppress industry support for strong relationships with HCP, healthcare providers and healthcare commissioners, which promote partnership, joint working and which foster innovation in the mistaken view that the industry needs to be additionally controlled by increasingly elaborate mechanisms, imposing significant administrative burdens onto companies that have been designed without long-term efficiency and effectiveness considerations.

In view of the above, Eucomed believes that where financial transparency schemes are considered, they should be developed considering the following aspects:

1. Categories of payments / transfers of value to be reported

   We suggest that the activities and related payments as well as contributions in kind relating to the following types of educational, medical research and scientific activities could be disclosed [excluding activities performed for non-commercial purposes such as regulatory compliance]:

   - **Consulting agreements** (e.g. honorarium, proctoring);
   - **Charitable donations**;
   - **Research and educational grants to institutions**;
   - **Direct sponsorship of HCPs to congresses** (i.e. congress fee and related costs);
   - **Compliant gifts and give-aways,** other than those defined in section 2 below;
   - **Hospitality, travel and accommodation provided to HCPs**, in accordance with the provision of the Eucomed Code, and above a reasonable threshold.

   Moreover, Eucomed strongly recommends that reporting on transfers of value and payments made within the framework of **early stage Research & Development and product development** (i.e. minimum 4 years or until CE mark approval) should be suspended until market entry of the product. This reporting deferral is justified because of the confidential and proprietary nature of the information, which for competition law compliance should be reported differently.

   In addition, in order to avoid misinterpretations, it is also important to explain the context in terms of patient education and/or responsible decision-making, i.e. via a rationale for the amounts paid which should be available in a meaningful and easily understood format.

2. Carve outs

Unreasonable, excessively detailed and very low threshold disclosure requirements will be unlikely to provide more transparency and risk imposing a significant administrative burden on the companies. In addition, unreasonable requirements will not contribute to the provision of meaningful and constructive information, in particular relevant to the decision-making of patients, purchasers or/and payers of medical devices. A balanced system requires certain exceptions to be taken into account.

We believe that the following should be excluded from the scope of disclosure requirements:

- **Fee-for-service, honoraria and payments to HCPs below a reasonable threshold per year per HCP**, if national legislation does not provide a lower/different payment threshold, the payment should not be reported. – *This also includes in particular unique, short-term cooperation, such as for example a one-time honorarium for a lecture at a congress.*
- **Hospitality, travel and accommodation payments**, made in accordance with the Eucomed Code and applicable legislation, **and below a reasonable threshold per year per HCP,** do not have to be collected and reported – *There should be a reasonable threshold for items such as coffee or sandwiches, below which companies should not be required to collect and/or report data.*
- **Compliant gifts/give-aways, samples and items of limited value**, as defined by the Eucomed Code, **below a reasonable threshold per year per HCP**, do not have to be collected and reported. Above the threshold, all items need to be reported. – *Amounts related to small promotional items such as branded pens or pads are difficult to be referenced to specific individuals to whom these were given, and therefore should not be tracked and therefore cannot be reported.*
- Disclosure requirements should not include reporting of **discounts, rebates, or other pricing information.** – *Such information is commercially sensitive and should not be reported for competition law compliance.*
- **Utilization of physicians as expert witnesses**. Companies anticipating or involved in litigation often utilize HCPs to serve as expert witnesses or provide other expertise. – *Disclosure of such relationships could violate attorney-client privilege, unfairly require the disclosure of legal strategies and should therefore be exempt from the requirements of legislation.*

3. Recipients of payments / transfers of value

HCPs are defined as "individuals (clinical or non-clinical, including but not limited to physicians, nurses, technicians and research co-ordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical devices"[4].

[4] Preamble, Eucomed Code of Ethical Business Practice.

4. Obligation to publish / disclose

Interactions between the industry and HCPs are not necessarily limited within a single country and may have a cross-border character. In order to avoid confusion and legal uncertainty, we suggest that any disclosure obligation should follow the laws of the country where the recipient HCP is mainly professionally active.

The disclosure obligation should be per legal entity of the company that is responsible for the payment or transfers of value to the HCP[5] and ideally, such a company will also be based in the country where HCP is mainly professionally active. If this is not the case, this obligation should be fulfilled by responsible company's affiliated company which does operate in the country where the HCP is professionally mainly active.

5. Level of detail

Disclosure should be based on the following elements:

- HCP name, and if applicable the national unique registration number, where permitted under national privacy laws;
- For individuals, the institution name and location where the individual HCP practices;
- Ideally, disclosure should be within an established scale of fixed ranges expressed in terms of financial value to the recipient HCP, i.e. the maximum amount per category of activity/per HCP.

For privacy reasons, Eucomed strongly recommends that disclosure takes place via a unique national reporting platform, like a website, rather than on individual company websites. This should ensure legal certainty and protection from a data privacy point of view, as well as maintaining uniformity and consistency of the reported data, based on unique identifiers of HCPs.

Moreover, to the extent that the disclosure obligation is not imposed by law but voluntarily agreed via, for example, sector initiatives, given the personal and sensitive nature of the data, data protection laws will require that HCP give their individual explicit **consent** on the disclosure of the data, including specific values[6].

6. Publication frequency

Reporting should take place once a year for the payments made in the previous calendar year.

[5] This disclosure requirement would equally apply to distributors and agents, managing sales and marketing of medical technologies.

[6] This requires that the reporting scheme allows for sufficient time for companies to review and validate the values / amounts with the HCPs, before publishing the data.

7. Publication place

As outlined above, there should be one national independent **secured website** or other reporting platform administered by the relevant authority department or independent third-party. This authority should be the sole controller of the data, as defined in the data protection legislation, and this should also allow concerns regarding data completeness to be addressed.

In the absence of a unique "public" website or other reporting platform the publication on any other website, such as individual company websites, raises different issues such as comparability of the data as well as data protection as well as other security and logistical issues. If the option of the company website is chosen nevertheless, it will be necessary to clarify which affiliate or branch will be responsible for the website (e.g. providing for cases where there is no national affiliate).

8. Timing

It is important to keep in mind that the construction and management of a disclosure scheme requires a significant amount of time for the authorities to set up such a scheme in practice as well as for the companies to collect the data and report it as requested. In particular, companies will need time to allocate necessary internal resources in order to build the tracking and reporting systems. Therefore, we believe that a *step-by-step* approach should be taken to ensure that the industry is allowed sufficient time to implement such reporting systems.

About Eucomed

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We represent designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

The industry we represent employs more than 500,000 highly skilled workers, turns over €95 billion per year, invests some €7.5 billion in R&D and encompasses of approximately 500,000 different medical technologies from sticking plasters and wheel chairs through to pacemakers and replacement joints.

Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society.

For more information visit www.eucomed.org