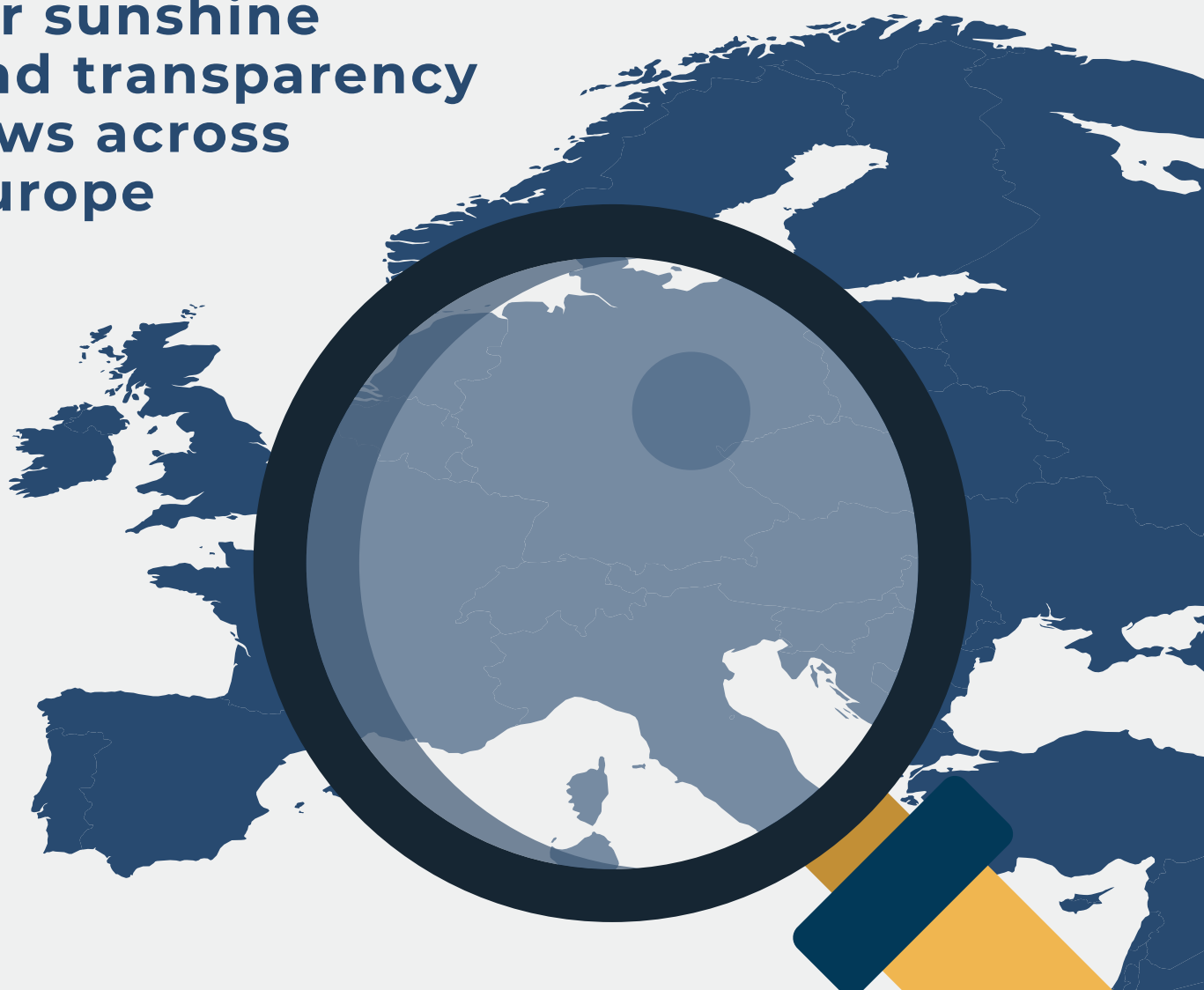


SHEDDING LIGHT ON TRANSPARENT COOPERATION IN HEALTHCARE

The way forward
for sunshine
and transparency
laws across
Europe



**SHEDDING LIGHT ON
TRANSPARENT COOPERATION
IN HEALTHCARE:
THE WAY FORWARD FOR
SUNSHINE AND TRANSPARENCY
LAWS ACROSS EUROPE**

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LIST OF ABBREVIATIONS

COI – Conflict of Interest

CME – Continuing Medical Education

CPGs – Clinical Practice Guidelines

DTC – Direct to Consumer

EU – European Union

HCO – Healthcare Organisation

HCP – Healthcare Professional

OTC – Over the Counter

PO – Patient Organisation

R&D – Research & Development

EXECUTIVE SUMMARY

Mental Health Europe is concerned about the lack of transparency in the relationship between the health industry (e.g. pharmaceutical and medical device industry), healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs), especially when it comes to the mental health sector. A lack of transparency around interactions between these stakeholders has led to the over-medicalisation of mental health and a worrying reliance on drugs as the main form of treatment for mental ill-health. It has also caused unethical and biased decision-making in mental healthcare.

Interactions between the pharmaceutical industry and HCPs or HCOs can be divided into two main categories: research-oriented interactions and promotion practices. A large part of these relations, not only very complicated and technical, remains opaque for patients and citizens. Even though this cooperation is to some extent inevitable and can be beneficial, substantial risks and ethical dilemmas remain. Extensive marketing and biased medical education, among others, may lead to conflicts of interest, which create a risk of potential harm to users and patients, such as receiving suboptimal treatment, undue medicalisation or waste of private and public money.

Regulations and rules introducing disclosure mechanisms around 'transfers of value' between the industry and HCPs, HCOs or POs are being adopted globally, acknowledging the existence of conflicts of interest. In Europe the situation varies considerably depending on each state's approach to regulating cooperation between health industries, HCPs, HCOs and POs. The main differences can be observed between self-regulation and legally binding rules or regulations. The self-regulatory approach of the pharmaceutical industry has been implemented all over Europe (except Luxembourg) and beyond, while legally binding rules or regulations have been introduced in some EU member states (e.g. France, Belgium, Portugal, Denmark, Romania), making it obligatory for the main healthcare actors to disclose information on their financial cooperation.

Self-regulation of the health industry represents a substantial step forward. However, this approach cannot ensure full transparency with regard to transfers of value due, among others, to its voluntary nature, the requirement of consent from HCPs, the format of disclosed information, and a number of exclusions from disclosure. Considering the existing shortcomings of self-regulation and the fact that currently the whole EU transparency system in this field remains incoherent, it seems important to bring about improvements in transparency provisions.

Fully transparent cooperation among all actors in the (mental) healthcare sector can only be ensured through legally binding laws implemented across Europe. Robust disclosure and monitoring mechanisms, along with educational activities, appear to be a suitable way to improve relationships between the industry, HCPs, HCOs and POs. Ideally, such changes should be facilitated at the EU level in order to ensure harmonisation and equal access to information at least in all member states. It would allow for users and patients to make well informed choices, as well as strengthening trust between HCPs, users and patients. Additionally, it would contribute to ensuring greater effectiveness, safety and independence of the medical education and practice.

Therefore, our recommendations are:

- ❑ to promote and adopt a comprehensive legally binding approach to the disclosure of transfers of value, including disclosure of financial and professional relationships between health industries, healthcare professionals, healthcare organisations and patient/user organisations, comprising at least mandatory disclosure on an individual level; the widest possible scope of transfers with a low or no threshold; user-friendly, searchable and downloadable databases; and effective mechanisms of monitoring and ensuring compliance;

- ✦ to set legal minimum standards for the harmonisation of transparency reporting at the European level;
- ✦ to raise awareness of conflicts of interest in medical education and medical practice, along with effective ways of managing them;
- ✦ to support initiatives offering independent initial and continuing medical education for medical students and healthcare professionals;
- ✦ to ensure unbiased research in health sciences via sufficient independent funding; and
- ✦ to raise awareness among users of mental health services on conflicts of interest and how to deal with available information regarding disclosure and involve users throughout the implementation of transparency provisions.

1. INTRODUCTION

The relationship between the medical profession and the pharmaceutical industry has a major impact on people's health and well-being. It can lead to scientific progress and development in healthcare, but also to over-prescription and biased scientific results.¹ A lack of transparency in the relationship between the health industry and healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs), has contributed to overreliance on the purely biomedical model in the field of mental health. It also has an impact on the independence of health professionals and organisations, leading to unethical and biased decision-making in mental healthcare.

Although the mental health sector is particularly affected by a lack of transparency as it limits support available to users of services, the issue affects the entire health sector. Most of the risks (e.g. over-medicalisation) are of a universal nature. Transparency is crucial to shaping health systems that provide a range of appropriate support. It is essential to ensure proper quality and safety of the services delivered to all users.

Generally, transparency refers to the disclosure of as much information as possible to the public, so that citizens are able to check, analyse, verify and control the actions of public servants and public bodies as a whole, through accessible information. In relation to healthcare, there is a wide range of interpretations of the concept of transparency across countries, care settings, and stakeholder groups. Components of transparency in healthcare include: transparency regarding quality of care, patient/users' experience, financial transparency, governance, and individual health data, as set out in the table below.²

Quality of care	Patient/user experience	Finance	Governance	Individual health data
Mortality / survival rates	Treatment outcomes	Disclosure of payments, gifts, hospitality to healthcare staff (transfers of value)	Procurement	Data privacy and safeguarding policy
Hospital re-admission rates	Patient/user satisfaction	Pricing	Public decision making	Information on use of individual data
Adverse events reporting	Patient/user complaints	Financial performance	Public involvement	Shared clinical data

Table 1 Transparency components in healthcare (Source: Through the looking glass. A practical path to improving healthcare through transparency, KPMG International. 2017)

Particular concerns about transparency have been raised when it comes to the relationship between the healthcare and pharmaceutical sectors. While the pharmaceutical industry contributes to improvements in treatment outcomes, it is also at risk of creating harm if it leads to abusive practices.³ With a global spending on health of around US\$6.5 trillion annually, the interaction between the pharmaceutical industry and the healthcare sector is an attractive target for potential malpractices.⁴

Private stakeholders, which are mainly profit-oriented, play a growing role in ensuring access to healthcare services in Europe. To a large extent, the pharmaceutical industry, which is an example of such a stakeholder, is responsible for introducing innovative therapies to the market. Every year, a plethora of new medication, devices and treatments are introduced to the market and to (mental) health professionals, accompanied by intensive marketing activities. Within this system there is a substantial information imbalance between producers, providers and those who use their services – patients and users.⁵ The healthcare system is so very often classified as the most vulnerable public sector.⁶ It was created with the purpose of taking care of our most valued resource – health – and yet it is simultaneously exposed to the influence of a number of actors whose first interest is not necessarily directly the well-being of people. Potential undue influences from the industry, unparalleled resources and profit maximisation going beyond ethical norms create a risk of negative impact on health outcomes and public health objectives.⁷

In this report, we will first look at the different types of interactions between the pharmaceutical industry and (mental) healthcare professionals and organisations, their ethical dimensions and possible ways of managing such interactions. We will then provide an overview of current means to ensure transparency, both at the national and European level, before assessing how to ensure greater transparency in the future.

2. UNDERSTANDING THE INTERACTIONS BETWEEN THE PHARMACEUTICAL INDUSTRY AND HEALTHCARE PROFESSIONALS AND ORGANISATIONS^a

Despite the relevance of the relationship between healthcare professionals and organisations, there is a lack of wider public awareness or media interest in the topic. This implies that arrangements between the two parties are often worked out behind the scenes. Because of the potential implications of the interactions between the industry and HCPs or HCOs, it is of utmost importance to ensure a better understanding among the general public of the cooperation between these parties.

Throughout this chapter, we will discuss the types of interaction between the industry and HCPs, HCOs and POs, the ethical concerns these interactions might raise within the healthcare sector, including the influence of conflicts of interest on medical practice, as well as look at how these interactions can be effectively managed.

2.1. TYPES OF INTERACTIONS

Interactions between the pharmaceutical industry and HCPs or HCOs can take many forms, including research-oriented collaboration and pharmaceutical marketing. In the United States it is estimated that almost 94% of physicians enter into some kind of relationship entailing economic benefits with the pharmaceutical industry.⁸ The table below shows the frequency with which various types of economic interactions take place.

	Frequency of Physician-Industry Relationships (percentage of respondents)
Gifts	83%
Drug samples	78%
Reimbursements	35%
Payments for consulting	18%
Payment for serving as a speaker or on a speaker's bureau	16%
Payments for serving on an advisory board	9%
Payments for enrolling patient in clinical trials	3%
Any of the above relationships	94%

Table 2 Frequency of physician - industry interactions (percentage) Source: Campbell EG. *Doctors and Drug Companies – Scrutinizing Influential Relationships*.⁹

Research-oriented interactions

As pharmaceutical and biotechnology companies contribute significantly to the development of new therapies, support for and cooperation with the medical community increases rapidly. Research-oriented interactions between companies and the medical community include supporting, funding or sponsoring research projects. Industry stakeholders maintain the narrative that collaboration with the medical community is inevitable and necessary to ensure patient safety and effective treatment that fits into patient needs.¹⁰ Many medical practitioners and other HCPs so participate in the design and implementation of clinical trials, for instance as consultants or researchers.

a. This chapter contains contributions from Emilia Kaczmarek PhD and Prof. Klaus Lieb. To access the full contributions of these authors see Annex 1.

Drug promotion practices

The World Health Organisation (WHO) defines drug promotion as “all informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs”.¹¹ Companies may use different forms of drug promotion:

✦ Direct marketing

Direct marketing mainly consists of direct advertisements of products to consumers or direct contact with HCPs through pharmaceutical sales representatives.

In the European Union direct-to-consumer (DTC) advertising of prescription medications has been banned, while commercials of over-the-counter medicines (OTC) – which are the medicines for which there is no prescription needed – and dietary supplements can still be advertised. The rationale for the prohibition of DTC advertising of prescription medications seems to be clear, as the objective of commercials and marketing is not only to inform clients about a given product but also to increase its demand. This implies creating artificial health needs which can be a threat to the individual, and to public health. Although prescription medication cannot legitimately be advertised directly to patients, advertisements can be directed to HCPs through, for example, pharmaceutical sales representatives.

Pharmaceutical sales representatives meet HCPs, tell them about the advantages of marketed products, and distribute free drug samples and leaflets. They also provide physicians with small gifts and free lunches, and with invitations to participate in conferences or in postgraduate education. The majority of HCPs meet pharmaceutical representatives at least once a month. This frequency differs depending on the workplace and profile of the physician. Junior physicians seem to receive more benefits from marketers than senior physicians.¹²

✦ Continuing medical education

Continuing medical education (CME) is a form of education that occurs after graduation and obtaining a professional licence. The main aim of CME is to keep up to date with the latest developments in one's area of expertise, but also to develop professional skills and capacities. In many countries, attending a certain number of CME courses is a condition for maintaining a licence or the right to practice. A large part of the available CME options is funded and organised by the pharmaceutical industry.

✦ Indirect marketing - health campaigns, ghost-writing, astroturfing

In addition to direct-to-consumer advertising and activities of pharmaceutical sales representatives, indirect marketing strategies for drug promotion might also take place.

First, health campaigns through content marketing and advertorials can be used to promote medicines. Such non-direct, hidden commercials may take the form of sponsored health campaigns that are devoted to different health problems, social media profiles, press articles or on-line content featuring specific methods of treatment.

Another form of indirect marketing, commonly known as ghost-writing, consists of scientific articles being prepared by professional copywriters employed directly by pharmaceutical companies, and then signed in the name of a well-known expert in the medical field, with their consent, to give the report more scientific prestige.¹³

Finally, pharmaceutical companies may also engage in astroturfing, cooperating with patients' organisations (e.g. through the funding of health campaigns) or even establishing new health-related seemingly bottom-up organisations. Astroturfing masks the sponsors of a message and gives the public the impression of widespread grassroots support for a product or policy. As such, products can be given credibility by withholding information about the organisation or cooperation behind it.

Ghost-writing, cooperation with, or setting up of, seemingly grassroots organisations, or health campaigns – sponsored by pharmaceutical companies but run through patient associations – are all marketing practices conducted in a way that should convince the recipient of the independence and objectivity of the messages conveyed. The recipients do not receive the messages directly from a pharmaceutical company, but through entities that are trusted and perceived to have authority in the field.

2.2. ETHICAL DIMENSIONS OF THE INTERACTIONS

As described in the section above, there are different ways in which pharmaceutical companies can approach and build a relationship with HCPs or HCOs. Each tie with companies potentially compounds the relationship. Even scientific cooperation between the pharmaceutical industry and HCPs carries many risks and threats to objectivity, user/patient centred care and the rational use of new therapies, if the main driver for such cooperation is not a better quality of care for patients. Issues arise when these interactions create a conflict of interest, impact on HCPs behaviour, patient safety and public health, and do not have patient care and well-being as their ultimate goal.

Conflict of interest

A conflict of interest (COI) appears when an individual has “personal, financial, professional, or political interests that are likely to undermine his or her ability to meet or fulfil his or her primary professional, ethical, or legal obligations”.¹⁴ A COI is considered to be a risk factor, which increases the probability of occurrence of various types of misconduct. The problem is therefore not primarily the COI itself, but the biased or distorted judgment or action of those who have such conflict.

COIs are thus not per se bad or reprehensible, as the person with a COI will not necessarily behave in a way inappropriate for his or her profession. Nonetheless, a COI provokes a combination of stimuli and motivators that can have harmful effects through their influence on judgments and actions. A situation when a physician holding shares in a pharmaceutical company gives a lecture on a medication manufactured by this company is not a “potential COI that could result in a real COI; it is simply a COI that could result in real bias”.¹⁵

2.2.1. IMPACT ON HCPS' BEHAVIOUR, PATIENT SAFETY AND PUBLIC HEALTH

Ethical questions emerge when a COI impacts on the behaviour of healthcare professionals. Physicians are obliged to base their prescription and treatment choices solely on up-to-date scientific knowledge. However, while interacting with HCPs and HCOs, the pharmaceutical industry uses various methods to influence prescribing behaviour and decision-making.

It is not always easy for practitioners, even those who abide most by ethical codes, to recognise the extent of the influence and pressure to which they are subjected.¹⁶ Numerous studies show that physicians usually do not believe that gifts from pharmaceutical representatives can influence their prescription habits, and although some HCPs show scepticism about the knowledge of medical representatives many others perceive them as an effective and convenient source of information on medication.¹⁷

Nevertheless, extensive research has been pointing at a correlation between HCPs and HCOs receiving benefits from pharmaceutical companies and a higher frequency of making decisions concordant with the interests of these companies.¹⁸ The closer the relationship to a pharmaceutical company, the greater the risk of bias in medicine, which may take various forms.

Prescription behaviour. The interaction between pharmaceutical sales representatives and physicians has one of the greatest impacts on prescribing behaviour.¹⁹

Physicians who have received free meals or educational trainings from the producers of a certain original medication are more likely to prescribe such medication even when cheaper generic equivalents are available on the market.²⁰ The rate of prescriptions increases after psychiatrists see a representative or accept free samples.²¹ Physicians who attend company-sponsored CME events have more positive attitudes towards, and higher inclination to prescribe, the branded drug, even if others may be more effective, safer, and less costly.²² On the other hand, physicians who refuse CME sponsorship seem to prescribe a higher proportion of generics and lower expenditure medicines.²³ Finally, participation by HCPs in clinical trials conducted by the pharmaceutical industry may also result in higher prescription rates of a tested medication after its approval.²⁴

Research results. Pharmaceutical companies funding trials often control and manage data and have a final say when it comes to making it public.²⁵ This can result in selective publishing of research papers.²⁶ For instance, researchers from the DataLab at the University of Oxford found that out of 7274 completed trials in the EU Clinical Trials Register only 49.5% had reported their results.²⁷ Selective reporting of trials, which mainly occurs due to negative or unfavourable results, can contribute to suboptimal treatment decisions.

Another form of bias in research reporting is the exaggeration of positive results of a clinical trial in the conclusion of a scientific paper, compared to findings shown throughout the article.²⁸ Research sponsored by pharmaceutical companies shows results favouring drug manufacturers more often than research without the participation of pharmaceutical companies.²⁹

Clinical Practice Guidelines. Research-oriented cooperation may also lead to undue influence on Clinical Practice Guidelines (CPGs). CPGs are very often developed by respected and high profile experts that industry actively seeks to serve as Key Opinion Leaders. Many of these receive payments of which consistent sums (\$10,000 or more) are undisclosed.³⁰ Biased CPGs can propose one specific, high-priced drug as a first line or best solution in treating certain conditions, or lower diagnostic thresholds.³¹

Accuracy of information on medication. Pharmaceutical representatives might spread exaggerated assertions about the safe use of a certain medication and inform HCPs inaccurately about certain therapies, in a way that is favourable to drug producers.³² Such practices were, for instance, documented during the recent opioid crisis in the United States. Some companies were sued and had to pay fines because their pharmaceutical representatives wrongfully informed HCPs about addictive characteristics of certain drugs.³³

Additionally, during sponsored educational courses, alternatives to medication promoted by the event sponsors are played down.³⁴ This can be observed especially in psychiatry, where a worrying reliance on medication as the main form of treatment for mental ill health takes place. This unbalanced relationship may reinforce a narrow biological conception of the nature of mental health, which understates the adverse effects of psychiatric drugs.

Accuracy of information on diseases. Medication manufacturing companies can spread exaggerated claims about the frequency and burdensomeness of a certain disease. The pharmaceutical companies or other parties with financial interests may want to enlarge the market for treatment. This can happen either by narrowing the definition of health (so that normal experiences get labelled as pathologies) or by expanding the definition of disease (in order for milder or presymptomatic forms to be treated as a full-blown disease).³⁵ Dissemination of these claims can happen either directly or through organisations receiving support from companies, as well as by the media which uncritically repeat these claims.

Off-label use. Off-label use implies that a medication is either prescribed for an unlicensed use, or to an unlicensed patient group (e.g. older people or children), or at an unlicensed dosage. An example of such practice is the case of GlaxoSmithKline illegally marketing several of its drugs (antidepressants, among others) for uses that had not been approved by safety regulators. The company paid \$3bn to settle charges in the U.S. after admitting to hiding

unsupportive scientific evidence, manipulating articles in medical journals and providing gifts to doctors.³⁶ Off-label use of a medication can be promoted by pharmaceutical representatives or during sponsored lectures.³⁷ A 2003 report showed that off-label use accounted for 21% of all prescriptions for commonly used medications, with over 50% of off-label use among psychiatric drugs.³⁸ Off-label use, especially without supporting evidence, poses a risk for patient safety and may represent wasteful medication use.

Lobby for medication reimbursement. HCPs' prescribing behaviour, especially concerning innovative and expensive therapies, is shaped by policy developments in the area of drug reimbursement. These therapies are widely administered only if reimbursement is ensured, which in turn has an impact on public resources. Medication producers lobby for the reimbursement of a medicine, sometimes via patient organisations that they sponsor, even if another, equally good and much cheaper drug is present on the market.³⁹

The biases mentioned above may lead to potential harm to patients, such as receiving suboptimal treatment, undue medicalisation⁴⁰, iatrogenic illnesses (i.e. illnesses caused by medical examination or treatment), or the waste of private and public money. Besides this, conflicts of interest directly cause another negative consequence – they undermine social trust in medicine.

2.2.2. IMPACT ON USER TRUST

Medicine is a social practice where patients and users' trust in their physicians and medical institutions is key to ensuring the best possible health and well-being outcomes. Numerous surveys show a correlation between the patient's belief that physicians receive gifts from pharmaceutical industry and lower levels of trust in medicine.⁴¹ There is a negative perception of COIs among patients, although not all types of interactions between physicians and the pharmaceutical industry are assessed in a similar way. For example, receiving remuneration for consultations from pharmaceutical companies does not undermine trust in physicians to the same extent as holding company shares does.⁴²

Research reveals that patients have very little awareness about their physicians' competing interests but do want to know in what kind of interactions with the pharmaceutical industry their healthcare professionals entered.⁴³ Patients indicate that disclosure of transfers of value and links with the industry would improve their confidence in HCPs. An Australian study shows that 77% of patients who believe that physicians are not unduly influenced feel it is nevertheless important for their physician to disclose these benefits, 75% believe that such disclosure would help them make better informed treatment decisions, and 73% agree they would have more confidence in their physicians' decisions with full disclosure. However, other studies show that trust tends to decrease with a disclosure of links to the pharmaceutical industry, depending on the types of benefits received by HCPs.⁴⁴

Once trust in one's HCP falters, users might try to confirm the validity of information on therapies or diagnoses from other sources of knowledge that they perceive as impartial. This crisis of trust may encourage an increasing number of patients to seek health services outside of professional healthcare which may pose a threat to public health. Independent research as well as independent institutions are necessary for medical practice to remain cogent.

In order to preserve a trustworthy relationship between HCPs, HCOs and patients and users, all COIs that are avoidable should be avoided. It is important to note that limiting conflicts of interest does not mean banning the cooperation between HCPs or HCOs and the pharmaceutical industry. This cooperation is necessary – without it, companies will not be able to create new medicines and monitor the effectiveness of the ones which have already been marketed. However, models of cooperation should be designed to minimise violations of rules of impartiality and to not undermine trust in medicine.

2.3. MANAGEMENT OF THE INTERACTIONS

Patients must be able to trust their treating physicians to work with them to make the best possible choice for their well-being, regardless of HCPs' secondary interest. An important step in the management of COIs is ensuring

transparency through, for example, disclosure mechanisms.

As further described in chapter 3, variations of disclosure mechanisms have been introduced in many countries. The main purpose of introducing such disclosure obligations is to provide objective information on the financial cooperation between the pharmaceutical sector, medical devices sector, HCPs and HCOs. The availability of such information allows patients and users to assess the health services market, make a more informed choice of provider, strengthen the trust between the physician and the patient and conduct research on the impact of this cooperation on prescribing behaviours.

Initiatives on transparency about COIs through disclosure mechanisms have the following advantages:

- ✘ The disclosure includes all pharmaceutical companies, it is mandatory and does not require approval by one health care professional - it allows for full transparency.
- ✘ If financial support is not reported by a pharmaceutical company, severe penalties are due - this promotes the obligation of transparency.
- ✘ Data is aggregated for all companies on one website - this allows the information about payments to physicians to be fully available and accessible to everyone.

However, transparency initiatives need to be further developed in order to obtain a more comprehensive picture of COIs:

- ✘ Only financial COIs are disclosed, although it is known that non-financial (e.g. intellectual, theoretical, or school of thought commitments) COIs can also lead to harmful effects on research and patients.⁴⁵
- ✘ Disaggregated data for financial COIs must be provided. For example, financial support for well-designed clinical trials and for the widely criticised post-marketing studies must be listed separately.⁴⁶ The same is necessary for payments for advisory boards for marketing purposes and those for purely scientific aspects. This may help to distinguish harmful relationships from those that may be important for the further development of drugs and can thus be potentially helpful for patients.
- ✘ Transparency must be accompanied by well-understood information, so that the nature and extent of the relationship is understood even by a layman.

Disclosure mechanisms might also carry substantial negative consequences. First, an increased bias might occur for HCPs when offering advice. For instance, HCPs may feel justified in providing biased information because the advisee has been informed about the conflict of interest.⁴⁷ Second, the relationship between pharmaceutical companies and HCPs is not eliminated just by disclosing information about its existence, which *ipso facto* does not contribute to decrease of the effect of the conflict of interest. Implementation of compulsory disclosure solutions can also contribute to disregarding the actual conflict of interest (disclosed = solved) and other means of its management. Finally, by obliging HCPs to disclose details of their cooperation with the pharmaceutical industry, a bigger pressure and responsibility is exerted on users and patients, charging them with the assessment and judgement of selecting HCPs.

Although mandatory transparency is important, the “bias” reported in section 2.2 can thus not be reduced by transparency alone. Transparency is a first important step towards greater independence of physicians and scientists but must be accompanied by further measures to reduce COIs and their management.⁴⁸ These measures

must by no means be neglected over the introduction of transparency initiatives and may consist of:

- ✦ Educating physicians and other healthcare professionals and students about COIs and their effects.
- ✦ Ensuring mandatory and complete transparency of COIs of all kinds in important areas (e.g. at CME events or in the preparation of guidelines).
- ✦ Supporting initiatives that aim to reduce COIs or offer independent CME courses and conferences (e.g. with CME scoring only for industry-independent CME events or increased CME scores for such events).
- ✦ Ensuring mandatory rules for dealing with COIs (e.g. in the preparation of guidelines, if such are unavoidable).
- ✦ Conducting more research about COIs, their transparency and management in order to end up with wanted, and to avoid unwanted, effects of COIs management.

Such measures provided in addition to comprehensive transparency can help improve health and well-being and to maintain the trust of patients and users in the medical profession and in a just healthcare system.

3. CURRENT MEANS OF ENSURING TRANSPARENCY

Throughout this chapter, we will provide an overview of the current means of ensuring transparency, both at the national level as well as at the European level.

3.1. OVERVIEW OF SUNSHINE AND TRANSPARENCY LAWS, REGULATIONS AND CODES ACROSS EUROPE

Until a few years ago, there was little regulation governing relationships between the industry, healthcare professionals (HCPs) and healthcare organisations (HCOs). Pharmaceutical companies and the medical devices industry did not need to disclose whether they, for example, sponsored events or made transfers of value (i.e. donations, gifts) to HCPs or HCOs.⁴⁹

The Physician Payment Sunshine Act⁵⁰ (now referred to as “Open Payments Program”) introduced in the U.S. in 2010, created a new standard of transparency for financial relationships between pharmaceutical companies and HCPs. The Act requires manufacturers of drugs, medical devices or biological or medical supplies who participate in federal healthcare programs to report direct or even indirect payments or other transfers of value exceeding \$10 to physicians and academic hospitals. The data is submitted to the Open Payments Program, run by the Centers for Medicare and Medicaid Services since 2013.⁵¹ Certain benefits are exempted from disclosure, such as meals offered at large conferences, product samples, certified and accredited continuing medical education that are considered independent and educational material directly benefiting patients.⁵²

Implementing the Sunshine Act facilitated information gathering about all forms of financial support by the U.S. Industry above a minimum limit of \$10 per year since 2013. In 2016, a total of \$8.18 billion was paid by 1,481 companies to 631,000 physicians and 1,146 teaching hospitals. \$2.8 billion was spent on general payments (e.g. invitations, CME sponsorship, travel reimbursements, etc.), \$4.36 billion for research activities, and \$1.02 billion for equity interests (e.g. patents royalties).⁵³

While U.S. rules mandate federal-level disclosure requirements, regulation in Europe differs from country to country. In almost all European countries there is a self-regulatory approach of the pharmaceutical industry, as introduced in 2013 by the European Federation of Pharmaceutical Industries and Associations (EFPIA), in the form of The European Disclosure Code. The Code applies to HCPs and HCOs and represents a significant and welcome step forward in ensuring transparency in the healthcare sector.⁵⁴ Users and patients organisations are not included in the Disclosure Code, however obligation to disclose information has been enforced on member companies through the EFPIA Code of Practice on relationships between the pharmaceutical industry and patient organisations, which is described further in this report.

In addition to self-regulation and following the adoption of the U.S. legislation, some European countries enacted similar laws and regulations at the national level – with France and Portugal at the forefront.⁵⁵

Finally, a range of countries have transparency or anti-corruption provisions in place which apply to the relations between the industry and the healthcare sector.

The table below provides an overview of the situation across Europe presenting the characteristics of transparency provisions in different European countries. Our analysis gathered information from 27 member states of the European Union (EU) (excluding Luxembourg, which is covered neither by self-regulation, nor by any national legislation) and from seven non-EU states, as self-regulation of the European industry goes beyond the EU and those states have interesting approaches to transparency. Data from each country includes the following information:

- ✘ type of policies (self-regulation, regulation, transparency / anticorruption law)
- ✘ covered industries (pharmaceutical, medical device)
- ✘ reportable parties / covered recipients - HCPs, HCOs, POs
- ✘ reportable information (benefits in kind, payments in cash, other benefits)
- ✘ consent requirements (need for obtaining prior consent of healthcare professionals or organisations to disclose information about transfers of value)
- ✘ threshold for disclosure (limit above which all payments and transfers ought to be disclosed)
- ✘ repository of disclosed information.

Information was collected through a legal analysis of national and European legislation, as well as a desk research of relevant public sources (e.g. national and European associations, literature review etc.). In addition, a survey was conducted among Mental Health Europe's membership concerning all the above-mentioned categories.

The analysis is however limited by a number of factors. First, the availability of information in local languages has hindered a more detailed analysis. Second, in the analysis of self-regulation we mainly looked into the innovative pharmaceutical industry. Initiatives from the generic industry are not included in the table but presented in detail in section 3.3.2. Regarding the medical device industry, although self-regulation is in place and has been implemented by MedTech Europe in 2018, the first round of disclosure has not started yet. Third, the analysis relates to a policy area which is rapidly changing, more recent standards might have been adopted since the analysis was conducted in December 2018.

In the European context, it is worth mentioning a similar mapping exercise, but on a smaller scale, carried out by a team of researchers from The University of Sydney, Health Action International, The University of Latvia and Lund University.⁵⁶


Table 3 Overview of the transparency provisions across Europe

	Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic
Type of policy	Self-regulation	✓		✓	✓	✓	✓
	Regulation		✓				
	Transparency / anticorruption law				✓		
Industries covered	Pharmaceutical	✓	✓	✓	✓	✓	✓
	Medical devices		✓				
Reportable parties / Covered Recipients	All HCPs	✓	✓	✓	✓	✓	✓
	Selected HCPs						
	Patient / user organisations	✓	✓	✓	✓	✓	✓
	Healthcare organisations (hospitals, universities)	✓	✓	✓	✓	✓	✓
Reportable information	In kind	✓	✓	✓	✓	✓	✓
	Meals, drug samples, educational and promotional materials included in disclosure						
	In cash	✓	✓	✓	✓	✓	✓
	Other						
Consent required	Yes	✓		✓	✓	✓	✓
	No		✓				
Threshold for disclosure		No	No	No	No	No	No
Repository of disclosed information		Separate PDF on each company website	Centralised database	Separate PDF on each company website	Separate PDF on each company website	Separate PDF on each company website	Centralised database on the website of the National Organisation

	Country	Denmark	Estonia	Finland	France	Germany	Greece
Type of policy	Self-regulation	✓	✓	✓		✓	✓
	Regulation	✓			✓		✓
	Transparency / anticorruption law	✓				✓	✓
Industries covered	Pharmaceutical	✓	✓	✓	✓	✓	✓
	Medical devices	✓			✓		
Reportable parties / Covered Recipients	All HCPs	✓	✓	✓	✓	✓	✓
	Selected HCPs						
	Patient / user organisations	✓ (self-regulation)	✓	✓	✓	✓	✓
	Healthcare organisations (hospitals, universities)	✓ (self-regulation)	✓	✓	✓	✓	✓
Reportable information	In kind	✓	✓	✓	✓	✓	✓
	Meals, drug samples, educational and promotional materials included in disclosure				✓	✓	
	In cash	✓	✓	✓	✓	✓	✓
	Other						
Consent required	Yes		✓	✓		✓	
	No	✓			✓		✓
Threshold for disclosure		No	No	No	10 euro	No	15 euro
Repository of disclosed information		Centralised database	Separate PDF on each company website	Separate PDF on each company website	Centralised database	Separate PDF on each company website	Separate PDF on each company website, Centralised database on the website of National Organization for Medicines, Centralised database for donations to HCOs

	Country	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania
Type of policy	Self-regulation	✓	✓	✓	✓	✓	✓
	Regulation					✓	
	Transparency / anticorruption law	✓			✓		
Industries covered	Pharmaceutical	✓	✓	✓	✓	✓	✓
	Medical devices						
Reportable parties / Covered Recipients	All HCPs	✓	✓	✓	✓	✓	✓
	Selected HCPs						
	Patient / user organisations	✓	✓	✓	✓	✓	✓
	Healthcare organisations (hospitals, universities)	✓	✓	✓	✓	✓	✓
Reportable information	In kind	✓	✓	✓	✓	✓	✓
	Meals, drug samples, educational and promotional materials included in disclosure					✓ (included in regulation)	
	In cash	✓	✓	✓	✓	✓	✓
	Other						
Consent required	Yes	✓	✓	✓	✓	✓ (under co-existing self-regulation)	✓ (including HCOs)
	No					✓	
Threshold for disclosure		No	No	No	No	No	No
Repository of disclosed information		Separate PDF on each company website	Separate PDF on each company website	Separate PDF on each company website	Separate PDF on each company website	Separate PDF on each company website (links on one website)	Separate PDF on each company website

	Country	Malta	The Netherlands	Norway	Poland	Portugal	Romania
Type of policy	Self-regulation	✓	✓	✓	✓		✓
	Regulation					✓	✓
	Transparency / anticorruption law		✓		✓		
Industries covered	Pharmaceutical	✓	✓	✓	✓	✓	✓
	Medical devices		✓			✓	✓
Reportable parties / Covered Recipients	All HCPs	✓	✓	✓	✓	✓	✓
	Selected HCPs				✓ (anti-corruption law applies to national consultants)		
	Patient / user organisations	✓	✓ (voluntarily)	✓	✓	✓	✓
	Healthcare organisations (hospitals, universities)	✓	✓ (voluntarily)	✓	✓	✓	✓
Reportable information	In kind	✓	✓	✓		✓	✓
	Meals, drug samples, educational and promotional materials included in disclosure					✓ (except drug samples)	
	In cash	✓	✓	✓	✓	✓	✓
	Other						
Consent required	Yes	✓	✓	✓	✓		
	No				✓ (for national consultants)	✓	✓
Threshold for disclosure		No	500 euro / year / company	No	National Consultants only - approx. 90 euro	60 euro	No
Repository of disclosed information		Separate PDF on each company website	Centralised database (Healthcare Transparency Register)	Separate PDF on each company website	Separate PDF on each company website (links on one website)	Centralised database	Centralised database

	Country	Russia	Slovakia	Serbia	Slovenia	Sweden
Type of policy	Self-regulation	✓	✓	✓	✓	✓
	Regulation		✓			
	Transparency / anticorruption law		✓	✓	✓	
Industries covered	Pharmaceutical	✓	✓	✓	✓	✓
	Medical devices		✓			
Reportable parties / Covered Recipients	All HCPs	✓	✓	✓	✓	✓
	Selected HCPs					
	Patient / user organisations	✓	✓ (self-regulation)	✓	✓	✓
	Healthcare organisations (hospitals, universities)	✓	✓ (self-regulation)	✓	✓	✓
Reportable information	In kind	✓	✓	✓	✓	✓
	Meals, drug samples, educational and promotional materials included in disclosure		✓			
	In cash	✓	✓	✓	✓	✓
	Other					
Consent required	Yes	✓	✓ (HCOs, POs)	✓	✓	✓
	No		✓			
Threshold for disclosure		No	No	No	No	No
Repository of disclosed information		Separate PDF on each company website	MoH website, Separate PDF on each company website (links on one website)	Separate PDF on each company website	Separate PDF on each company website	Separate PDF on each company website (links on one website)

	Country	Switzerland	Spain	Turkey	Ukraine	UK
Type of policy	Self-regulation	✓	✓	✓	✓	✓
	Regulation		✓			
	Transparency / anticorruption law		✓			✓
Industries covered	Pharmaceutical	✓	✓	✓	✓	✓
	Medical devices					
Reportable parties / Covered Recipients	All HCPs	✓	✓	✓	✓	✓
	Selected HCPs					
	Patient / user organisations	✓	✓	✓	✓	✓
	Healthcare organisations (hospitals, universities)	✓	✓	✓	✓	✓
Reportable information	In kind	✓	✓	✓	✓	✓
	Meals, drug samples, educational and promotional materials included in disclosure					
	In cash	✓	✓	✓	✓	✓
	Other					
Consent required	Yes	✓ (including HCOs)		✓ (required before transfer)	✓	✓
	No		✓			
Threshold for disclosure		No	No	value exceeding 10% of the current monthly minimum wage	No	No
Repository of disclosed information		Separate PDF on each company website	Separate PDF on each company website.	Separate PDF on each company website	Separate PDF on each company website (links on one website)	Centralised database on the website of National Association

3.2. NATIONAL LEVEL

At the national level relationships between the pharmaceutical industry and healthcare professionals and organisations are regulated through full legislation, partial legislation, or anti-corruption and transparency regulation.

3.2.1. EXAMPLES OF FULL LEGISLATION AT THE NATIONAL LEVEL

Some European countries have enacted a full legislation regulating relationships between the industry and other stakeholders in healthcare. Such legislation, called sunshine law, means that states enforce disclosure obligations on the industry, healthcare professionals and healthcare organisations and are responsible for monitoring the disclosure. For countries with full legislation, transparency is required when it comes to various transfers of value from the industry to HCPs. Companies and/or HCPs and HCOs have to disclose information about their cooperation at the individual level, ideally in public databases. National legislation can set a threshold for disclosure and a range of fines for breaching the rules. Usually, there is no consent of HCPs required for disclosure.

BELGIUM

In Belgium there were several laws imposing transparency requirements on pharmaceutical companies in relation to internal recordkeeping and samples given to HCPs but in 2016 the new Sunshine Act⁵⁷ was enacted as a full legislation, executed by a Royal Decree in 2017.⁵⁸ The Act now obliges entities acting on the pharmaceutical and medical device market, regardless of their legal forms, to disclose any information about interactions with healthcare professionals, healthcare organisations and patient organisations. They need to submit reports concerning the premiums and benefits granted to these stakeholders to the Federal Agency for Medicines and Health Products (AFMPS).⁵⁹ The information is published in a searchable, public database. The scope of the Act is the same as that of the EFPIA Disclosure Code, although its implementation is exercised by a federal entity. The report on research and development spending may aggregate all R&D-related transfers of value, while all other types of transfers of value must be reported for each HCP and HCO.⁶⁰ Possible fines range between €1,600 and €120,000.

DENMARK

In Denmark, a Sunshine Act came into place in 2014. Before its implementation, medical doctors, dentists and pharmacists had to obtain a prior permit from the Danish Health and Medicines Authority to have a professional or economic affiliation with a pharmaceutical company. Since the Act, there are disclosure obligations imposed on the pharmaceutical and medical device companies conducting business in Denmark. Apart from doctors, beneficiaries include dentists, nurses and pharmacists, and a wider range of professionals such as radiographers, midwives and senior employees in retail shops selling medical devices.⁶¹

Under the Act, companies not only need to apply for permission for cooperation, or notify the relevant authority (permission is not required, for example, for lecturing and research), but they are also obliged to forward annual reports to the Danish Health and Medicines Authority comprising details about any healthcare professionals who have been affiliated with the company in certain periods of time.⁶² Reports are made available to the public by the Danish Health and Medicines Authority. Interestingly, the notification of payments is also related to activities taking place outside the territory of Denmark.⁶³ The new law prohibits companies from providing unlawful economic benefits to HCPs and abolishes the provision of courtesy gifts and the use of competitions/raffles when promoting pharmaceutical products. Cooperation with patient associations and hospitals is covered by the Danish Ethical Rules for Promotion of Medicinal Products towards Health Care Professionals.⁶⁴ Each company discloses grant agreements on its website.

FRANCE

In 2011, France became the first European country to pass a Sunshine Act, commonly known as la Loi Bertrand. The French Act was established, among others, as a consequence of the Mediator scandal. A weight-loss, amphetamine derivative drug, called Mediator, which it is believed could have caused up to 2,000 deaths in France, was marketed to overweight diabetics but often prescribed to healthy

women as an appetite suppressant.⁶⁵ As a result, French authorities enacted a law regulating links between the pharmaceutical industry and the medical community, creating disclosure obligations. Although the Act came into force in 2013, it retroactively demanded disclosure of transactions which had occurred from 2012 on.

The content of the French Act is pretty similar to the one of the U.S. Open Payments Program. The Act requires the publication of information on any agreements with healthcare providers within 15 days counting from its execution and on any benefits in cash or in kind that exceeds the amount of €10. From the donors' side, it imposes obligations on the entities acting on the market of medicines, medical devices and cosmetics. When it comes to beneficiaries the act covers HCPs, patient organisations, representative associations, medical centres, students and universities. At first, the reporting of actual fees for services (e.g. consultancy) was not required. Nevertheless in 2015, following a complaint from civil society groups, the French Council of State ruled the establishment of such an obligation.

In January 2017, a proposal to amend the Sunshine Act, extending the scope of the regulation and clarifying the definition of benefits which must be disclosed, was presented. The proposal broadens the scope of companies and professionals who are bound by the Act and the amount of remuneration paid as part of contracts must now also be disclosed. In France, the penalty that can be imposed on the basis of the national regulation reaches the amount of €225,000 and may be accompanied with other sanctions, such as the suspension of business activities. Disclosed information can be accessed by the public through the website <https://www.transparence.sante.gouv.fr>.

PORTUGAL

In Portugal, a sunshine law was first established in 2006 and then revised in 2013.⁶⁶ Following a decision of the Portuguese National Authority of Medicines and Health Products (INFARMED), it became mandatory to disclose transfer of values exceeding €25 from pharmaceutical and medical devices companies, to HCPs or HCOs. In October 2014 that limit was raised to €60.⁶⁷

All the information about cooperation between the industry and the healthcare sector is gathered in the centralised database managed by the INFARMED.⁶⁸ Failure to comply with reporting obligations, retention of supporting documentation, including action programmes or events, can be subject to a fine ranging between €2,000 and €180,000 (to be determined by INFARMED).

ROMANIA

In Romania the sunshine regulation obliges the pharmaceutical and medical device sectors to publish information on the sponsorship and other benefits provided to HCPs and HCOs.⁶⁹ More precisely, entities that fall under the law are manufacturers, marketing authorisation holders or their representatives to Romania and wholesale and retail distributors of medicinal products, medical devices and healthcare material. Additionally, member companies of the Asociatia Romana A Producatorilor Internationali de Medicamente (ARPIM) disclose information under a self-regulatory process. Covered recipients

include physicians, medical assistants, professional organisations, patient organisations and any other types of organisations in the healthcare system. Reports are submitted to the Ministry of Health and the National Agency for Medicines and Medical Devices (ANMDM). At the moment, declarations and information delivered by donors and beneficiaries are available at the ANMDM's website.⁷⁰

SLOVAKIA

In Slovakia there are two Sunshine Acts, requiring transparency in relation to medicinal products and devices as well as benefits granted to HCPs introduced in 2011. The Acts require the pharmaceutical industry to submit annual reports to the Slovakian Ministry of Health, indicating the value of advertising and marketing expenses but also non-monetary benefits transferred to HCPs. Disclosure obligations do not include research and development (R&D) payments and benefits acquired by HCOs (e.g. donations, grants).⁷¹

3.2.2. EXAMPLES OF PARTIAL LEGISLATION AT THE NATIONAL LEVEL

In some countries, partial sunshine provisions were enacted, which means legal obligations are included in other more general legal frameworks, or legal frameworks only include certain obligations, or only apply to certain stakeholders of the healthcare sector, without being as comprehensive as what we consider full legislation. Such provisions cover, for example, obligations to disclose information about payments to a regulatory agency, but not to the public, or requirements for the pharmaceutical industry, which do not apply to other industries.

GREECE

In 2014, Greece adopted a law with a sunshine obligation.⁷² The law, which came into force in January 2016, states that every pharmaceutical organisation is obliged to disclose all benefits provided to HCPs and HCOs, including donations, sponsorship, registration fees to congresses or seminars, accommodation and trip fees, as well as any other benefit relevant to the promotion of prescribed medicines. The disclosure needs to take place within the first six months of the year and be published on the website of the pharmaceutical organisations and on the website of the National Organisation for Medicines. The benefits relating to research and development, as well as non-interventional studies, should be disclosed in totality by every pharmaceutical organisation. Expressly excluded are market research, meals and drinks, as well as objects of negligible value for training and medical use connected with the conduct of everyday practice of HCPs and HCOs. Negligible value is defined as a value not exceeding €15.

The Hellenic Data Protection Authority, however, has published a legal opinion relating to the sunshine obligation which limits the scope of disclosures. In this ruling, the Authority found that there were gaps in the relevant legal provisions and concluded that the disclosure obligation only relates to those benefits concerning promotional but not scientific conferences. Furthermore, disclosures should include only essential personal data and excludes information such as Tax Registration Number and

Social Security Number. Moreover, the Authority has concluded that the reporting of the amounts of benefits must be carried out in a specific way which ensures the protection of the privacy of HCPs. For example, the creation of profiles for HCPs is prohibited and disclosure must be done in a way that ensures that their personal information does not appear on search engines. As a result of this legal opinion, pharmaceutical companies who had published disclosures with personal data of healthcare professionals on their websites, have subsequently deleted this information.

The Hellenic Association of Pharmaceutical Companies has announced that it will comply with any relevant directive issued by the National Organisation for Medicines and other relevant authorities. The National Organisation for Medicines has not yet issued any relevant directive regarding disclosures of transfers of value, but it has contested the decision of the Hellenic Data Protection Authority and a new decision is expected to be delivered.

LATVIA

Latvia's national regulation requires pharmaceutical companies to report their payments to associations of HCPs, foundations, medical treatment institutions as well as individuals that have professional or scientific purposes related to health.⁷³ The regulation does not cover the medical devices industry.⁷⁴ The generally applicable law coexists with the self-regulatory provisions, covering a broader range of payments to HCPs and HCOs.⁷⁵ Governmental regulation covers organisation and sponsorship of promotional and scientific events attended by specialists (including travel and accommodation), support to specialist professional associations and medical institutions for scientific or professionally oriented events. Reports appear on the website of the Health Inspectorate, supervised by the Ministry of Health.⁷⁶

TURKEY

Sunshine rules were introduced in Turkey in 2015, requiring the disclosure of transfer of value between marketing authorisation holders and HCPs or HCOs (including unions, universities, and other health related organisations) to the Ministry of Health. Transfers of value exceeding 10% of the legal minimum wage must be reported to the Turkish Pharmaceutical and Medical Device Agency. The regulation demands healthcare professionals and organisations to consent to the disclosure before entering into a relationship with the pharmaceutical industry.⁷⁷ Turkish legislation does not cover the disclosure of transfers of value to the general public.

3.2.3. EXAMPLES OF ANTI-CORRUPTION AND TRANSPARENCY LEGISLATION AT THE NATIONAL LEVEL

In some European states sunshine policies are of limited scope, posing just a little requirement for reporting and public disclosure. Such limited policies can mainly be found in anti-corruption law and regulations regarding advertising and promotional activities, which might apply to healthcare.

In **Croatia**, there are penal laws that could potentially cover corruption, however these laws have never been used to control activities of pharmaceutical companies.

German legislation does not impose any specific disclosure obligation on producers of licensed pharmaceutical products. Certain regulations do, however, impose some more general disclosure obligations. For example, all HCPs who enter into service contracts with, or receive benefits from, the pharmaceutical companies are obliged to disclose this to their employer. The German Medical Products Act (Arzneimittelgesetz) imposes disclosure obligations in relation to observational drug studies. Germany adopted a new anti-corruption law which came into force in 2016 and makes it illegal for all HCPs, including General Practitioners, to accept gifts in return for prescribing medicines.

In **Hungary**, under the Act XCVIII of 2006 on the Safe and Economic Supply and Distribution of Medicines and Medical Aids and the Distribution of Medicinal Products, sponsorship of HCPs to attend professional conferences or courses must be submitted to the National Institute for Quality and Organisational Development in Healthcare and Medicines. This obligation covers holders of the marketing authorisation of a medicinal product or therapeutic medical devices, authorised distributors of medicinal products or therapeutic medical devices, manufacturers or distributors of medical aids or other economic operators working on behalf of the aforementioned.

Italian law, just like the German and Spanish laws, does not have any autonomous transparency regulation. Nevertheless, according to the Legislative Decree No 219 of 24 April 2006, it is demanded that companies holding the authorisation to produce, market or import pharmaceuticals in Italy and entities commercialising such products, must inform the Italian Medicines Agency (AIFA) when organising or contributing to an event referring to a product put into the Italian market. Recently, media reported on attempts to introduce sunshine law in Italy, which would make all payments above €10 public.⁷⁸

There is no statutory legal obligation in **the Netherlands** for pharmaceutical companies to report payments made to HCPs or HCOs. However, the Dutch Medicines Act contains relevant articles. Advertisement, targeting public and professionals, is forbidden for medicines that are only available on prescription. The Medicines Act also prohibits improper inducements unless certain conditions are met (e.g. event of purely scientific purpose and limited hospitality, reasonable fees for relevant services upon written agreement, minor gifts, bonuses and discounts related to the purchase of medical devices). The Netherlands also have a self-regulatory system in place. Although there is no generally applicable legal sunshine framework, governmental authorities are nevertheless involved.⁷⁹ The Code of Pharmaceutical Advertising prepared by the Foundation for the Code of Pharmaceutical Advertising in 2012 contains rules on the transparency policy setting basis for the database⁸⁰ of industry set up with the support of the Dutch Ministry of Health.⁸¹

A limited disclosure obligation does exist in **Polish** law under the Act on Consultants in Healthcare but only covers national health consultants. The disclosure obligation rests on national consultants rather than industry who must issue individual declarations in which they disclose transfers of value (approx. €90) as well as other interests. These disclosures have been made publicly available on a government website since 2013.⁸² Advertisement of medicinal products directed at HCPs is widely regulated in the Pharmaceutical Law.⁸³ This law stipulates that it is forbidden to direct any form of advertisement of medicinal products at persons authorised to issue prescriptions and persons marketing medicinal products. Advertisement consists of giving, offering or promising: material benefits, gifts and various facilities; prizes; travel; and organisation and financing of meetings of promotional medicinal products, during which the hospitality goes beyond the main purpose of the meeting.

Slovenia does not have a specific sunshine law but the Medicinal Products Act requires holders of marketing authorisation for medicinal products to keep records in relation to advertising of medicinal products as well as training of HCPs. In addition, it only allows the giving, offer of or promise of gifts, financial advantages or benefits of a limited value to persons qualified to prescribe or supply medicinal products.⁸⁴ Slovenia has anti-corruption legislation which might also apply in some circumstances.⁸⁵

Spanish transparency policy embraces medicinal and health products. It partially covers entities of the pharmaceutical market, requiring companies to disclose details of benefits granted to HCPs and HCOs, particularly in connection with conferences, congresses and publications. There is also a need to notify financial involvement in the creation of scientific materials containing information about marketed product, directed at professionals. In Spain, payments made after January 2017 do not require prior consent of a healthcare professional. That does not apply to payments related to R&D, which are still disclosed in an aggregated form.

There is no direct statutory legal obligation in **Sweden** for pharmaceutical companies to report payments made to healthcare professionals or organisations. However, other anti-corruption legislation could be applicable, including the Medicinal Products Act and anti-corruption rules under the Criminal Code.⁸⁶

In the **UK**, transparency provisions can be partially found in the Bribery Act of 2010, stating that failure to prevent bribery is a new corporate offence applying to all businesses. In addition, in April 2016, the National Health Service (NHS) also introduced a new policy requiring a range of medical personnel, including senior doctors, to reveal data about received payments or non-monetary benefits from the industry.⁸⁷ Finally, the Association of the British Pharmaceutical Industry runs Disclosure UK, a database that gathers all information collected under the implementation of the self-regulatory practices. This information is then uploaded into searchable databases available to the public.⁸⁸

3.3. EUROPEAN LEVEL

At the European level, several legal frameworks concerning transparency and advertising, as well different types of self-regulation of the pharmaceutical and medical device industry exist. However, legally binding provisions of disclosure obligation are currently missing.

3.3.1. EU REGULATIONS CONCERNING TRANSPARENCY AND ADVERTISING

Directive 2001/83/EC on the Community code relating to medicinal products for human use

Directive 2001/83/EC⁸⁹ is widely known as the Pharmaceutical Code. The Directive reflects how the pharmaceutical market is currently regulated by EU law.

According to the preamble, the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health. At the same time, it is equally important that this purpose should be attained by means which will not hinder the development of the pharmaceutical industry or trade of medicinal products within the EU.

The Directive states it is necessary to control the entire chain of distribution of medicinal products, including their manufacturing or import into the territory of the EU, their distribution, advertisement, and last but not least, supply to the public. Laws should guarantee that drugs are stored, transported and handled in suitable conditions.

Narrowing it down to the stage of the trading of medicinal products, which initiates relations between pharmaceutical companies and HCPs, HCOs and POs, a part of the Pharmaceutical Code refers to the advertising of drugs to persons qualified to prescribe or supply them. The Directive states that advertising significantly contributes to the information available to such entities and as such remains desirable. Nevertheless, it should be subject to stringent conditions and effective monitoring, as health professionals must be able to perform their functions objectively, without being influenced by direct or indirect financial incentives from industry. However, according to motive 52 of the Pharmaceutical Code, it is up to the member states to take all measures necessary to this end, in light of their own individual context.

Specific provisions of Directive 2001/83/EC concerning the advertisement of medicinal products to healthcare professionals

According to the motives described above, Directive 2001/83/EC regulates all stages of medicinal products' trading, including their advertisement. There are two types of advertising, each with different requirements.

The first one concerns the advertising of medicinal products to the general public, whereas the second one is the advertisement directed at persons qualified to prescribe or supply drugs. Contrary to the advertisement of medicinal products to the public, which is widely regulated, the advertisement aimed at professionals is scarcely addressed by Directive 2001/83/EC. The Directive states that any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include essential information compatible with the summary of product characteristics and supply classification of the medicinal product. All the information must be accurate, up-to-date, verifiable and sufficiently complete to enable their recipient to form their own opinion on the therapeutic value of the drug at issue.

When it comes to the role of medical sales representatives in the distribution chain of medicinal products, the Pharmaceutical Codes require that they are given adequate training and have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the products they promote. During each visit, medical sales representatives shall give the person visited, or have available for them, summaries of the product characteristics of each medicinal product they present. What is more, their duty is to transmit to the scientific service held by the market authorisation holder all information acquired from professionals about the use of a promoted drug, in particular its adverse reactions.

According to the Directive, when medicinal products are promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised, unless they are inexpensive and relevant to the practice of medicine or pharmacy. Hospitality at sales promotion shall always be of reasonable cost and secondary to the main purpose of the meeting. It cannot be extended to others than health professionals' entities.

Article 96 of the Directive regulates the handling of free samples of medicinal products. They shall be provided on an exceptional basis to persons qualified to prescribe or supply drugs, upon their written request.

Finally, the role of particular member states in medicinal products advertisement is invaluable as they ensure that there are adequate methods to monitor advertising and to enforce the requirements stated in the Directive, mainly through competences conferred upon courts or administrative organs.

List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector

The European Commission set up the 'Process on Corporate Responsibility in the Field of Pharmaceuticals' (2010-2013) to facilitate discussions on ethics and transparency, and on non-regularity conditions for better access to medicines after receiving marketing authorisation. Within this process three platforms were launched. Through one of them, i.e. the Platform on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders' group – including, among others, EFPIA – has adopted a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector".⁹⁰

This document reads "[...] adhering to principles of good governance, ethics and transparency, can have a profound positive impact on healthcare policy and practice, and ultimately on patient outcomes. This List of Guiding Principles [...] aims at contributing to ensure that patients receive proper treatment and are provided with relevant, factual and unbiased information."

The document states that the pharmaceutical industry commits to working together with all stakeholders to set out a clear approach to full transparency of financial transactions – including non-monetary benefits – and

other declarations of interest. The List of guiding principles addresses each stakeholder active in the field of pharmaceuticals (industry, HCPs, HCOs, and competent EU, regional and national authorities).

Transparent collaboration between HCPs and the industry was named as necessary in order to avoid any conflict of interest. According to these principles competent authorities should play a pivotal role in establishing and following good governance principles through the creation of a transparent environment for all stakeholders, in which public disclosure of conflict of interest should be ensured. Nevertheless, in several paragraphs the document points at the importance of data privacy issues concerning individual level data of HCPs.

3.3.2. SELF-REGULATION AND TRANSPARENCY INITIATIVES

The self-regulatory system is a legal structure aimed to develop and write down certain standards of conduct of entities operating on the market. Self-regulation is a type of voluntary initiative which enables economic operators, social partners, non-governmental organisations or associations to adopt common guidelines amongst themselves and for themselves.⁹¹ First and foremost, self-regulatory acts, known also as codes of conduct, contain norms of a deontological and ethical character, reflecting the values that are respected in a given community.

Self-regulation of the pharmaceutical sector through codes of good practice is perceived as an instrument of soft law, as codes of good practice constitute a set of standards whose infringement by market operators is sanctioned. On the other hand, codes of good practice are created and respected directly only by their signatories. They thus assume the form of a multilateral civil agreement of which the content is negotiated and which is characterised by the voluntary accession to the code, and the possibility to withdraw from the code on agreed terms.

The EFPIA HCP/HCO Disclosure Code and subsequent national codes

The Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations, commonly known as Disclosure Code, was adopted by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 2013. It required implementation in national codes by the 31st of December 2013.

The Disclosure Code, although not being part of generally applicable law, is regarded as a turning point in European Sunshine policy.⁹² Following the Disclosure Code, national associations (consisting of EFPIA members), acting in 33 countries, including non-EU countries, introduced national codes of conduct based on the one prepared by the EFPIA. Exceptions were allowed if member organisations were unable to implement provisions of the Code due to differing national legal systems, such as having national sunshine regulations in place. This was the case in France where the Code of the French Industry Association (Les Entreprises du médicament (LEEM)) stated that applying French law equalled fulfilling obligations under the EFPIA Code.

According to the Code, stakeholders are obliged to document and disclose transfers of value, whether done directly or indirectly to or for the benefit of the recipient. In the meaning of the Code, transfers of value are understood as “direct or indirect, whether in cash, in kind or otherwise, made either for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicines exclusively for human use”. The following categories of transfers are subject to disclosure:

- ✘ donations and grants to HCOs that support healthcare, including those to institutions, organisations or associations that are comprised of HCPs or that provide healthcare;
- ✘ contributions to costs related to events for HCOs and HCPs through HCOs or third parties, including sponsorship to HCPs to attend events, such as registration fees, travel and accommodation;
- ✘ fees for service and consultancy related to contracts with HCOs and HCPs.

The regulation differs when it comes to research and development transfers of value (R&D). This category embraces transfers of value which are related to the planning or conducting of non-clinical studies, clinical trials or non-interventional studies that are prospective in nature and that involve collection of patients' data from or on behalf of individual, or groups of, HCPs specifically for the studies. Whereas non-R&D transfers are usually to be disclosed on an individual basis, R&D transfers shall be disclosed by each member on an aggregated basis under one category.

Some categories are excluded from the disclosure obligation. These are transfers of value related only to OTC medicines, transfers other than those enlisted above, as well as transfers that are part of ordinary course purchases and sales by and between a member company and a healthcare professional or organisation.

By the term "healthcare organisation" the Code understands any legal person that is a healthcare, medical or scientific association or organisation, irrespective of its legal form, such as hospitals, clinics, foundations, universities or other teaching institutions or learned societies. Healthcare professional means any natural person that is a member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities may prescribe, purchase or supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe.⁹³

When it comes to sanctions, the Code states that each Member Association should include provisions governing the imposition of sanctions for violation of its Code. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences.

The EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals

The EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals, called also the EFPIA HCP Code, was established in 2007. It is a revised version of the EFPIA HCP Code adopted in 1991 being one of the first signs of understanding that the European pharmaceutical industry needs to provide a well-managed framework for collaboration to introduce greater transparency around interactions with HCPs and HCOs. The Code was amended several times as a consequence of changes in law, the last one taking place in 2013 concomitantly with the establishment of the Disclosure Code.

The EFPIA HCP Code seeks to ensure that pharmaceutical companies conduct promotion of medicinal products and interaction with HCPs and HCOs in a truthful manner, avoiding deceptive practices and potential conflict of interest. The scope of the Code covers all methods of promotion to healthcare professionals of prescription-only medicinal products and interactions between them and EFPIA member companies.⁹⁴

The Code partially covers the area of transparency as well. It requires that the promotion of drugs is transparent. Any materials related to medicines and their uses, whether promotional in nature or not, if sponsored by a company, must clearly indicate such sponsorship. Also, it is permitted to hire healthcare professionals as consultants and advisors, if there is a signed and written agreement in advance of the commencement of the services, specifying the nature of the services to be provided and the basis of those services. It is also recommended that companies encourage HCPs to declare being a consultant to the company whenever they publicly speak about matters that are subject of the agreement or any other issue relating to that company.

The EFPIA Code of practice on relationships between the pharmaceutical industry and patient organisations

The EFPIA Code of practice on relationships between the pharmaceutical industry and patient organisations, also known as the EFPIA PO Code, was implemented in order to ensure that such relationships take place in an ethical and transparent manner.⁹⁵

The Code covers the field of cooperation between pharmaceutical industry and patient organisations, laying down transparency obligations as well. It states that each company must make a list of POs to which it provides financial support or significant indirect or non-financial support publicly available. Such information should include

a description of the nature of the support that is sufficiently complete to enable the average reader understand the significance of the support regardless of its nature. In addition, each signatory to the Code must publish a list of POs that it has contracted to provide significant services. Such information should also include the nature of the services provided and the total amount paid per patient organisation over the reporting period.

The Medicines for Europe Code of Conduct

Medicines for Europe is an organisation that represents the generic and biosimilar industry. Medicines for Europe members are bound to the provisions presented in the Medicines for Europe Code of Conduct. However, similarly to the EFPIA Code, Medicines for Europe also acknowledges that business models in particular countries may vary due to regulatory, legal and market factors. Therefore, not all provisions of the Code are relevant to all member companies in all countries.⁹⁶

The Code contains provisions concerning cooperation of pharmaceutical industry with patient organisations, healthcare organisations as well as healthcare professionals. Provisions of the Code touch upon the whole range of interactions that could happen on the pharmaceutical markets, such as fees for service and consultancy, meetings and hospitality, educational support, site visits, sponsorship events, educational materials, medical utility items and inexpensive gifts, samples, promotional materials and information. They also refer to the transparency and data protection. The first disclosure reports were published in 2018.

According to the Code, when companies provide financial or non-financial significant support to patient organisations, there must be a written agreement containing the amount of funding and its purpose, e.g. unrestricted grant, specific meeting or publication. When it comes to healthcare organisations and healthcare professionals, member companies may engage with them to provide services, such as speaking engagements or participation in research, if it is supported by a legitimate need for such services.

The MedTech Europe Code of Ethical Business Practice

MedTech Europe is the European trade association representing medical technology industries. In December 2015 MedTech Europe launched the Code of Ethical Business Practice as a self-regulatory act touching upon the ethical aspects of their functioning on the market. Its implementation was concluded at the end of 2017.

The implementation was conveyed to the MedTech national associations.⁹⁷ The Code is divided into two parts. The first part, Guidelines on the interactions with HCPs and HCOs, concerns educational events, conferences, procedure trainings, support of individual HCPs, company events, grants and charitable donations, arrangements with consultants, research, royalties, educational items and gifts, demonstration products and samples.

The second part leads directly to disclosure guidelines, that applies to all member companies in their interactions with healthcare organisations. Member companies need to document and disclose all payments made to healthcare organisations that are based or registered in Europe without limitation of their value. The disclosure shall be done on an aggregate basis, allocating the transfer of value to one of the categories stated by the Code, which are educational grants to support third party organised events and other educational grants to HCOs including scholarships, grants or fellowships for public awareness campaigns. The object of the grant can also be disclosed but only if desired by the donor.

Disclosures are placed on the EthicalMedTech website. The information disclosed shall be available in the public domain for three years after its publication.⁹⁸ At the time of writing this report, information was not disclosed yet. According to the Code, MedTech members are no longer allowed to provide sponsorship directly to HCPs when attending conferences organised by third parties. The MedTech Europe Code of Ethical Business Practice, just like the EFPIA Code of Disclosure, has been implemented across countries by national associations. It sets standards on the medical device markets in Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland and Turkey.

Guidelines on transparency by CPME

CPME is the Standing Committee of European Doctors (*Comité Permanent des Médecins Européens*), whose main goal is to represent medical associations across Europe, committed to contributing the point of view of medical professionals to EU institutions.

CPME's Guidelines on transparency differ from the codes of good practices mentioned above, as they have been established for the benefit of healthcare service representatives. According to the preamble of the Guidelines, on the one hand a physician's decision in prescribing medicines, as well as using devices, material, equipment, and diagnostic tools in the course of treatment, should in no way be induced by commercial factors, as conflicts of interest can harm the independence of medical doctors and in consequence limit their capacity to take proper decisions. On the other hand, interaction with pharmaceutical and medical technology industries is vital and necessary at all stages of the development and use of medicinal products and health technologies, in order to secure the safety of patients and efficacy of therapies.⁹⁹

The Guidelines establish that physicians, when attending medical events and conferences that are partially or fully sponsored by commercial companies, shall make sure that they are for scientific or professional purpose only. They also demand hospitality to be reasonable and strictly limited to the purpose of the events. When external sources of funding are used, they should all be publicly disclosed together with commercial interests or financial ties between the organisers and lecturers. The same requirements are set up for continuing medical education or professional development if it is sponsored or organised by commercial entities. When it comes to research and scientific publications with the participation of an HCP, a declaration of interest should be included. Finally, the Guidelines refer to consultancy activities, that are supposed to be publicly disclosed when a physician involved publishes an article or report, gives a lecture or any other sort of public presentation.

Generally, the shape of the Guidelines indicates that the interaction between pharmaceutical industry and healthcare professionals is desirable, as it keeps physicians up-to date with the most recent research, products and technologies. Physicians in turn provide the industry with their best knowledge, guiding the direction of its development. The Guidelines however are of very general character and do not give any further details of how the disclosure should happen nor what sort of information is to be published.

Finally, CPME has also collaborated with EFPIA on a joint statement on cooperation between the industry and HCPs.¹⁰⁰

European Patients' Forum Transparency Guidelines

The European Patients' Forum (EPF) is a European non-governmental organisation which was set up in 2003 to become the collective patients' voice at EU level.

EPF's Transparency Guidelines were published in 2018 in the form of a toolkit for member organisations which covers areas such as memberships, governance, finances and cooperation with funding partners, advocacy and communication.¹⁰¹ Apart from the Transparency Guidelines, the EPF Annual General Assembly adopted in 2009 (updated in 2014) the Framework for Cooperation, outlining how EPF works with its partners who provide unrestricted funding contributing to the activity of the organisation. The framework presents a list of principles in relation to funding i.e. independence, mutual respect, unrestricted and sustainable funding, no single company or governmental source and transparency.

EPF also applies the EFPIA Code of Good Practice on working with patients' organisations in relation to any funding coming from the pharmaceutical industry. The Transparency Guidelines encourage member organisations to make fully public information relating to the Framework of Cooperation, list of sponsors, policies on conflict of interest and gift and hospitality policy. The document outlines extensively practical steps that should be taken by organisations in order to ensure their independence and diversity in funding.

4. THE WAY FORWARD: WILL BRIGHTER SUN SHINE ON EUROPE?

4.1. NECESSITY TO CHANGE THE EXISTING EUROPEAN FRAMEWORK

As mentioned in section 3.3.1., the current main instrument at the European level regulating the pharmaceutical market is Directive 2001/83/EC on the Community code relating to medicinal products for human use. The preamble of the directive states that the aim is to cover all stages of marketing medicinal products, mainly to ensure patient safety. The objectivity of healthcare professionals and the independence of their practices are undoubtedly critical to patient safety. However, important factors affecting independence and objectivity are not fully regulated at present.

Article 97 of the Directive lays down an obligation for member states to implement proper procedures aimed at monitoring the advertising of medicinal products. It states however that such monitoring mechanisms shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies. That means that, although pharmaceutical advertisement can still be subject to self-regulation, it does not exempt individual member states from implementing national monitoring procedures.

Considering what is already known about the impact of financial and non-financial conflicts of interest on medical practice, it is important to ensure implementation of effective transparency mechanisms.

Nowadays, most EU countries are covered by self-regulatory or co-regulatory acts based on the EFPIA Disclosure Code or other transparency codes of conduct. Pharmaceutical companies argue that self-regulation has several advantages in comparison to laws of general application. First, self-regulators, as active participants in the market claim a high level of industry specific knowledge. They are aware of upcoming changes and innovative solutions, and the standards they set thus correspond to the market. Also, implementation of self-regulation is far less formal, and more responsive to changes in the market making it more flexible than a legislative approach.

Nevertheless, there are major disadvantages to self-regulatory systems, the biggest being the scope of application of self-regulation codes, as these are only binding to those organisations who voluntarily join them or are members of associations that introduce them. In the case of codes concerning pharmaceuticals, their application is usually limited to member companies of national or European associations issuing the codes. There are very few cases of non-member companies agreeing to abide by those rules. That can significantly decrease the efficacy of self-regulation. Another serious disadvantage of self-regulation is non-compliance with statutory requirements, making some parts of codes of conduct invalid.

There is also evidence that codes of conduct in the pharmaceutical sector are ineffective even on their own terms. Studies carried out in Sweden and in the United Kingdom between 2004 and 2012 explicitly showed that 46 companies active in the pharmaceutical market remained in serious breach of the codes. Seven of them infringed the codes severely more than 10 times.¹⁰²

When it comes to sanctions for the breach of self-regulatory provisions on transparency, codes of self-regulation show very little deterrent effect. For example, economic sanctions imposed on the industry in relation to estimated revenues from drug sales in Sweden were estimated at 0.014% between 2009 and 2012, while in the UK they were of 0.0046% between 2004 and 2009 and of 0.0051% between 2009 and 2012.¹⁰³

Furthermore, many codes of conduct include an opt-out which means that HCPs may choose not to disclose any information. Studies conducted in 2016 by the Association of the British Pharmaceutical Industry showed that only

49% of HCPs allowed their details to be disclosed. In Austria in 2015, only 20% of HCPs gave their consent for the disclosure of individual level data.¹⁰⁴ Opt-out clauses have been eliminated in Belgium, France, Portugal and Latvia, where that option has been made unavailable through national sunshine laws.

Finally, the way data is made available within current self-regulation codes is not user friendly. With only a few exceptions, disclosed information is generally presented in non-searchable files uploaded separately on each company's website.

These loopholes, exclusions and inconsistencies ensure that the whole system for making the pharmaceutical market fully transparent remains incoherent and ineffective in most European countries.

4.2. PROPOSAL FOR A EUROPEAN LEGAL FRAMEWORK

4.2.1. CONTENT OF A EUROPEAN LEGAL FRAMEWORK

The pharmaceutical industry operates across national boundaries and companies are able to exploit the differences in approach between EU member states. In this section, we will thus provide some substantive recommendations for a European legal framework on transparency, covering stakeholders subject to disclosure requirements, scope of disclosure, financial threshold, database and sanctions, monitoring and enforcement mechanisms.

Stakeholders

In some member states, the disclosure duties embrace not only HCPs, but also HCOs, POs, medical students, and all other entities engaged in health services with potential effects on public health. As the spectrum of stakeholders and their involvement in healthcare is growing, extending the scope of the transparency obligations should be considered. In practice, this means that transparency rules regarding payments in cash or in kind should apply to the pharmaceutical industry (innovative and generic) as well as the medical device industry. The list of recipients to be covered should include HCPs, HCOs and POs.

The definition of HCPs should include physicians as well as members of medical, dental, pharmacy, and nursing professions or any other person, who in the course of their professional activities may prescribe, purchase, supply, recommend or administer medicinal products. HCOs should cover entities such as: healthcare, medical or scientific associations or organisations, irrespective of their legal forms, such as hospitals, clinics, foundations, universities, other teaching institutions or learned societies through which healthcare professionals provide healthcare services. This definition should include distributors of medicines as well. POs would comprise not-for-profit institutions that primarily represent the interests and needs of patients and or users, their families or caregivers.

Additionally, individual patient representatives, who more commonly represent patient interests in a personal capacity and have an important say in the decision-making process, should be included. The same should apply to employees of national and European agencies with a capacity to decide on the reimbursement of medicines and to shape drug policies. Finally, consideration should be given to a growing trend emerging in media and social media, which manifests itself in an increasing number of sponsored content and individual campaigns about personal experiences on the use of different therapies.

Scope of disclosure

Studies conducted so far have shown that even the most limited transfer of value can affect clinical practice. To allow for an accurate overview of the types of benefits transferred from the industries to identified stakeholders we recommend dividing them into the following types:

- ✘ donations and grants
- ✘ hospitality (registration fees, accommodation, travel, sponsorship agreements, meals and drinks etc.)
- ✘ consultancy and fees for services
- ✘ gifts, educational and promotional materials, items of medical utility
- ✘ initial and continuing medical education

Current exclusions from the disclosure obligations under self-regulation include meals and drinks, drug samples, transfers related to over the counter (OTC) drugs, small gifts, educational and promotional materials, and items of medical utility. At the same time, regulations enacted for example in France and Portugal eliminated those exclusions making it obligatory to record and disclose information related to even small transfers of value, such as drinks, meals, drug samples and even payments related to OTC drugs. We suggest including those items while designing future European frameworks.

Financial threshold

A European legal framework could indicate the minimum value of the threshold to be respected by national legislators. In order to assess the actual value of transactions, parties should be obliged to use a market price of the subject of transfer. Ideally, the lower the threshold, the more benefits can be covered. Belgium's approach could be considered an example of good practice when it comes to the financial threshold; the country has decided not to establish any threshold, which means that all benefits are to be reported.

Database

The information disclosed based on an EU transparency act should be placed in purposely established national databases, with a European gateway redirecting to national databases.

A database should consist of three sub-databases created for three categories of beneficiaries, which are HCPs, HCOs, and POs. The division would simplify data analysis, making it more user-friendly. The information should be published in a way that is comprehensible and easily searchable. It should be possible to extract for further study or monitoring. The minimum information that needs to be published should be the name of the donor and beneficiary, product's brand, type of payment and its value. Looking up an overall amount transferred in a reference year to each beneficiary should be made available. Where due to the non-financial character of the transaction, the value is difficult to estimate, there should be the requirement for the donor to clearly describe the non-monetary benefit and its cost to the provider.

Sanctions, monitoring and enforcement

Sanctions should be at a level sufficient to deter very wealth companies from unethical behaviour. We suggest setting a percentage of the annual turnover of any company, to be paid in case of a breach. To strengthen the preventive role of a European legislative framework, it is advised to establish a list of people or organisations in breach with the rules, as part of national databases. The main responsibility for data disclosure must rest with the industry. However, disclosed data should be cross-checked by both donor and beneficiary. Governments should facilitate the disclosure process and monitor compliance with the regulation.

4.2.2. FORM OF A EUROPEAN LEGAL FRAMEWORK

When considering which form would fit best when it comes to establishing a European legal framework on transparency, the main instruments are either a regulation or a directive. As the scope of application of the act

should be as wide as possible and independent of the good will of stakeholders, co-regulation as a possible method of regulation is not considered here.

Due to many national factors affect the functioning of sunshine practices on individual markets of member states, a regulation, although formally admissible, is not recommended as a basis for the EU transparency policy. Regulations do not leave much space for national legislators to adjust established solutions to national realities.

A directive appears to be a more suitable form for transparency regulation across member states, considering its scope of application, enforcement mechanisms, and allowance for national differences. A directive allows member states to achieve specific results while leaving some freedom in the scope of application, in order to adjust to national markets' realities. Additionally, there is a need to consider that in some states adequate, well-functioning provisions have already been enacted for some time now.

4.3. OTHER LEGAL ACTS REQUIRING CONSIDERATION

The regulations mentioned below might give some useful insights into aspects of a European Transparency Act, particularly relating to processing of personal data. These legal acts should be considered when discussing a European legal framework on transparency.

Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (GDPR)

The regulation applies to the processing of personal data and states which conditions the personal data processing should fulfil. Personal data shall be processed lawfully, fairly, and in a transparent manner. It should be collected for specific, explicit and legitimate purposes. It appears that the legal basis for processing personal data for a purpose of public disclosure can be established by the EU or member states. Based on such regulation, prior consent of an individual is not required.

Regulation (EC) no 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies

The regulation applies to the processing of personal data by all Community institutions and bodies insofar as such processing is carried out in the exercise of activities, all or part of which fall within the scope of the EU law. The rules of data protection are similar to those stated in Regulation 2016/679. Article 5 enumerates the criteria of the lawfulness of the data processing, establishing that the processing is lawful as far as it is necessary for compliance to which the controller is subject.

5. CONCLUSION

Collaboration between the industry and stakeholders active in the healthcare sector, although beneficial for drug development and scientific progress, is likely to carry substantial risks for public health, users and patients. Undue influence of the health industry, especially the pharmaceutical industry, on the provision of healthcare, often takes on a financial nature, regardless of whether it relates to research, education, promotion or other types of cooperation. This influence can lead to conflicts of interest, altered prescribing behaviours, unethical and biased decision-making in health care, which in turns can have an impact on public spending and impair trust in medicine. In relation to mental health, it contributes to overreliance on the biomedical model of mental health, as well as over-medicalisation.

There is a clear trend emerging across Europe towards greater regulation in the area of transparency around the relationships between all relevant stakeholders in the healthcare sector. This trend has been accelerated through self-regulation of the pharmaceutical industry and the adoption of legislation at the national level. Progress towards greater transparency in these relationships is welcome and very necessary. Although industry self-regulation is a substantial step forward and should be recognised as a valuable initiative, it is not a sustainable solution for reasons previously outlined. Fully transparent cooperation among all actors in the healthcare sector can only be ensured through legally binding laws implemented across Europe. Ideally, it should be facilitated at the European level in order to ensure harmonisation and equal access to information in all member states.

The advantage of a European legal framework is first of all to provide patients and users with the opportunity to evaluate the safety of health services, to make well informed choices of providers, to strengthen trust between HCPs and users, and to ensure greater independence of medical practice. It can also facilitate research on the long-term impact of commercial relationships in the healthcare sector on prescribing behaviours and the quality of care, thanks to available data. A harmonised European approach to transparency and disclosure would allow for easier comparisons across countries and would equalise access to information for citizens.

We have reached a number of conclusions as a result of our research:

- ✘ Clear and robust sunshine policies, which are legally binding and harmonised at EU level, are needed to ensure that there is full transparency around the relationships between the health industry, HCPs, HCOs and POs. These actors are often at the heart of how our mental health policy is shaped and how mental health systems, and health systems in general, work.
- ✘ To enhance the effectiveness of transparency provisions, compulsory disclosure of transfers of value should not be the sole solution to the problem of undue influence. In order to ensure the effectiveness, safety, and independence of the medical practice, it is also necessary to properly educate both HCPs and medical students about potential conflicts of interest, and in particular about the promotion of pharmaceutical products and its effect on the medical curriculum and medical practice.
- ✘ It is necessary to educate and raise awareness about the phenomenon of conflicts of interest among service users as studies show that only 12% of patients know that information about cooperation between the pharmaceutical industry and the healthcare sector is, to some extent, publicly available.¹⁰⁵ Solid disclosure mechanisms implemented along with educational activities and effective monitoring could strengthen and improve the level of independence in healthcare and ensure that users are able to make informed decisions about their own treatment.
- ✘ Some countries, such as France and Sweden, have already put in place restrictions on industry funding and the presence of sales representatives in healthcare settings. To ensure greater

independence of medical practice and education, there is a need for increased public and independent funding in health sciences for education and research.

✘ The most important aspect is to consider ways to enable a more effective involvement of users in the implementation of transparency provisions and to raise awareness about the utility of transparency tools among users. User-friendly registries and disclosure mechanisms should be elaborated in collaboration with users, who should be active partners that need to be respected, regarded, and informed. Users have the right to know whether their HCPs receive any benefits from companies producing prescribed drugs or devices, and which could unduly influence treatment decisions. Users need to be supported in understanding disclosed information and assess the information for own treatment decisions. The interests of users need to be at the heart of the process.

Therefore, our recommendations are:

- ✘ to promote and adopt a comprehensive legally binding approach to the disclosure of transfers of value, including disclosure of financial and professional relationships between health industries, healthcare professionals, healthcare organisations and patient/user organisations, comprising at least mandatory disclosure on an individual level; the widest possible scope of transfers with a low or no threshold; user-friendly, searchable and downloadable databases; and effective mechanisms of monitoring and ensuring compliance;
- ✘ to set legal minimum standards for the harmonisation of transparency reporting at the European level;
- ✘ to raise awareness of conflicts of interest in medical education and medical practice, along with effective ways of managing them;
- ✘ to support initiatives offering independent initial and continuing medical education for medical students and healthcare professionals;
- ✘ to ensure unbiased research in health sciences via sufficient independent funding; and
- ✘ to raise awareness among users of mental health services on conflicts of interest and how to deal with available information regarding disclosure and involve users throughout the implementation of transparency provisions.

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90. List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector, Platform on Ethics and Transparency, European Commission, DG GROW, (http://ec.europa.eu/growth/sectors/healthcare/competitiveness/corporate-responsibility_en)

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ANNEX 1

External contributors

In this section we include contributions from external authors who represent expertise in the field of transparency, conflict of interest and bioethics. We asked them to contribute to the final report with more in-depth reading on transparent relationships between the health industry, healthcare professionals, healthcare organisations and patient organisations. Excerpts from some of these contributions appear in chapter 2.

HOW TO MAXIMISE THE POTENTIAL OF SUNSHINE LAWS?

Ancel.Ia Santos Quintano

HEALTH ACTION INTERNATIONAL

The last few years have seen an increase in the transparency of financial relationships between the pharmaceutical industry and healthcare professionals in Europe. Transparency has helped to shed some light on the extent and nature of such relationships. In 2017 alone, pharmaceutical companies in Spain paid over €182 million to healthcare professionals in fees for service or sponsorship, while health organisations (e.g. medical societies) received more than €130 million.¹ Meanwhile, in the United Kingdom, pharmaceutical companies spent £128.4 million (about €146 million)² on payments and other benefits in kind to healthcare professionals and organisations.³ The figures in both countries exclude payments related to research and development (R&D) activities.

Financial relationships between the industry and healthcare professionals raise serious concerns about bias in medical practice. For example, studies conducted in the United States found positive associations between physicians' receipt of payments, prescription rates of brand-named medicines, and prescribing costs per patient.⁴⁻⁵ In both studies, information on payments was retrieved from the Open Payments national transparency programme, managed by the Centers for Medicare and Medicaid Services (CMS). According to the CMS, increased transparency is important to allow patients to make better informed decisions about healthcare professionals and treatment, and to deter inappropriate financial relationships that may lead to increased healthcare costs.⁶

Like the U.S., a number of countries in Europe have passed legislation that mandates disclosure of financial relationships between the industry and healthcare professionals.⁷ In countries where no such law has been implemented, transparency is governed through industry self-regulation (for example, in Spain and the UK). In most of these countries, companies follow the code of practice of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which has been transposed by national industry associations into their codes. The Netherlands is an example of a country following a multi-stakeholder self-regulatory approach.

A comparison of government-led and self-regulatory approaches across nine European countries shows that the situation differs substantially from country to country, and important differences exist between these two approaches.⁸ For example, while governmental provisions apply to all the companies operating in the country, most of the self-regulatory codes apply only to members of a specific industry trade association. Secondly, the majority of the self-regulatory codes require that healthcare professionals give their consent to data disclosure at the individual level. This is the case, for example, in the UK, where in 2017, only 49% of healthcare professionals receiving payments or other benefits agreed to have data published against their name.⁹ The comparative study also found that self-regulatory approaches fail to report information on complimentary meals for healthcare professionals. Overall, it was found that important gaps remain. For example, only two of seven self-regulatory approaches present data in a centralised, searchable registry, and one of the three countries with government-led

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2. Euro-to-Pound Average annual exchange rate <https://www.statista.com/statistics/412806/euro-to-gbp-average-annual-exchange-rate/>

3. The Association of the British Pharmaceutical Industry (2018). Pharmaceutical industry continues to invest significantly in UK research and development. ABPI. Available online <http://www.abpi.org.uk/media-centre/news/2018/june/pharmaceutical-industry-continues-to-invest-significantly-in-uk-research-and-development/>

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rules does not have such a registry. Where centralised databases are missing, the data are available in separate PDFs, which are usually on each company website (or, on occasion, a single webpage).

Shortfalls in current practices are problematic because they hinder the benefits expected from transparency. The self-regulation approach is problematic because it brings an intrinsic conflict of interest. Since information on financial relationships between the pharmaceutical industry and the healthcare sector is of public interest, its publication should be mandated by law. In 2017, Health Action International issued a report, 'The Sun Shines on Europe: Transparency of Financial Relationships in the Healthcare Sector', which includes key recommendations to governments with the purpose of ensuring that payment disclosure initiatives are implemented in ways that maximise their potential.¹⁰ These recommendations are to:

1. ADOPT A COMPREHENSIVE LEGISLATIVE APPROACH TOWARDS THE DISCLOSURE OF FINANCIAL AND PROFESSIONAL RELATIONSHIPS

Countries shall be proactive and enact rules that mandate the disclosure of relationships between the healthcare industry, healthcare professionals, healthcare organisations and other groups (e.g. patient associations). Such rules should be mandatory for all industries operating in the healthcare sector (pharmaceutical and medical device industries) and with a potential for detrimental effect on public health (e.g. nutrition, cosmetics). Disclosures should be made in a centralised and searchable database managed by the government, which offers the possibility to extract data for analysis.

2. MANDATE DISCLOSURE OF TRANSFERS OF VALUE ON AN INDIVIDUAL LEVEL

To allow for an accurate overview of the extent of industry influence, companies should report any transfer of value (direct or indirect), regardless of its value. Information about the value and nature of benefits (e.g. grant, gift, hospitality, fee for service) should be disclosed, as well as the name of the product linked to each payment. Some key information about agreements entered into between companies and beneficiaries should also be published. Since there is a public interest in disclosure, consent by beneficiaries to publish the data on an individual level should not be required. Instead, beneficiaries should be given the opportunity to review the data and, in case of disagreement, the data can be marked as being disputed in the database. In any case, reporting deadlines must always be complied with.

3. IMPROVE MONITORING AND COMPLIANCE

Governments must actively monitor compliance with reporting requirements. The main responsibility for data disclosure must lie with the industry, and non-compliance by companies with reporting requirements should be met with dissuasive sanctions. Reporting from beneficiaries should be encouraged and facilitated so data can be cross-checked.

As a concluding remark, it is important to emphasise that although transparency of financial relationships between the healthcare industry and healthcare professionals is important, it cannot be an end in and of itself. Stricter regulation of pharmaceutical promotion is needed, as well as better education on promotion and conflicts of interest among healthcare professionals.

10. Santos A. The Sun Shines on Europe: Transparency of financial relationships in the healthcare sector. Health Action International, 2017

CONFLICTS OF INTEREST, IMPARTIALITY AND TRUST

Emilia Kaczmarek, PhD, University of Warsaw

In the European Union, contrary to the United States, direct-to-consumer (DTC) advertising of prescription drugs has been banned, while commercials of over-the-counter (OTC) medicines and dietary supplements can still be aired on radio and television. The rationale for prohibition of DTC advertising of prescription drugs seems to be clear as the main objective of commercials and marketing is not only to inform clients about a given product but also to increase its demand. However, prescription medicines are not the ordinary consumer goods available on the free market. Only authorised healthcare professionals can decide what will be prescribed to patients. Convincing people that they should consume, for example, more antibiotics than they really need would be a threat not only to the individual, but also to public health. Overall there is a lot of controversy about creating demand for medicines, as this implies creating artificial health needs, while the use of unnecessary medicines is a threat to life and health.

Although prescription drugs cannot legitimately be advertised directly to patients, advertisements can be directed to doctors. As mentioned previously, the main method of drug promotion practice is direct contact with doctors through pharmaceutical sales representatives. They are the ones who meet physicians, tell them about the advantages of marketed products, and distribute free drug samples and leaflets. They also provide doctors with small gifts, invite them to educational meetings or offer sponsorship of their participation in scientific conferences. They are often rewarded for growing sales rates of a promoted drug in a certain area.² Physicians are legally obliged to base their prescription choices solely on scientific knowledge. Numerous studies show that doctors usually do not believe that gifts from pharmaceutical representatives can influence their prescription habits.³

In addition to direct-to-consumer advertising and activities of the pharmaceutical sales representatives, indirect marketing strategies through content marketing and advertorials can also be used to promote medicines. Such non-direct, hidden commercials may take the form of sponsored campaigns that are devoted to different health problems, social media profiles, press articles or online content featuring specific methods of treatment (sometimes written by a professional copywriter and signed with the name of an independent expert, called ghost-writing). Finally, pharmaceutical companies may also cooperate with patients organisations or even establish new health-related seemingly bottom-up organisations (astroturfing), as indirect marketing strategy.

Ghost-writing, astroturfing or health campaigns sponsored by pharmaceutical companies – but run through patient associations – are all marketing practices conducted in a way that should convince the recipient of the independence and objectivity of the messages conveyed. The recipients do not receive the messages directly from a pharmaceutical company, but through entities that are trusted and perceived to have authority in the field.

1. The commercials for food supplements, at least in Poland, often unlawfully suggest that products of these kind are able to treat diseases. The majority of Poles are wrongly convinced that dietary supplements are supervised in the same way as medicines, and their consumption is rapidly growing. This is why the Polish Chamber of Physicians and Dentists in an official statement proposed the banning of DTC advertising of every type of drug as well as food supplements. Dietary supplements are regulated under Directive 2002/46/EC, so new solutions on DTC advertising of health-related products could be discussed and worked out, not only at national but also at European level. See: The statement of the Polish Chamber of Physicians and Dentists <http://www.nil.org.pl/aktualnosci/apel-prezydium-nrl-podjete-16-wrzesnia-2016-r.>; Polish Supreme Audit Office Report, <https://www.nik.gov.pl/plik/id,13031,vp,15443.pdf>

2. Steinbrook R. For Sale: Physicians' Prescribing Data, *The New England Journal of Medicine*. 2006; 354

3. Makowska M. Polish physicians' cooperation with the pharmaceutical industry and its potential impact on public health. *PLoS One*. 2017; 12(9), e0184862

CONFLICT OF INTEREST

A way to define the notion of conflict of interest is by saying that, “an individual has a conflict of interest when he or she has personal, financial, professional, or political interests that are likely to undermine his or her ability to meet or fulfil his or her primary professional, ethical, or legal obligations”.⁴ A conflict of interest (COI) is considered to be a risk factor which increases the probability of occurrence of various types of misconduct. It is a risk factor, and not an abuse per se, as the person being in a situation of conflict of interest will not necessarily behave in a way inappropriate for his or her profession. Nonetheless, a conflict of interest provokes a combination of stimuli and motivators that generate a sort of temptation. By its nature, a COI involves risk; therefore, distinguishing a potential COI from a real one (as it is often done in literature), only brings confusion to the debate. A situation when a doctor holding shares in a pharmaceutical company gives a lecture on a drug manufactured by this company is not a “potential COI that could result in a real COI; it is simply a COI that could result in real bias”.⁵

For several years extensive research has been pointing at a correlation between receiving benefits from pharmaceutical companies and a higher frequency of making decisions concordant with the interests of these companies by persons or organisations with a conflict of interest. Conflicts of interest may lead to bias, and bias in medicine may take various forms, such as:

- ✘ prescribing original drugs more frequently when cheaper generic equivalents are available on the market by physicians who have received free meals or educational trainings from the producers of original drugs;^{6,7}
- ✘ selective publishing of research papers⁸ or exaggerating positive results of a clinical trial in the conclusion, compared to findings shown throughout the article;⁹
- ✘ lowering diagnostic thresholds in guidelines regarding clinical practice created by authors with conflicts of interest;¹⁰
- ✘ spreading exaggerated assertions by pharmaceutical representatives about the safe use of a certain drug;^{11,12,13}
- ✘ spreading exaggerated claims about the frequency and burdensomeness of a certain disease by drug manufacturing companies, patient organisations receiving support from these companies, as well as by the media which uncritically repeat these claims¹⁴

4. Resnik DB, Shamoo E. Responsible Conduct of Research, 2nd Ed. Oxford. Oxford University Press

5. McCoy MS, Emanuel EJ. Why There Are No “Potential” Conflicts of Interest. JAMA. 2017; 317:17, p.1721.

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8. All Trials campaign, <http://www.alltrials.net/>

9. Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database Syst Rev. 2. 2017; doi: 10.1002/14651858.MR000033.pub3

10. For example, in the case of the so-called “statin controversy”, some authors claim that cholesterol guidelines may be too strict, because taking statins by some groups of patients – those who take them only as a prophylactic measure – may not be fully justified. However, the case is still vividly debated, also in the context of difficult access to the results of all clinical trials. See: Lenzer J. Majority of panelists on controversial new cholesterol guideline have current or recent ties to drug manufacturers. BMJ. 2013; 347:f6989

11. For instance, such practices were documented during the recent opioid crisis in the United States. Some companies were sued and had to pay compensation, because their reps wrongfully persuaded doctors that painkillers containing opioids aren’t as addictive as they in fact are, see: Meier B.,

In Guilty Plea, OxyContin Maker to Pay \$600 Million, The New York Times, <http://www.nytimes.com/2007/05/10/business/11drug-web.html>

12. Bellon T. U.S. state lawsuits against Purdue Pharma over opioid epidemic mount, Reuters 2018, <https://www.reuters.com/article/us-usa-opioids-litigation/u-s-state-lawsuits-against-purdue-pharma-over-opioid-epidemic-mount-idUSKCN1I62WU>

13. Another study showed that patient organisations which had received funding from opioids producers were more critical toward new guidelines targeting over-prescription and over-use of this kind of drugs, see: Lin D.H., Lucas E., Murimi I.B., Kolodny A., Alexander G.C., Financial Conflicts of Interest and the Centers for Disease Control and Prevention’s 2016 Guideline for Prescribing Opioids for Chronic Pain. JAMA Internal Medicine, 177(3)(2017).

14. According to some authors this was the case of promoting restless legs syndrome (RLS), e.g. some of the U.S. TV commercials for drugs used in treating RLS could give the impression that every person who experiences tingling in the legs caused by sitting without movement for a long time may have RLS, see: Woloshin S, Schwartz LM. Giving legs to restless legs: A case study of how the media helps make people sick. PLoS Med. 2006; 3(4): 170

- ✘ promoting off-label use of a drug during sponsored lectures or by pharmaceutical representatives;^{15,16}
- ✘ striving for the reimbursement of a medicine (produced by the patient organisation's sponsor) even if another, equally good and much cheaper drug is present on the market.¹⁷

Above-mentioned biases may lead to potential harms to patients, such as receiving suboptimal treatment, undue medicalisation¹⁸, iatrogenic illnesses or waste of private and public money. Besides these potential harms, conflicts of interest directly cause another negative consequence – they undermine social trust in medicine.

IMPARTIALITY AND TRUST

Medicine is a social practice which is particularly characterised by trust. Since the abandonment of the paternalistic model of the doctor-patient relationship, blind obedience to the authority of medicine can no longer be expected; medical institutions thus need to gain and maintain the trust which they receive from patients.

Numerous surveys show a correlation between the patient's belief that doctors receive gifts from the pharmaceutical industry and lower levels of trust in medicine.^{19,20} There is a negative perception of COIs among patients, although not all types of relationships between doctors and the pharmaceutical industry are assessed in a similar way. For example, receiving remuneration for consultations from pharmaceutical companies does not undermine trust in doctors to the same extent as holding company shares.²¹

Another example highlighting how COIs undermine trust in medicine can be found in the rhetoric used by anti-vaccination movements. As indicated by systematic reviews of content of websites run by opponents of childhood vaccinations, conspiracy theories and belief in hidden intentions of experts acting under the influence of COIs are a lasting and essential motif present in the narrative about vaccinations.^{22,23} A parent scared by the information about alleged harmfulness of a vaccine will not believe in assertions about its efficacy and safety made by an expert financially connected with the vaccine manufacturer.

Striving to confirm the validity of information from an impartial source of knowledge may be considered justified. Financial conflicts of interest lead to situations that are contrary to the principles of impartiality. This crisis of trust may encourage an increasing number of patients to seek health services outside of professional healthcare which, as in the case of the anti-vaccination movement, may pose a threat to public health in the future. Independent research as well as independent institutions are thus necessary for medicine to remain cogent.

15. That was the case with Neurontin, an anti-epileptic medicine – some reps encouraged doctors to prescribe it in treatment for restless legs syndrome and other diseases for which it was not registered in the U.S., see:

US Department of Justice, Press Release, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion, https://www.justice.gov/archive/opa/pr/2004/May/04-civ_322.html

16. Göttsche PC. Deadly medicines and organised crime. How big pharma has corrupted healthcare. Radcliffe Publishing, London. 2013

17. For instance, according to Polish sociologist Paulina Polak, some of the patient organisations were involved in the PR produced by pharmaceutical companies against Polish produced insulin, despite generic insulin produced in Poland being safe and much cheaper than the original. see: Polak P. Nowe formy korupcji. Analiza socjologiczna sektora farmaceutycznego w Polsce. Nomos. 2011, p. 183 – 192.

18. Kaczmarek E. How to distinguish medicalization from over-medicalization. Medicine, Health Care and Philosophy. 2018; <https://doi.org/10.1007/s11019-018-9850-1>

19. Grande D, Shea J A, Armstrong K. Pharmaceutical Industry Gifts to Physicians: Patient Beliefs and Trust in Physicians and the Health Care System," Journal of General Internal Medicine 27, no. 3 (2011);

20. Green M.J., Masters R., James B., Simmons B., Lehman E., Do gifts from the pharmaceutical industry affect trust in physicians? Family Medicine 44(5)(2012).

21. Perry JE, Cox D, Cox AD. Trust and Transparency: Patient Perceptions of Physicians' Financial Relationships with Pharmaceutical Companies. The Journal of Law, Medicine & Ethics. 2014; 42 (4): 475–491

22. Jolley D, Douglas KM. The Effects of Anti-Vaccine Conspiracy Theories on Vaccination Intentions. PLoS ONE. 2014; 9(2): e89177

23. Bean SJ. Emerging and continuing trends in vaccine opposition website content. Vaccine. 2011; 29: 10

According to Howard Brody, an American bioethicist, a situation when a doctor gives a lecture on various products used in the treatment of a certain disease, and who is sponsored by a manufacturer of one of these products, could be seen as an imperfect analogy of a situation when a judge is holding shares in a company whose activity he or she has to assess.²⁴ HCPs, just like judges, have specific credentials which oblige them to pay attention to impartiality. Similarly, to representatives of legal professions who have a monopoly on issuing judgements, representatives of medical professionals have a monopoly on the treatment of diseases. In many countries providing medical services without an appropriate license is a crime. What is more, both judges and doctors make decisions about values of special importance for individuals – such as personal freedom or health. Although physicians do not pass sentences, their diagnoses, prescriptions, advice or jointly endorsed clinical recommendations can have extremely significant influence on the health and life of many patients. In the case of a judge, however, receiving any kind of gifts from one of the defendants or holding shares in a company whose activity they have to assess is unacceptable. Assertions about the impartiality of such a judge would not sound credible. Why? Firstly, one of the requirements of impartiality is the principle that nobody should be a judge in his own case. Secondly, in order to maximise the chance of making an unbiased decision, one has to strive to eliminate the factors which may disturb decision-making. Therefore, according to Howard Brody, all COIs that are avoidable should be avoided, also in the field of medicine.

It is important to note that limiting conflicts of interest does not mean banning the cooperation between doctors and the pharmaceutical industry. This cooperation is necessary – without it, companies will not be able to create new medicines and monitor the efficacy of the ones which have already been marketed. However, such models of cooperation should be designed to limit potential violations of the rules of impartiality and undermining of patients' trust in medicine.

24. Brody H. Clarifying Conflict of Interest. *The American Journal of Bioethics*. 2011; 11: 1

CONFLICT OF INTEREST AND ITS MANAGEMENT

Professor Klaus Lieb, MD, University of Mainz

Patients must be able to trust their treating physicians to work with them to make the best possible choice for their well-being, regardless of secondary interests of their doctors. Such secondary interests may result from financial ties with pharmaceutical companies and cause conflicts of interest (COIs) for the doctors or other healthcare professionals.¹⁻² There are a number of studies showing how such financial ties can affect the proper conduction of clinical trials and the prescribing behaviour of physicians, and thus may possibly harm patients in many ways.³⁻⁴

An important step in the management of COIs is transparency. However, it has been difficult for a long time to find out about COIs of physicians. In the United States, the largest transparency initiative to disclose financial conflicts of interest among U.S. physicians, based on the Physician Payments Sunshine Act (PPSA), has provided information about all forms of financial support by the U.S. Industry above a minimum limit of \$10 per year since 2013.⁵ In 2016, a total of \$8.18 billion was paid by 1,481 companies to 631,000 physicians and 1,146 teaching hospitals. \$2.8 billion was spent on general payments (e.g. invitations, CME sponsorship, travel reimbursements, etc.), \$4.36 billion for research activities, and \$1.02 billion for equity interests (e.g. patents royalties). Similar transparency is not given e.g. in Germany, where data are available for less than 20% of the physicians.

Transparency about COIs, as provided by initiatives such as the PPSA, has the following advantages:

- ✘ The disclosure includes all pharmaceutical companies, it is mandatory and does not require approval by one doctor – it allows full transparency.
- ✘ If financial support is not reported by a pharmaceutical company, severe penalties are due – this promotes the obligation of transparency.
- ✘ Data is aggregated for all companies on one website – this allows the information about payments to physicians to be fully available and accessible by everyone.

However, transparency in the way the PPSA provides it, needs to be further developed in order to obtain a more comprehensive picture of COIs:

- ✘ Only financial COIs are disclosed, although it is known that non-financial (also called intellectual or indirect) COIs (for example, active participation in a professional association or the representation of a specific “therapy school”) can also lead to harmful effects on research and patients.⁶

1. Thompson DF. Understanding financial conflicts of interest. *The New England Journal of Medicine*. 1993 329: 573-6

2. Lo B, Field MJ. Conflict of Interest in Medical Research, Education, and Practice. National Academies Press, Washington DC, 2009

3. Schott G, Pacht H, Limbach U, et al. The financing of drug trials by pharmaceutical companies and its consequences. Part I: a qualitative, systematic review of the literature on possible influences on the findings, protocols, and quality of drug trials. *Deutsches Ärzteblatt International*. 2010; 107:279-85

4. Lieb K, Brandtönes S. A survey of german physicians in private practice about contacts with pharmaceutical sales representatives. *Deutsches Ärzteblatt International*. 2010; 107:392-8

5. Centers for Medicare & Medicaid Services: Open Payments: <https://www.cms.gov/openpayments/> last access: August 8, 2018)

6. Lieb K, von der Osten-Sacken J, Stoffers-Winterling J, et al. Conflicts of interest and spin in reviews of psychological therapies: a systematic review. *BMJ Open*. 2016; 6(4):e010606

❏ The aggregation of financial COIs must be differentiated. For example, financial support for well-designed clinical trials and for the widely criticised post-marketing studies must be listed separately.⁷ The same is necessary for payments for Advisory Boards for marketing purposes and those for purely scientific aspects. This may help to distinguish harmful COI from those that may be important for the further development of drugs and can thus be potentially helpful for patients.

❏ Transparency must be accompanied by well-understood information, so that the nature and extent of the relationship is understood even by a layman.

Although mandatory transparency is important, it must not be left without parallel measures to improve management and reduce COIs. COIs can be defined as situations that create a risk that professional judgment or action that relates to a primary interest (in this case, to do the best for the patient/user) is unduly influenced by secondary interests (here: relationships with industry).¹⁻⁵ The problem is therefore not primarily the COIs themselves, but the biased or distorted judgment or action (bias) of those who have the conflicts. COIs are not per se bad or reprehensible, but they can have harmful effects through their influence on judgments and actions.

From this it is also easy to understand that transparency of COI alone does not eliminate the actual problem, namely the bias, whose probability of occurrence is increased by COIs. The closer the relationship to a pharmaceutical company is, the greater the risk of bias. For example, the actions of a physician who, as a result of attending a sponsored CME event, prescribes the drugs of the inviting pharmaceutical company, while others may be more effective, safer, and less costly, may cause harm to the individual patient and the healthcare system.⁸

The judgment of a member of a commission developing guidelines may cause even more harm, if they support a guideline recommendation in favour of a pharmaceutical product for which they are a lecturer on satellite symposia of a company.⁹ Such “bias” cannot be reduced by transparency alone, but only by reducing the COIs and, if not possible, adequately managing their dealings with them. Transparency is therefore only a first important step towards greater independence of physicians and scientists, which must be accompanied by further measures to reduce COIs and their management. These measures must by no means be neglected over the introduction of transparency initiatives as described above and may consist of:

❏ Educating physicians and other healthcare professionals and students about COIs and their effects.

❏ Ensuring mandatory and complete transparency of COIs of all kinds in important areas, e.g. at CME events or the preparation of guidelines.

❏ Supporting initiatives that aim to reduce COIs or offer independent CME courses and conferences (e.g. with CME scoring only for industry-independent CME events or increased CME scores for such events).

❏ Ensuring mandatory rules for dealing with conflicts of interest, e.g. in the preparation of guidelines, if such are unavoidable.

❏ Conducting more research about COIs, their transparency and management in order to end up with wanted, and to avoid unwanted, effects of COIs management.

Such measures provided in addition to comprehensive transparency can help to maintain the trust of patients and users in the medical profession and in an integral healthcare system.

7. Spelsberg A, Prugger C, Doshi P, et al. Contribution of industry funded post-marketing studies to drug safety: survey of notifications submitted to regulatory agencies. *BMJ*. 2017; 356: j337.

8. Lieb K, Scheurich A. Contact between doctors and the pharmaceutical industry, their perceptions, and the effects on prescribing habits. *PLoS One*. 2014; 9(10):e110130.

9. Schünemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB, Macbeth F, Phillips SM, Robbins C, van der Wees P, Qaseem A; Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Annals of Internal Medicine*. 2015; 163: 548-53.

ANNEX 2

Organisations' statements

The principle that stands at the centre of the Shedding Light project implementation is to ensure the presence of all relevant perspectives. Therefore, Mental Health Europe asked several organisations to contribute to the final report with their standpoints on transparent relationships between the health industry, healthcare professionals, healthcare organisations and patient organisations. While publication does not entail endorsement by Mental Health Europe of content, we hope that this will result in continued dialogue on transparency in health care.

The publication of the following articles should in no way be considered as the mutual endorsement of the position of each organisation and individuals.

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 40 leading pharmaceutical companies (Member Companies) and 36 national associations (Member Associations), EFPIA's mission is to create a collaborative environment that enables members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. EFPIA's vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

Working in partnership with various stakeholders including healthcare professionals (HCPs), healthcare organisations (HCOs), patient organisations (POs), regulatory authorities, governments and the public, improves health, quality of life, and contributes to the value of future research. A more open and transparent interaction between the stakeholders involved in the healthcare system benefits the whole society.

EFPIA aims to foster an environment where the public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients. Consequently, EFPIA and its Member Associations, have adopted deontological Codes to ensure that these interactions take place in an ethical and transparent manner and meet the high standards of integrity that patients, governments and other stakeholders expect.

PRESENTATION OF EFPIA CODES AND THEIR DISCLOSURE REQUIREMENTS FOR HCPS, HCOS AND POS

EFPIA adopted, in 1991, the first version of its **Code on the promotion of prescription-only medicines to, and interactions with, HCPs**. This Code provides additional requirements to the European legal framework, mainly the Directive 2001/83/EC.¹

The main provisions of this Code concern the promotional activities and communication with any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicinal product. This Code covers all methods of promotion (oral, written, face-to-face, digital) and the provision of informational or educational materials, items of medical utility, hospitality in relation to promotional, scientific or professional events and medical samples. It also covers interactions between Member Companies and HCPs including those in the context of research or contractual arrangements.

In 2007, EFPIA adopted the **Code of practice on relationships between the pharmaceutical industry and POs** which builds upon the following principles of independence, mutual respect, transparency and multiple sources of funding.

This Code sets transparency requirements applicable to POs since 2013.

Each Member Company must disclose a list of POs to which it provides financial support and/or significant indirect/non-financial support or that it has engaged to provide contracted services. This disclosure should include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or arrangement. In addition to the name of the PO, Member Companies must also make public the total amount paid per POs over the reporting period.

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

In 2014, EFPIA adopted the **Code on the Disclosure of transfers of value from pharmaceutical companies to HCPs and HCOs**. The Disclosure Code requires Member Companies and companies that are members of Member Associations to disclose transfers of value² made to HCPs and HCOs. This disclosure includes, by HCP or HCO, the total amounts of value transferred, by type of activity, which could consist of, for instance, a grant to an HCO, a consultancy fee for speaking or registration fees to attend a promotional, scientific or professional event. Member companies began disclosing in 2016 the transfers of value provided during the calendar year 2015.

In these Codes, implementation and procedure rules for Member Associations were also agreed including sanctions such as the publication of the outcome of complaints.

RATIONALE FOR DISCLOSURE THROUGH SELF-REGULATION

Bringing greater transparency to this already well-regulated and vital relationship, builds understanding of industry-POs and HCPs/HCOs collaboration and, in the context of increasing societal expectations on transparency, directly addresses public concerns about interactions between the medical community and the pharmaceutical industry.

Increasing transparency through the disclosure of transfers of value is a step towards building stable and important collaboration between all stakeholders involved in the healthcare system. Nevertheless, the disclosure landscape is complicated by the existence of diverse legislation related to disclosure in some European Countries, including the adoption of central platforms³ as well as the inclusion of other sectors and partners. Some countries have chosen to enshrine transparency requirements in legislation depending on the political context, national attitudes to transparency and national data privacy regulations.

The disclosure includes personal data e.g. the names, the address of the HCPs and the amounts of transfers of value provided to them.

The General Data Protection Regulation 679/2016 (GDPR) considers that companies can legally process the personal data (that do not contain sensitive personal data) if they rely on one of the 8 legal bases. Of these EFPIA believes the following three would be most relevant in this context:

- ❑ Legal duty: there is a legislation in place allowing the personal data treatment i.e. transparency legislations
- ❑ Consent: the individuals agree with the treatment of their personal data. This consent must be specific, unambiguous, informed and freely given.
- ❑ Legitimate interest ground: the data processor considers that there is a public interest higher than the private interests of the individuals.

The appropriateness of these legal bases may differ between Member States.

For the Disclosure Code implementation, EFPIA considers that the consent basis is the most prudent approach though the legitimate interest ground can also be used after consulting the national Data Protection Authority.

2. Transfers of Value are direct and indirect payment, whether in cash, in kind or otherwise or reimbursement provided to HCPs and HCOs.

3. A central platform is one single, searchable database at a national level where users can search by HCP and/or by company. EFPIA supports the creation of mechanisms such as gateways and portals collating links to company disclosure pages as a minimum standard in order to make the data more accessible.

For example, the legitimate interest ground has been endorsed by the Spanish Data Protection Authority⁴ that has granted a waiver for the implementation of the Disclosure Code meaning that consent is not needed for the disclosure in Spain.

Additionally, the Dutch self-regulation regime and the national transparency laws have also acknowledged that there is a clear societal interest for the disclosure of individual information.

At the European level, since the first disclosure in 2016, EFPIA observed some variances in rates of consent between countries, HCPs areas of specialty, etc. These differences depend on the levels of engagement on disclosure with the HCP/HCO community, mixed reactions from the medical and media communities and cultural attitudes to transparency.

EFPIA strongly believes that transparency is best achieved without legislation.

Experience of existing national legislation demonstrates significant inconsistencies in the scope and approach of disclosure requirements. Each legal framework has its own specificities preventing a global and consistent approach for companies across Europe and common understanding for the public.

For these reasons, EFPIA and its members are fully committed to self-regulation as the optimal way to define, implement and enforce the highest ethical standards including for disclosure of transfers of value. Member states that value the transparency of these relationships over and above the individual's privacy rights have the option to endorse the legitimate interest approach to disclosure through their data protection authorities, negating the need for individual consent.

In order to continue to be successful, transparency requirements need to respond to the evolving demands of society and to solve the discrepancies emerging during their application. Self-regulation is ideally suited to address the continuous challenge and proactive adaptation.

There are significantly different socio-economic and cultural attitudes to transparency across Europe which can be reflected through self-regulation approach but that would make drafting and implementing a European legal framework costly and problematic.

4. The Spanish DPA considered that the individual disclosure of the transfers of value is justified on the legitimate interest ground because it is essential (i) to decrease the perception risk on the influence that the HCP might have received to carry out a specific prescription, dispensing and administration of medicines; (ii) to promote a culture of integrity in transactions with HCPs and (iii) to promote the confidence of the general public in the integrity and independence of the HCPs.

EUROPEAN MEDICAL STUDENTS' ASSOCIATION

Lina Mosch (EMSA European Health Policy Director)

Orsolya Süli (EMSA Vice President of External Affairs)

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The European Medical Students' Association is a non-profit, non-governmental organisation representing medical students from all across Europe. The association provides a platform for high-level advocacy, projects, trainings, workshops and international meetings. Its activities gather around medical education, medical ethics and human rights, health policy, public health, medical science and European integration and culture.

IN WHAT FORM IS TRANSPARENCY REFLECTED IN THE WORK OF YOUR ORGANISATION?

Transparency is a key aspect of the management of the European Medical Students' Association. Measures are taken to ensure transparency both on the international and national level, in all fields. The Internal Rules (IRs) of our association is the base of our operation; this document involves different regulations regarding our partnerships, collaborations and sponsorships. Agreements with any other party need to be shared with our members and they have the power to disapprove the decision of the Executive Board, thus invalidate the collaborations or sponsorships.¹ The IRs also give guidelines for these collaborations, as it is stated, that "EMSA is collaborating with organisations and constitutions, that share the same principles and objectives".² The leadership of the association is bound to report on their activities and any use of financial resources of the association, which is then voted upon by our members for approval. Our members, the Faculty Member Organisations also report on their annual activities and collaborations. EMSA is registered in the European Commission's Transparency Register, making most important operational and budget information available for the public. The organisation is also bound by the Code of Conduct of the Register.³

WHAT IS THE STANDPOINT OF YOUR ORGANISATION ON THE OBLIGATION TO DECLARE POTENTIAL CONFLICTS OF INTEREST AND THE OBLIGATION TO DISCLOSE TRANSFERS OF VALUES BETWEEN THE HEALTHCARE INDUSTRY AND HCPS AND HCOS?

The European Commission highlights scientific and professional integrity as one of its highest priorities for requirements of ethics and social responsibility in the framework for teaching, research and health practices.⁴ Scientific and professional integrity rely on both a transparent approach to conflicts of interest and clear policies to regulate them. Physicians face conflicts of interest for the first time in their education at university - knowingly or unknowingly.

If medical students lack awareness of existing conflicts of interest in their academic surrounding, they risk being influenced in their independence of decision making. The *report of the Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice* underlines this, stating that the quality of medical

1. EMSA Internal Rules

2. EMSA Internal Rules

3. http://ec.europa.eu/transparencyregister/public/staticPage/displayStaticPage.do?locale=en&reference=CODE_OF_CONDUCT

4. ALLEA - All European Academies: The European Code of Conduct for Research Integrity, Berlin 2017

education is a very important primary interest in healthcare that should be protected against secondary interests.⁵

Therefore, how universities handle conflicts of interest is of great importance for the scientific and professional integrity of future European doctors. So far, there has been no structured, comprehensive assessment of conflict of interest policies at European universities. In contrast, the American Medical Students' Association (AMSA) regularly evaluates medical schools' conflict of interest policies since 2008. The AMSA scorecard assesses policies annually; aiming to decrease the influence of pharmaceutical and medical device industries on medical trainees.⁶ By 2013, the percentage of medical schools receiving overall A grades had increased steadily to 25.9%, from 4.7% in 2008.⁷ Since its inception, the AMSA scorecard has generated considerable media attention and has influenced the development or strengthening of COI policies at many academic institutions.⁸ The effectiveness of the implementation of conflict of interest policies at medical schools in the USA has been demonstrated: King et al. found in 2013 that the probability that a physician who had attended a medical school with an active gift restriction policy was less likely to prescribe a newly marketed medication. The medications studied did not represent radical breakthroughs in their respective classes over existing alternatives.⁹

In Europe, the topic is just beginning to gradually move up the agenda. Recent developments prove a growing relevance for stakeholders in some European countries. In France, this was caused by the publication of a study assessing conflict of interest policies at French medical schools.

The results indicate that protection of medical students from undue commercial influence is rarely a priority, neither through institutional policies nor in medical education.¹⁰ The French Medical Students' Association (ANEMF) brought its official support to this study and asked for change at a national level and in each medical school. As a result, French medical faculties became aware of the topic and took action: 2017, the Deans' Conferences of Medicine and Odontology Schools in France adopted a charter, acknowledging that the independence of medical education towards secondary interests is a public health issue.¹¹ Further, it defines medical schools' responsibility to raise awareness and educate their medical students on conflicts of interest. Therefore, EMSA welcomes the ongoing study on conflict of interest policies at German universities¹², as well as plans for studies in Spain and Belgium. The involvement of medical students in studies on this topic has been decisive: almost no changes were to note in countries where the scorecard was introduced without the involvement of medical students (Australia¹³, Canada¹⁴). All of the above-mentioned studies assessing universities' conflict of interest policies were conducted or supported in a decisive way by medical students. This shows that they are a driving force in bringing forward the development of sustainable conflict of interest policies.

WHAT IS THE RIGHT APPROACH TO ENSURE GREATER TRANSPARENCY OF COOPERATION BETWEEN HEALTHCARE INDUSTRY, HCPS, AND HCOS?

Taking into account the effects studies about conflict of interest policies at universities had on the public relevance of the topic and the adoption of efficient conflict of interest policies and framework by universities, it is necessary to strive for a regular and Europe-wide assessment of conflict of interest policies of universities by a central institution. The evidence gathered here should be a base for policy design and implementation.

European universities must adopt a policy or guidelines regulating their handling of conflicts of interest. These guidelines must oblige professors and employees of universities, as well as the bodies of the university, to disclose

5. Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Washington (DC): National Academies Press (US); 2009.

6. AMSA Scorecard 2014. American Medical Student Association. <https://www.amsa.org/scorecard/>

7. AMSA Scorecard 2014. American Medical Student Association. <https://www.amsa.org/scorecard/>

8. Hobson K. Med Schools Improve on Conflict-of-Interest Scorecard. Wall Street Journal Health Blog; 2012.

9. BMJ 2013;346:f264

10. Scheffer P, Guy-Coichard C, Outh-Gauer D, Calet-Froissart Z, Boursier M, Mintzes B, et al. Conflict of Interest Policies at French Medical Schools: Starting from the Bottom. PLoS One; 2017.

11. formindp.fr/wp-content/uploads/2017/11/dean-charter-english.pdf

12. <http://www.interessenskonflikte.de/methodik/>

13. Mason P, Tattersall M. (2011) Conflicts of interest: a review of institutional policy in Australian medical schools.

14. Shnier A, Lexchin J, Mintzes B, Jutel A, Holloway K. Too few, too weak: conflict of interest policies at Canadian medical schools. PLoS One; 2013.

conflicts of interest with industrial companies and make them accessible to the public. Further, medical faculties around Europe are to implement and emphasise courses on 1) professional ethics and professional conduct, 2) assessment of conflicts of interest as well as 3) principles and rules of scientific integrity in the medical curriculum. A guideline for this could be the proposals of the Pharmfree Curriculum published by AMSA, adopted by the French Deans' Conference in their ethical charter mentioned above. Recommendations include the teaching of five competencies: professionalism and conflicts of interest, drug and device development, determining drug and device safety and efficacy, marketing, and physician practice and continuing medical education (after medical school).¹⁵

EMSA works to raise awareness among medical students about conflicts of interest and transparency and sensitise them to the topic. NGOs should tackle the problem by implementing transparency guidelines into their Internal Rules.

15. <https://www.amsa.org/wp-content/uploads/2015/03/ModelPharmFreeCurriculum.pdf>

EUROPEAN NETWORK OF (EX)USERS AND SURVIVORS OF PSYCHIATRY

ENUSP is the only independent federation at European level composed exclusively of and directly representing (ex-)users and survivors of psychiatry, with 32 member organisations and 42 individual members in 26 countries. Only organisations with a majority of (ex-)users and survivors both in their membership and their management structures are eligible to become members. ENUSP accepts individual members if they are (ex-)users or survivors of psychiatry. Therefore, according to the Statutes from the outset, only (ex-)users and survivors of psychiatry are entitled to influence the policy of ENUSP.

1. IN WHAT FORM IS TRANSPARENCY REFLECTED IN THE WORK OF YOUR ORGANISATION?

As a principle, ENUSP has never accepted any contribution of any kind from the pharmaceutical industry and it supports the "position paper of the European Public Health Alliance from 2001 on the independence of patients' organisations". Therefore, there is no issue of a conflict of interest possible and ENUSP could be seen to represent consumers directly. Although this may be the case, we recognize that each user/survivor is unique and has the right to his/her own opinion, and that there are differences in terms of deciding to rely on a pharmacological approach or not. These differences and exchanges of opinions and experiences occur regularly through ENUSP activities, contacts and advocacy.

What brings ENUSP together is the goal of achieving full Human Rights and the appropriate support of their choice for people experiencing mental distress or psychosocial disabilities and the free and informed consent of all users to any treatment or hospitalisation, as provided for in the UN Convention on the Rights of Persons with Disabilities (UN CRPD). In addition to full and true consent, transparency in relations with health care providers is of the utmost importance, particularly when a paternalistic and often hypocritical system of community treatment orders prevails in Europe. The protection of mental integrity under the UN CRPD can only be ensured through consent and full information provided to patients.

A lack of transparency among health care professionals with their patients can also have a huge psychological impact on patients, particularly as regards full information on treatments and options. As the most vulnerable stakeholders (particularly psychiatric patients), they are subject to potential adverse effects they are unaware of, and can even lose their health and life. This leads to mistrust in HCPs and HCOs and as a result, users avoid and deny medical assessment and treatment even if it is necessary and perhaps life-saving. HCPs lose their credibility, and finally drug firms lose their credibility, which is already more and more the case. This lack of transparency cannot be in anyone's interest.

For enlightened and self-confident citizens of the 21st century, transparency at all levels of life should be a matter of obviousness, particularly for patients, whether in the somatic or in the psychiatric field. Seven decades worth of a chance to develop rules of self-commitment by the health care industry now make strong regulations necessary.

2. HAS YOUR ORGANISATION ADOPTED A POSITION ON TRANSPARENCY OR ANY DOCUMENT RELATED TO TRANSPARENCY (E.G. CODE OF CONDUCT, DISCLOSURE CODE, ETHICAL GUIDELINES)? WHAT AREAS ARE COVERED BY THIS POLICY / THESE POLICIES?

ENUSP does not engage in relations with the pharmaceutical industry, recognizing that the power and influence of modern biological psychiatry depends on legally sanctioned force and coercion that would be regarded as fundamental human rights violations in any other sector of society.

3. WHAT IS THE STANDPOINT OF YOUR ORGANISATION ON THE OBLIGATION TO DECLARE POTENTIAL CONFLICTS OF INTEREST AND THE OBLIGATION TO DISCLOSE TRANSFERS OF VALUES BETWEEN THE HEALTHCARE INDUSTRY AND HCPs AND HCOs?

It can be said that the issue of transparency of relationships between the healthcare industry and other stakeholders is a matter of life and death for people ENUSP is representing. It is a well-known fact that people diagnosed with the major psychiatric diagnoses have significantly reduced life expectancy. In particular, people diagnosed with (and treated for) schizophrenia die in Europe on average twenty-two years earlier than others. Adverse effects of medication play a key role in this unhealthy situation.

From mainstream HCPs and HCOs, as well as from the health care industry, until now there has not been much support to promote alternatives to pharmacological treatment and reform mental health care in accordance with human rights standards, especially those articulated in the UN CRPD. Moreover, they have prevented the development of non-medical approaches by propagating and supporting the myth of a chemical imbalance as the cause for depression and psychosis. Putting it in the words of the UN Special Rapporteur on the Right to Health, Dainius Pūras, “the majority of mental health investments in low-, middle- and high-income countries disproportionately fund services based on the biomedical model of psychiatry” and “we have been sold a myth that the best solutions for addressing mental health challenges are medications and other biomedical interventions.”

It is self-evident, that no medical treatment is free of risks. But the consideration of the pros and cons, according to the law and the UN CRPD, is the responsibility of the patient, after receiving effective information on risks, damages and alternatives. The informed consent of the patient must be respected at all times. To support this legal and ethical requirement, the health care industry and collaborating HCPs have to deliver balanced information sheets on their products, including risks and damages, currently available alternatives, withdrawal problems, and critical information sources.

The situation we have with transparency now is not very promising. HCPs are supported by transfers of values from the health care industry to influence the development of new diagnoses for the DSM and ICD and to influence guidelines in commissions, to give lectures, write articles or books or give their names as authors and researchers to promote their drugs. The health care industry supports not only psychiatric mainstream HCOs in different ways, but also parents’ and patients’ organisations, publishers and journalists, who all receive major consideration mostly for the promotion of new, patented and expensive drugs. Lack of transparency is also very often the case in the practice of lobbying parliamentarians internationally and nationally.

In general, all those transfer of values happen in an intransparent way. The amount of money and the contracts covering those transfers and their purposes are hidden, which is completely unacceptable.

4. WHAT IS THE RIGHT APPROACH TO ENSURE GREATER TRANSPARENCY OF COOPERATION BETWEEN HEALTHCARE INDUSTRY, HCPs, AND HCOs?

The approach to ensure greater transparency of cooperation between the health care industry, HCPs, and HCOs must be implemented both at the national and at the European level. A European regulation for the strongest level of transparency would be an encouraging signal for all political parties, HCOs and HCPs to develop meaningful regulations in their states and in their organisations. The EU commission and other EU agencies could set a starting point and deny funding of HCPs and HCOs which have demonstrated conflicts of interest, at least as long as they do not adopt and implement serious conflict of interest policies and strengthen disclosure policies. HCPs and HCOs which do not disclose their conflicts of interests in a correct and complete form should be forced by law to pay the hidden value into a fund controlled by patients’ organisations that do not have conflicts of interest for support in

recovery from treatment damages and for support in withdrawal of drugs in case of dependence and withdrawal problems.

To implement the right to informed consent, patients and their confidants should have unlimited access to results of studies and reports on adverse effects on all levels, also if not published. To assess the independence of HCPs, all people should be able to be aware of the transfers of values between the health care industry and HCPs unlimitedly. The same goes for HCOs, including patients' organisations.

Transparency would allow all stakeholders to build an independent opinion about statements coming from HCPs and HCOs once information on the transfers of values between them and the health care industry is readily available. It would enhance the chances for compensation of people who have been damaged by products of the health care industry. In case of a deadly outcome of treatment, there would be a better chance for compensation to the bereaved ones. Monitoring and prevention systems could be improved if transparency is enforced.

MEDTECH EUROPE

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

IN WHAT FORM IS TRANSPARENCY REFLECTED IN THE WORK OF YOUR ORGANISATION?

Cooperation with healthcare professionals is integral to everything the medtech sector does, and we live up to high ethical standards. We work with healthcare professionals to develop solutions that advance the best possible patient care and address real medical needs. We work alongside them by supplying our expertise in developing devices and bringing their ideas to life.

Transparency is one of the key principles upon which the medtech industry is basing itself. However, within the healthcare sector, 'transparency' is defined in various ways. These include:

❏ Transparency laws/code (also sometimes referred to as "sunshine"): Laws and/or ethical codes that require medtech and/or pharmaceutical companies to track and report publicly any payments made to healthcare professionals and organisations (i.e. HCPs and HCOs, covering individuals as well as entities). Here MedTech Europe developed a two-pillar approach in its Code of Ethical Business Practice¹: firstly, we decided to stop direct financial support of HCPs to attend third party organised educational conferences (and provide only educational grants to HCOs) and secondly, those grants will need to be disclosed on a public website (TransparentMedTech).² Scope and details of that disclosure are described in the Code's Disclosure Guidelines.

❏ Transparency principle: Laws and/or ethical codes' provisions that require medtech and pharmaceutical companies to issue prior written notification or approval to the hospital administration, the HCPs' superiors or other locally-designated competent authority to disclose the purpose and scope of the interaction between a company and a HCP. Our Code of Ethical Business Practice also provides for this kind on transparency.

HAS YOUR ORGANISATION ADOPTED A POSITION ON TRANSPARENCY OR ANY DOCUMENT RELATED TO TRANSPARENCY (E.G. CODE OF CONDUCT, DISCLOSURE CODE, ETHICAL GUIDELINES)? WHAT AREAS ARE COVERED BY THIS POLICY/THESE POLICIES?

As described above, transparency is one of the core principles of the MedTech Europe's Code of Ethical Business Practice (including Disclosure Guidelines) guiding members in their interactions with healthcare professionals (HCPs) and healthcare organisations (HCOs).

1. https://www.medtecheurope.org/wp-content/uploads/2018/09/MedTech-Europe-Code-of-Ethical-Business-Practice_QAs_July.pdf

2. <https://www.ethicalmedtech.eu/transparent-medtech/>

Improvements in the clinical care of patients are rooted in the interaction between HCPs/HCOs and medical technology (medtech) companies. HCPs and HCOs 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. The industry has an absolute responsibility to train healthcare professionals on the medical devices that it develops to ensure the best and safest use of these devices for the sake of patients. Medtech companies provide HCPs and HCOs 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.

WHAT IS THE STANDPOINT OF YOUR ORGANISATION ON THE OBLIGATION TO DECLARE POTENTIAL CONFLICTS OF INTEREST AND THE OBLIGATION TO DISCLOSE TRANSFERS OF VALUE BETWEEN THE HEALTHCARE INDUSTRY AND HCPS AND HCOs?

MedTech Europe and its members support transparency in general and more specifically commit to ensuring that HCPs make independent decisions regarding the healthcare and treatment of patients and the development and improvement of medical technology. As such, the device and diagnostics industry developed a new strong Code of Ethical Business Practice which supports and promotes strong ethical standards in all interactions with HCPs and HCOs.

Transparency is one of our five essential principles which frames industry's collaboration with HCPs. This collaboration is necessary to promote the safe and effective use of medical technologies as well as the development of innovative and advanced technologies.

Information specifically regarding transfers of value between the healthcare industry and HCPs and HCOs should be disclosed in a form that makes the context of the payment clear, so that patients can understand the payment's purpose and appropriateness. The MedTech transparency rules provide for that.

The industry has invested a tremendous amount of time, resources and effort to comply with any national legal requirements as well as the MedTech Europe Code. Any efforts towards voluntary international harmonisation would be of considerable interest, provided that requirements do not differ in terms of thresholds, types of interactions covered, persons involved, level of detail, publication place and frequency as well as implementation periods etc.

WHAT IS THE RIGHT APPROACH TO ENSURE GREATER TRANSPARENCY OF COOPERATION BETWEEN HEALTHCARE INDUSTRY, HCPS, AND HCOs?

MTE strongly supports transparency as a broad principle for all stakeholders and in particular applying to companies' interactions with HCPs and HCOs. Whether designed as a self-regulatory scheme - or as a legal scheme, we believe that "financial transparency" (i.e. "sunshine" type regulation) should be constructed considering the following important conditions:

- ✘ The implementation should 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 focused on 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 focused on information which is valuable to decision-making purchasing decisions, recommending and/or paying for medical technologies.

✘ Disclosed information should also aim to be as material as possible.

✘ It should prevent compromising personal and/or proprietary information, i.e. infringements on the rights of the healthcare professionals.

It should prevent unnecessary burden for companies, such as heavy and costly reporting processes, considering the time and resource necessary for companies to implement data collection systems.

ANNEX 3

Sunshine & transparency laws, regulations and codes across Europe

SUNSHINE & TRANSPARENCY LAWS, REGULATIONS AND CODES ACROSS EUROPE

