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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2013

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Introduction

The pharmaceutical industry is no stranger to the global trend for increased transparency and public scrutiny. Willingness to increase the transparency of the interactions between pharmaceutical companies and healthcare professionals ("HCPs") has already been demonstrated at a national level by the enactment of new legislation in the US and France, and by the implementation of new self-regulatory provisions in the UK and The Netherlands. However, the means by which transparency has been achieved at a national level has varied, and as such, the European Federation of Pharmaceutical Industries and Associations ("EFPIA") is seeking to encourage a consistent approach toward transparency in Europe, and to guide actions taken at national level.

EFPIA represents the pharmaceutical industry in Europe, with membership comprising of both national industry associations and leading pharmaceutical companies. Its two existing codes of practice, namely the Code of Practice on relationships between the pharmaceutical industry and patient organisations (the "PO Code"), and the Code of Practice on the promotion of prescription-only medicines to, and interactions with, HCPs (the "HCP Code"), already require disclosure of financial support and/or significant indirect/non-financial support provided to patient organisations[1], and encourage the disclosure of details of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare or conduct research[2].

However, in order to reflect the growing expectations for transparency, EFPIA is supplementing its two existing codes of practice with an additional Code on the Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (the "Disclosure Code"). The Disclosure Code will require detailed disclosures of the nature and scale of the interactions between the industry and HCPs (and with institutions, organisations and associations comprising HCPs and/or that provide healthcare or conduct research).

The final draft of the Disclosure Code is scheduled to receive formal approval at EFPIA's next annual meeting on 24-25 June 2013, following which it will be required to be transposed into the national industry association codes by 31 December 2013. EFPIA has recognised that developing appropriate systems and procedures for this level of disclosure may take some time, and as such, disclosures under the new Disclosure Code will not be required until 2016 in respect of payments made in 2015.

Scope of New Disclosure Code

At the time of preparing this chapter, the Disclosure Code had not yet been made publicly available. However, an overview of some of the key provisions was presented on 17 January 2013 at the annual conference of the International Congress Advisory Association ("IPCAA").

The IPCAA presentation indicates that the Disclosure Code will require annual reporting of:

- transfers of value ("ToVs") to HCPs and healthcare organisations ("HCOs") on an individual basis; and
- ToVs relating to research and development activities and certain other activities in aggregate form, where individual reporting is not practicable.

No definition of "ToVs" is provided in the IPCAA presentation, but this is likely to encompass both direct and indirect payments whether in cash, in kind or otherwise. Nor is there a definition of "HCOs", but in the interest of consistency this should be defined in similar terms to those set out in Article 11 of the HCP Code, which refers to "*institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research*".

The Disclosure Code will, therefore, focus primarily on disclosure of payments made by industry to HCPs and HCOs. EFPIA does not appear to view payments to, and support for, patient organisations as problematic from a transparency perspective, presumably because disclosure of such payments is already provided for under Article 5 of the PO Code.

The IPCAA presentation states that companies will be required to generate their own databases of the required information, although the Disclosure Code will describe how the disclosure process should take place. EFPIA's requirement that disclosure is made on a company-by-company basis avoids the more difficult question of whether, and if so how, more user-friendly systems could be developed in order for patients to be able to view details of payments made to individual HCPs without having to review individual company disclosures. This remains an issue to be addressed at a national level.

Individual Disclosure Requirements

In relation to ToVs to HCOs and HCPs, the IPCAA presentation indicates that disclosures on an individual basis will be required in relation to:

- Donations and grants

  Article 11 of the HCP Code sets out the circumstances in

which donations, grants and benefits in kind to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare or conduct research are permissible. Article 11 currently "encourages" companies to make available publicly information about such donations, grants and benefits in kind. The IPCAA presentation indicates that the disclosure of donations and grants should now be viewed as mandatory. Benefits in kind appear to be out of scope, presumably because of the difficulties associated with quantifying their value, and will therefore remain subject to the non-mandatory requirements of the HCP Code.

- Fees for services and consultancy

  Services provided by institutions

  Article 12 of the HCP Code covers fees for services, and provides that "*contracts between companies and institutions, organisations or associations of healthcare professionals under which such institutions, organisations or associations provide any type of services to companies (or any other type of funding not covered under Article 11 or not otherwise covered by the EFPIA HCP Code) are only allowed if such services (or other funding): (i) are provided for the purpose of supporting healthcare or research; and (ii) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products*". To the extent such contracts are permissible under the HCP Code, the Disclosure Code will require disclosure of details of any ToVs resulting from such contracts on an individual company basis.

  Services provided by individual HCPs

  Article 14 of the HCP Code addresses the use of "*healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel*". To the extent that such arrangements are permitted under the HCP Code, the Disclosure Code will require disclosure of details of any payments or other ToVs made in relation to genuine consultancy services, on an individual consultant basis.

- Sponsorship, events and hospitality

  The IPCAA presentation indicates that this head of disclosure will include registration fees, travel and accommodation, and associated ToVs "*such as food, beverage & others exceeding threshold*". Events and hospitality are addressed in Article 9 of the HCP Code, which permits limited hospitality in connection with events in the form of travel, meals, accommodation and genuine registration fees, to the extent reasonable and provided any hospitality is limited to the main purpose of the event. Article 9 does not, however, currently provide for a monetary threshold, and as such either EFPIA or national self-regulatory bodies will be required to determine an appropriate threshold value.

Aggregate Disclosure Requirements

In addition to the individual disclosure requirements set out above, the IPCAA presentation indicates that aggregate disclosures of ToVs will be permissible in relation to:

- Research and development

  Disclosures of ToVs associated with research and development activities (specifically: pre-clinical studies; clinical trials in Phase I to Phase IV; investigator-sponsored studies; and observational, interventional and non-interventional studies) are indicated as being permissible on an aggregate basis.

- Donations and grants; sponsorships, events and hospitality; fees for services and consultancy

  As it may not be possible or feasible to disclose every ToV on an individual basis (whether as a result of the nature of the ToV in question, or from legal constraints to individual disclosure stemming from the personal data protection legislation), the Disclosure Code will contain a mechanism allowing aggregate disclosure in certain limited circumstances. In order to maintain transparency and avoid abuse, such aggregate disclosures will need to be provided together with some indication of the number of recipients covered by such disclosure.

Each member company will be required to publish a note summarising the methodologies used by it in preparing its disclosures and identifying transfers of value for each category of disclosure.

Legal Issues - Data Privacy

By their nature, any genuine transparency arrangements must disclose details of the recipients of payments made by pharmaceutical companies. Whilst this is not problematic in relation to payments to HCOs, one of the key hurdles in disclosing payments to HCPs is ensuring compliance with personal data protection legislation.

The collection, use and disclosure of HCPs' names and details of payments made to them constitutes processing of personal data for the purposes of EU Directive 95/46/EC (the "Data Protection Directive"). The Data Protection Directive imposes restrictions on anyone who "processes" personal data, and sets out a number of data processing principles. The most important of these principles is that data is processed fairly and lawfully. The legislation specifies a number of ways in which processing may be justified under this principle, one of which is to obtain the relevant data subject's consent. The Data Protection Directive requires consent to be unambiguous, and defines it as a freely given, specific and informed indication of the wishes of the individual by which agreement to processing is signified.

In the IPCAA presentation, EFPIA indicates that where payments or other ToVs are made to HCPs in the context of a contract, the contract provides a ready mechanism with which to obtain the HCP's consent to the processing of his/her personal data for the purpose of meeting that member's obligations under the Disclosure Code. It envisages that companies should ensure data protection compliance by relying on HCP's consent to the collection and disclosure of their data, and recommends that as a matter of good practice, companies should create and retain evidence showing that this consent was indeed given.

However, guidance from the EU's Article 29 Working Party (an advisory body comprising representatives from the data protection authorities of each Member State) emphasises that consent as a ground for lawful processing of personal data should only be relied upon if the individual data subject has a genuine free choice and is subsequently able to withdraw the consent without detriment. Even if it can be shown that consent is given freely (and this can be difficult to demonstrate when consent is given in the context of employment), the consequences of its withdrawal are problematic. An HCP's withdrawal of consent to the publication of details of the payments made to him should prevent any further processing of such data, unless that processing can be justified by another legal ground. If the requirement to collect and disclose this data were based on a statutory requirement (as is the case in the US, for example) then ongoing publication of this information could be justified without the HCP's consent. However, compliance with voluntary industry codes of

practice does not amount to such a justification, and companies will, therefore, require a somewhat unsatisfactory carve-out from the disclosure requirement exempting disclosure of HCP's personal data where they have withdrawn their consent.

Legal Issues - Competition

Under EU competition law, the Court of Justice has stated that an exchange of information between competitors is tainted with an anti-competitive object if the exchange is capable of removing uncertainties concerning the intended conduct of the participating undertakings[3]. This means that merely informing competitors of the levels of reward made to HCPs could be regarded as a concerted practice, and would lead to a presumption of a causal connection under which competitors are presumed to take account of the information provided.

Reporting payments as a total annual amount per year should be enough to remove the possibility that other pharmaceutical companies will be able to set their own remuneration accordingly. This might not be the case, however, if there are sufficient occasions on which individual HCPs are commissioned on only one occasion per year (and this fact is known to competitors - for example, because of the nature of the services provided or the area of expertise of the individual or otherwise), in which case, it might be possible to reverse engineer the data in order to identify payment levels. In such circumstances, it would be for the companies to prove that they did not take account of this information in their own decisions on setting payment levels.

National Transparency Initiatives in the EU

Pending the release of the Disclosure Code, the position in relation to transparency of payments to HCPs at a national level varies considerably between the different EU Member States. Summaries demonstrating the diversity of national approaches in a selection of Member States are set out below.

Transparency in the United Kingdom

In the UK, the principles of the HCP Code and the PO Code are incorporated in the Association of the British Pharmaceutical Industry's Code of Practice for the Pharmaceutical Industry (the "ABPI Code"). Under the ABPI Code, member companies have been required to publish aggregate data on payments made to HCPs and third parties since March 2013, including details of:

- donations and grants provided to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research[4];
- sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings organised by third parties[5];
- details of the fees paid to consultants in the UK, or to their employers on their behalf, for services rendered by them such as chairing and speaking at meetings, assistance with training and participation in advisory boards, etc.[6]; and
- payments made to consultants in relation to market research and payments in respect of accommodation (both in and outside the UK) and travel outside the UK in relation to fees for consultancy services[7].

Using information on payments published by ABPI member companies, ABPI has estimated that payments from the pharmaceutical industry working with HCPs in the UK amounted to around £40 million for 2012.

However, as the ABPI Code currently only requires disclosure of payment information on an aggregate basis, a number of changes will be required in order to implement the requirements of EFPIA's Disclosure Code in relation to disclosure on an individual basis. ABPI plans to circulate details of the proposed revisions for consultation during 2013. Subject to agreement at the ABPI's 5 November 2013 meeting, a revised ABPI Code will then come into operation on 1 January 2014.

In parallel, the Ethical Standards in Health and Life Sciences Group ("ESHLSG"), a group of 20 organisations representing the medical community and the pharmaceutical, medical device and diagnostic industries in the UK, has launched a consultation on establishing a public register of payments made to HCPs by commercial organisations. The consultation is seeking input from UK HCPs and life sciences companies on whether there is support for a system in which payments from commercial organisations to individually named HCPs are publicly declared, using a single central publicly searchable system hosted by one organisation. ESHLSG is considering whether and how HCPs should play a proactive role in disclosing the payments they receive from commercial organisations (rather than pharmaceutical companies disclosing the data on an individual basis), and the impact that public disclosure of payments at an individual level would have on a collaboration between HCPs and commercial organisations.

The consultation closed in April 2013 and ESHLSG's report on the consultation results is expected during 2013.

Transparency in The Netherlands

On 25 April 2013, the Healthcare Transparency Register (the "Register") was launched in The Netherlands[8]. The Register is unique (at least for the time being - an equivalent federal register will be established in the US in 2014) and provides insight into certain financial relationships between pharmaceutical companies and HCPs, partnerships of HCPs and institutions which employ HCPs.

The Register was established by physicians, HCPs and institutions and pharmaceutical companies with the aim of ensuring transparency concerning the cooperation between parties in the healthcare system. In 2014, it will be extended to include financial relationships with veterinary pharmaceutical companies, and the Dutch Minister of Health has indicated that financial relationships within the medical devices sector may follow.

The Register ensures insight into the financial arrangements surrounding the provision of services (e.g. the remuneration provided to an HCP by a pharmaceutical company for giving a lecture or presentation or publishing a medical-scientific article) and sponsorship (e.g. when a pharmaceutical company provides financial support for a project or a particular piece of research). The arrangements must be disclosed within three months following the year in which payment took place, and the information remains on the Register for three years, after which it is removed.

The Register lists the name of the professional or the relevant professional association or institution, the name of the company concerned, the nature of the financial relationship (either consultancy, advisory board, speaker, research, sponsorship or 'other'), and the total amount or fees paid in that year. Clinical research is not included in the Register; this is made public via the CCMO Trial Register[9].

All HCPs, healthcare institutions and pharmaceutical companies that are affiliated with the participating umbrella organisations take part in the Register. The small number of non-affiliated HCPs and pharmaceutical companies have been invited to voluntarily report any financial relationships.

The Register is regulated by way of a code of conduct drawn up by the CGR Foundation[10] in 2011 in close consultation with stakeholders. The CGR Foundation is responsible for enforcement of the code, and has powers to issue orders to comply, reprimands and publication. In addition to this, the umbrella organisation affiliated with the CGR Foundation can take action against members who do not comply with the code.

Transparency in Italy

Transparency of payments to Italian HCPs is partially addressed by Italian pharmaceutical regulations, which require (i) HCPs to declare that they are a consultant of a particular pharmaceutical company whenever they write or speak in public about a matter that is the subject of the consultancy agreement[11], and (ii) pharmaceutical companies to make available on their websites (and keep available for at least three years) details of any granted scholarships[12].

If HCPs are (as is generally the case) public employees, then stricter legislation relating to the transparency of public administrative activity, applies[13]. Whilst the rules are complex and subject to a number of exceptions, in essence, any remunerated service rendered by an HCP outside of his usual duties must be previously authorised by his/her employer. Authorisation is granted if: (i) there is no conflict of interest; (ii) the services do not imply a personal advantage for the consultant; (iii) consultancy fees are reasonable; and (iv) the consultancy activity is performed only occasionally and does not adversely affect the employee's ordinary job activity. The public employer then publishes a list of all the authorised assignments on its website, in each case, specifying duration and remuneration.

At the time of writing this chapter, no formal process has had been established in Italy in order to consider the impact of EFPIA's forthcoming Disclosure Code.

Transparency in France

France adopted in December 2011 its "Sunshine Act" to increase transparency in interactions between health products companies and HCPs (as well as other companies of the health sector, such as patient associations and health institutions). Pursuant to the French Sunshine Act, companies will be required by law to disclose publicly the existence of any contracts with HCPs (and other concerned entities), as well as any benefits in cash or in kind paid to them beyond a certain threshold. However, this new requirement will not enter into force until an implementation decree has been published, specifying amongst other things the relevant threshold and details of the information to be disclosed.

The French Ministry of Health has circulated several versions of the draft decree, which have been the subject of many discussions with various stakeholders (in particular, the French pharmaceutical industry professional association, LEEM). It raises many questions under French law, notably from a personal data protection standpoint and with respect to "business secrecy" protection (if the exact purpose of relevant contracts is disclosed). As of May 2013, the decree had not been published, and whilst it is expected before the summer, timings are currently uncertain.

Transparency in Spain

Payments to Spanish HCPs are governed by both legislation and codes of practice. EU advertising law is implemented through Law 29/2006 and Royal Decree 1416/1994 (although a new Royal Decree on advertisement of medicinal products to supersede Royal Decree 1416/1994 is currently being drafted). Some of Spain's Autonomous Regions have produced their own local guidelines. In addition, Farmaindustria (the Spanish pharmaceutical industry association) has adopted a Code of conduct on the promotion of medicinal products and interactions with HCPs, and has also adopted various guidelines giving practical indications on how to interpret the Spanish HCP Code.

Under Spanish rules, sponsorship to attend conferences, congresses, study trips, and similar events must be disclosed, on an annual basis, to the relevant health authority of the Autonomous Region where the company is located; however, there is no requirement to make this information publicly available. The Spanish HCP Code also encourages the publication of donations, grants and benefits in kind to institutions, organisations or associations that are composed of HCPs, but this is not mandatory.

The Spanish HCP Code requires that any payments to HCPs for legitimate expert services are made pursuant to a written agreement stating the nature of the services and the criteria used to calculate the amount of payment. Whilst the Code encourages companies to include a clause in these agreements requiring the HCP to declare his relationship with the company every time in any written material or when speaking at public events, the company is not required to publish the amounts it pays to HCPs.

The transparency requirements under Spanish law and guidance are, therefore, significantly less onerous than the proposed EFPIA regime, and significant amendments to the Spanish HCP Code will be required. Farmaindustria is currently working on the next version of the Spanish HCP Code to adapt it to the regime proposed by the EFPIA.

Transparency in Germany

German law and any industry guidelines do not require companies to disclose payments to HCPs or hospitals, regardless of whether such payment is based on collaboration or a charitable donation, nor payments for attending medical congresses. However, HCP's professional code requires them (rather than industry) to disclose any collaboration (agreements) with the industry to their regional professional associations.

In relation to clinical trials, German pharmaceutical companies have to disclose the key points of service agreement(s) concluded with the clinical trial site to the competent ethics committee. It is common practice in Germany that the "key points" include any remuneration paid to the (principal) investigator. Finally, if physicians conduct non-interventional studies (*Anwendungsbeobachtungen*) on behalf of the industry where the respective medicinal product is reimbursed by the statutory health insurance, companies have to disclose the remuneration paid for the medical service to Federal Association of the Statutory Health Insurance Fund (GKV-*Spitzenverband*), the German Medical Association (*Bundesärztekammer*), and the Private Health Insurance (Private *Krankenversicherung*).

Whilst an obligation on pharmaceutical companies to disclose payments to patient organisations has applied in Germany since 2008, due to public pressure and the legal environment in other countries (such as France and the US, but also in the light of EFPIA), German self-regulatory associations have announced that they will include an obligation for pharmaceutical companies to disclose payments to HCPs in their code of conduct in 2016.

Endnotes

1 Article 5 PO Code.

2 Article 11 EFPIA HCP Code.

3 Case C-8/08 Judgment of the Court (Third Chamber) of 4 June 2009 *T-Mobile Netherlands and Others*; Case T-587/08. Judgment of the General Court (Eighth Chamber) of 14 March 2013 *Fresh Del Monte Produce, Inc. v European Commission.*

4 Clause 18.6, ABPI Code.

5 Clause 19.4, ABPI Code.

6 Clause 20.2, ABPI Code.

7 Clause 20.3, ABPI Code.

8 www.transparantieregister.nl.

9 http://www.ccmo-online.nl/main.asp?pid=70.

10 www.cgr.nl.

11 Farmindustria Ethic Code, article 4.1.

12 Farmindustria Ethic Code, article 4.2.

13 Article 53 of Legislative decree 165/2001 on public employment; Legislative decrees n. 150/2009 and 33/2013.

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The EU lifesciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including three physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the lifesciences sector.

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