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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2015

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A practical cross-border insight into pharmaceutical advertising

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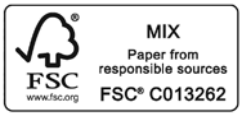

General Chapter:

Country Question and Answer Chapters:

Denmark

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in Denmark?

Chapter 7 of the Danish Medicines Consolidated Act No. 506 of 20 April 2013, (the "Act"), as amended, and executive orders Nos. 1244 of 12 December 2005 (Samples) and 1153 of 22 October 2014 (Advertising), collectively the "Advertising Order", and executive order No. 801 of 21 June 2013 (Television & Radio), which, together with the Advertising Order, hereinafter are referred to as the "Orders", govern the advertising of medicinal products in Denmark.

In addition to the Act and the Orders, the Danish Health and Medicines Authority (the "DHMA"), has issued guidance note No. 10356 of 29 December 2014 on the advertising of pharmaceuticals (the "DHMA Guide").

The Danish Marketing Practices Consolidated Act No. 1216 of 25 September 2013, (the "Marketing Act"), as amended, which basically sets out fair trading standards, governs advertising in general and authorises the Consumer Ombudsman to monitor marketing activities and to sanction non-compliance.

The Act, the Orders, the DHMA Guide and the Marketing Act (collectively the "Legislative Basis") are enforced by the DHMA and the Consumer Ombudsman.

In addition to said authorities, self-regulated bodies – proceedings before which are possible in addition to administrative and judicial proceedings – monitor the advertising of medicinal, borderline and dietary supplement products, and/or enforce ethical standards. The self-regulated bodies comprise: 1) the Ethical Committee for the Pharmaceutical Industry in Denmark ("ENLI"); 2) the Veterinary Marketing Practices Board ("VIF"); 3) the Pharmacist's Ethical Board ("AEN"); 4) the Medical Doctor's Ethical Board ("LEN"); and 5) the Health Trade Supplier Association's Ethical Board ("HBL"). Within the scope of their respective statutes, the bodies monitor that advertising initiatives comply with the Legislative Basis and ethical codes and/or that their respective members comply with applicable ethical standards.

Advertising initiatives addressing doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, midwives, laboratory technicians, clinical dieticians and radiographers, and/or students of such professions (collectively "Healthcare Professionals" or "HCPs"), have been monitored by ENLI since 1 April 2011. Effective as from 1 January 2014, ENLI was transformed into a private limited company, whose entire share capital is held by The Danish Association of the Pharmaceutical Industry ("LIF"). ENLI's jurisdiction, being contractually based, covers the members of LIF, The Danish Generic Medicines Industry Association ("IGL") and The Association of Parallel Importers of Medicinal Products ("PFL"), as well as corporations and associations, which could have been members of LIF, IGL or PFL, but have chosen not to be, merely to submit to the ENLI jurisdiction. The Danish Medical Association ("LF") and The Association of Danish Pharmacies ("DA"), which were members of ENLI's predecessor, the Legal Board of Self-Regulation concerning Pharmaceuticals ("NSL"), are now, respectively, monitoring medical doctors' co-operation with the industry (conferences, professional consultancies, advisory board memberships, visits by medical representatives and participation in clinical trials), and pharmacists' compliance with a set of DA Ethical Rules, leaving enforcement of advertising initiatives involving their members to the DHMA on the basis of the Legislative Basis.

ENLI's activities are based on a Co-Operation Agreement ("COA") entered into among LIF, IGL and PFL on 24 March 2015 and taking effect on 1 April 2015. The COA sets out ENLI's objective, competencies, organisation, management, organs (1st and 2nd instance) and economy. The rules and standards to be enforced by ENLI (the "ENLI Rules") comprise the Legislative Basis, as well as a range of ethical rules and Codices consisting of: i) an Advertising Codex of 19 February 2015 governing advertising *vis-à-vis* Healthcare Professionals (the "Advertising Codex") incorporating the IFPMA, EFPIA (HCP & Disclosure Codes), the EGA (European Generic & Biosimilar Medicine Association) and the WHO codes on advertising, and codex is supplemented by guidance notes of February 2015 on use of social media, including homepages, Version 1.3; ii) the Patient Organisation Co-operation Codex of 19 February 2015 incorporating the corresponding EFPIA and EGA codices; iii) the Lobbying Codex of 19 February 2015 (the "Lobbying Codex"); and iv) rules on the relations between the industry and the Danish Hospital Sector of 19 February 2015 (the "Hospital Codex"). The Advertising Codex, the Patient Organisation Co-operation Codex, the Lobbying Codex and the Hospital Codex, are hereinafter referred to as the "Codices". The Codices are available in, *inter alia*, the English language from ENLI's homepage: http://www.enli.dk/.

1.2 How is "advertising" defined?

The DHMA Guide defines "advertising" as any information dissemination, canvassing activity or inducement designed (intended to) promote the prescription, supply, sale or consumption

of medicinal products. Hence, advertising includes: the promotion of medicinal products to the general public and Healthcare Professionals; visits by sales representatives; supply of samples; any benefit or bonus, except when their intrinsic value is minimal; sponsorship of promotional meetings or scientific congresses attended by Healthcare Professionals; and payment of travelling and accommodation expenses for Healthcare Professionals attending such meetings or conferences. Two types of material are not considered covered by the advertising rules, even if their content as such may be of a promotional nature, namely, a) medicinal information prepared by public institutions aiming to promote rational drug consumption, and b) submission to a HCP of a scientific article on a clinical trial, provided that the article is not commented upon, additional material is not enclosed and the article has been published in advance in a reputable and independent Danish or international journal. This exception even applies to articles summarising comparative medicinal product studies. The advertising definition excludes i) labelling and the accompanying package leaflet comprising Summary of Product Characteristics ("SmPC") derived information, ii) correspondence, including appendices of a non-promotional nature, needed to answer a specific question about a particular medicinal product, iii) factual, informative safety announcements and reference material, for example packaging material changes, adverse-reaction warnings as part of general medicinal product precautions (safety) and recall announcements, iv) price lists and trade catalogues, which may comprise product names, forms, strengths, package sizes, prices and pictures of product packages, but not product claims or names of competing products, v) information brochures and homepages relating to human health or diseases, provided that there is no reference, even indirectly, to named medicinal products, vi) patient information leaflets provided by a prescribing doctor or the supplying pharmacist, provided that the leaflet only contains objective information of importance to patients and their relatives, and which does not contravene the SmPC, vii) press releases believed to be of interest to the general public from the advertising rules provided that: a) the information offered holds general news value; b) the release is addressing the press; and c) the release is targeting a plurality of journalists or reporters only, for the purpose of having such information assessed and elaborated upon prior to publication by such recipients, and viii) unedited and complete reproductions of package leaflets, the approved SmPC, a publicly available evaluation report and the depiction of a medicinal product packaging, provided that the information made available in such a way that users must actively seek out the information, see ECJ's case No. C-316/09. This means that a company, for example, may publish a list of its medicinal products on its website with links to the SmPC and the package leaflet for each drug. For non-HCP to access the latter, the user must make an active choice, e.g. by activating a link at the marketing authorisation ("MA") holders' homepage directing the user to the relevant document. This condition implies that the said documents may not be distributed directly to non-HCP users on the grounds that e.g. the SmPCs are not covered by the advertising definition. The Marketing Act, which governs advertising in general, is construed to supplement the scope of the advertising definition to include presentations made in order to promote the supply of goods, advertising which may affect the economic behaviour of the addressee or is likely to injure a competitor (misleading advertising) and advertising comparing competing goods (comparative advertising).

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Under the authority of par. 1-3 of article 68 of the Act, article 17 of the Executive Order on Advertising requires the marketing authorisation holder, or the one advertising, if different from the marketing authorisation holder, e.g. pharmacies, parallel distributors or even third parties without financial interests in the product sales, to store a copy of or corresponding documentation for the advertisement (reference is made to ECJ Case C-421/07). The file must be in printed form or digital and, if the latter, in a standard format such as, but not limited to, .pdf, .tiff or .jpeg. In addition, information on the target group, how the advertisement has been distributed, a list of media used and when the advertisement was published must be stored. The documentation must be kept for at least two years and must be made available to the DHMA on request. Advertising material includes not only printed advertisements, but also documentation for non-printed advertisements, such as electronic advertisements made available on the internet. The filing requirements can be complied with electronically by maintaining files in generally used and acknowledged formats The obligations on the filing of documentation related to donations, see question 4.3 below, are stricter. The DHMA has very broad powers to request copies for enforcement purposes, as it may address anybody who has been involved in the campaign, including advertising agencies. Otherwise, companies are not formally required to have compliance programmes in place.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no legal or code requirements for companies to have specific SOPs governing advertising activities. Considering, however, that companies having breached the norms are required to declare to ENLI that all necessary precautions to avoid repetition have been taken, and that sanctioned non-compliance will be published by ENLI, it is recommended that companies institute and operate compliance SOPs.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The Advertising Codex, but not the Legislative Basis, requires electronic notification of, but not pre-approval by, ENLI at www.enli.dk, in case of an ENLI subject:

a) hosting or co-hosting an arrangement (meetings, congresses, symposia, etc.) partially or wholly addressing Danish Healthcare Professionals;

b) sponsoring *litra* a) arrangements;

c) acquiring access to a sales pitch at a congress in Denmark; and/or

d) publishing, whether in physical media or electronically, advertising materials addressing Healthcare Professionals.

Each notification triggers a fee of DKK 325 + VAT (approx. EUR 45), which is payable quarterly in arrears. Notification deadlines

for each kind of initiative are set out in the Advertising Codex. Generally the deadlines are 10 days before the event or, with respect to advertising materials, the same day as publication takes place. Invitations must include information that the advertising initiative complies with the above and either that it complies with the Codices applicable or has been pre-approved by ENLI (there is a pre-approval charge of DKK 5,000 (DKK 25,000 for matters of urgency) or, if more than two hours of work on the application is required, DKK 2,000 per hour). If pre-approved, the advertiser cannot be fined, merely reprimanded by ENLI for non-compliance, provided, however, that the information on the basis of which ENLI has pre-approved the initiative has been correct. A reprimand may be given by the ENLI board of appeal if the initiative is found to constitute a breach in spite of pre-approval having been given. The position of the authorities, were they to disagree with ENLI, is not prejudiced by ENLI's position. However, the likelihood of an undertaking being prosecuted under such circumstances is low.

The Minister of the Ministry of Health (the "Minister") is authorised by § 70, par. 2 of the Act to require the DHMA to offer pre-assessment of intended advertising initiatives. Until the Minister may do so, the DHMA is precluded from offering such service. Consequently, the DHMA cannot require an undertaking to submit an intended advertising campaign for pre-approval.

Outside the scope of the Act and the Orders, the Marketing Act authorises undertakings to address the Consumer Ombudsman to obtain an assessment of the legality of intended campaigns addressing the general public.

During 2014, 5,298 notifications were made to ENLI (2013: 5,714/ first Q, 2015: 1,599). 292 pre-approval applications (2013: 325/ first Q, 2015: 80) were submitted.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/ or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Both the DHMA and the Consumer Ombudsman have the powers to require that an advertisement be stopped, to require a corrective statement be issued and to take or require appropriate corrective action to be taken. The DHMA Guide authorises decisions to be appealed to the Minister, whereas action taken by the Consumer Ombudsman may be brought before the ordinary courts of justice. However, decisions related to radio or television broadcasted advertisements may be appealed to the Board on Radio and Television Commercials, which may involve the DHMA and/or the Consumer Ombudsman in the complaint. Alternatively, or normally as a next step, the decision may be brought before the competent courts of justice.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The sanctions for a breach of the advertising provisions of the Act or the Marketing Act range from fines to imprisonment for up to four months. A breach of the Orders may be fined.

The DHMA enforces the Act and the Orders, whereas the Consumer Ombudsman enforces, or private interests initiate, enforcement of the Marketing Act, which is construed in accordance with the ICC Code of Advertising and Marketing Communication Practice. Sanctions imposed by the Consumer Ombudsman are subject to judicial review, if required.

The self-regulated bodies enforce their statutes and rules on the basis of their contractual authority. According to the ENLI "Regulations for Sanctions and Charges" (the "Sanctions"), and ENLI's "Procedural Rules" (the "Procedures"), both of 19 February 2015, ENLI may impose sanctions ranging from reprimands and fines to public reprimands. In addition, ENLI may require a company in breach to issue corrective statements, recall and/or prohibit the use of illegal advertising material, publish a corrective statement in professional periodicals, and cancel or amend the content of arrangements (conferences, congresses, etc.) planned, including the sponsoring of such arrangement. Sanctions imposed must be publicly available for a period of no less than two years at the ENLI homepage, provided, however, that only the name of the company in breach is made public, whereas names of any individuals involved due to data protection legislation will not be published.

The Sanctions authorise ENLI to impose fines for breach of rules governing i) advertising material in the range of DKK 15,000 (approx. EUR 2,000) for minor formal errors, such as a cover letter not being dated, an incorrect INN or API composition, to DKK 75,000 for misleading product claims, which may compromise public health, and ii) events in the range of DKK 30,000 for e.g. meal allowance at arrangements lasting less than two hours, to DKK 150,000 for e.g. meetings abroad with no professional content. Breaches of the Codices on counts other than incorrect advertising material/out of scope arrangements may trigger fines in the range of DKK 30,000 (approx. EUR 4,000) for e.g. unannounced canvassing visits to hospitals, to DKK 150,000 for contracting patient organisations to promote medicinal products. If several norms have been breached, ENLI may impose an accumulated fine considering all breaches. Individual fine levels for given breaches are predefined in the Sanctions. Under aggravating circumstances, such as repetition of the same breach within any current two-year period, the fines which are otherwise applicable may be doubled. If a company has been sanctioned, it is required to declare to ENLI that the illegal activity has been terminated and that all necessary precautions to avoid repetition have been taken. All decisions made by ENLI, whether in the first instance Scrutiny Board or by the second instance Appeal Board, will be submitted to the DHMA for information.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

A decision made by a self-regulatory body cannot be suspended or prejudiced by appeal to the DHMA. However, a party can bring a case before the DHMA even though the case has been or is being handled by a self-regulatory body, whose position may be considered by the DHMA assessing the case. Over recent years ENLI's predecessor, NSL, sanctioned several companies for having offered to Healthcare Professionals SMS-services for use by patients, enhancing drug consumption compliance. NSL was of the opinion that the companies, by offering such service, in effect

relieved the doctors from work normally vested in Healthcare Professionals, implying that the services partly constituted financial support to the doctor and partly impacted on the independence of the Healthcare Professional from the service provider. On request by NSL, the DHMA scrutinised this practice and reached the conclusion that the SMS compliance service was a service rendered to the patients on a voluntary basis and that doctors were not relieved of any workload, as they are not normally involved in day-to-day compliance monitoring. On the basis thereof NSL changed its practice, allowing for SMS compliance services to be offered to patients, although through the prescribing doctor. In principle, such scrutiny by the DHMA can be initiated not only by ENLI, but also by any interest-holding *locus standi*. In a judgment (Case UfR2009-1618S) quoting Case SH2009.V-0132-05, see question 2.3 below, the Danish Maritime and Commercial court dismissed a suit brought by MerckSerono against Ferring on the grounds that MerckSerono already had identical complaints heard by NSL and the DHMA, whose decisions were accepted by both parties and implemented by Ferring, which was also fined by NSL, and that MerckSerono consequently had no legitimate interest in also having the same complaints heard by the court.

ENLI may *ex officio* take up cases regarding companies that are subject to ENLI jurisdiction. As per 1 April 2015, the number of companies subject to ENLI jurisdiction was 60, comprising the members of LIF (33), IGL (10), PFL (3), and companies (13) and associations (1) having submitted to ENLI's jurisdiction voluntarily (1 January 2014: 68). Irrespective of the reduction in the number of subjects, ENLI remains in a strong position to enforce its rules against every relevant player on the Danish market, not at least indirectly due to ENLI having resolved to hear cases brought by members against non-members, although it obviously cannot enforce decisions in the disfavour of non-members, rather merely hope for the DHMA to notice potential criticism expressed.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

The Marketing Act sets out a legal standard requiring any act carried out for a commercial purpose to adhere to fair trading standards. Infringed parties may bring an action before the competent court of justice or may submit a complaint to the Consumer Ombudsman, who may also take action *ex officio*.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

The Act, the DHMA Guide and the "*EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals*" consolidated version 2013 (Statutory General Assembly approved on 6 June 2014), the "EFPIA Code", Section 1.01, prohibit the advertising of medicinal products for which a marketing authorisation has not been obtained as well as off-label advertising. As per § 77 of the Act, advertising is conditional not only on a marketing authorisation having been obtained, but also – with respect to products that must only be supplied by pharmacies – on the price applicable having been notified to the Danish Health and Medicines Authority ("DHMA"). Information provided on drug candidates for which Phase III data has not yet been published in an acknowledged international peer-reviewed publication is not, as a rule of thumb, considered advertising. "Rule of thumb" means that an aggressive pre-launch making product claims, etc., prior to publication of Phase III data may be considered advertising. Between the Phase III publication date and the grant of MA, presentations may be made at congresses and scientific meetings, which are not specifically organised or sponsored by the company holding product rights. The distinction implies that product information may be given in the context of a generic suitable presentation environment, e.g. at international congresses where a "sales" pitch is rented for the duration of the congress and not just for those hours where the target group is expected to be around. This is a relaxation of the rules applied in Denmark until approx. 2013, where the access to present product information prior to MA was considerably more limited than in most other EFPIA countries. Even upon the MA having been granted, the availability of scientific references may be limited in the early stage of the product lifecycle. Hence the marketing authorisation holder may face a challenge when being required to document product properties. Whereas information based on abstracts, posters and clinical trial data available from public databases such as www.clinicaltrials.gov and recommendations from foreign authorities are not permitted, "data on file" may be used, provided that the data has been reviewed and acknowledged by independent peers comparable to the peers assessing articles for acknowledged international publications. Use may only take place until the data is published or rejected. Providing off-label information promoting claims outside the scope of the SmPC will *per se* qualify as advertising for a medicinal product not having received the relevant marketing authorisation and is hence prohibited after publication of Phase III data for another indication.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

The Act and ENLI Rules reflect the requirements of Article 87 of Directive 2001/83/EC, as amended, prohibiting the advertising of medicinal products which have not been licensed in Denmark. However, informational material produced by public entities promoting rational drug consumption, see question 1.2 a) above, and scientific articles, which may comprise comparative investigations of drug properties, circulated uncommented to Healthcare Professionals on an "as are" basis, or, as per question 2.1 above, relating to medicines for which Phase III results have not been published, are normally not considered advertising.

Information provided by sources independent from the marketing authorisation holder may be caught by the advertising rules, see the *Damgaard* case (C-421/07). As a consequence of this case ENLI has taken the position that MA holders must monitor such social media, e.g. Facebook, Twitter, LinkedIn and YouTube, contributed to by the MA holder (the "MAH"), and remove communication, which may be considered advertising, even if provided by a third party. The scope of the advertising material to be removed is determined by whether the site is accessible by the general public (for which communication of the Legislative Basis, but not the Advertising Codex applies) or is available from *fora* to

which only Healthcare Professionals have access, in which case the Advertising Codex applies. ENLI has, however, also indicated that the MAH cannot be held liable for third party statements regarding third party products (e.g. competing products), even if published on a MAH-controlled medium. We do believe, however, that an MAH should remove such statements, as the MAH may easily be challenged under the provisions of the Marketing Act if no reaction is taken.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

The Advertising Codex and the DHMA Guide exempt press releases believed to be of interest to the general public from the advertising rules provided that: i) the information offered holds general news value; ii) the release is addressing the press; and iii) the release is targeting a plurality of journalists or reporters only for the purpose of having such information assessed and elaborated upon prior to publication by such recipients.

Subject to these conditions being met, the press release will be falling outside the scope of the advertising rules and hence it is irrelevant whether the medicinal product referenced is authorised or not. Identification of named medicinal products in press releases should be avoided, as such use as per ENLI and DHMA practice comprises advertising; see below. As per the DHMA, press releases may be made available at the relevant company homepages for up to a maximum of three weeks, after which the press release may be considered advertising, rendering the press release exception inapplicable. When drafting articles on the basis of press releases received, the press needs to be cautious, as their articles may easily be caught by the advertising definition; see the *Damgaard* case (C-421/07).

With respect to annual reports and other general information addressing stock market/investors, or other addressees falling outside the scope of Healthcare Professionals, such communications often include texts referencing medicinal products and indications being researched and developed, but not yet authorised. For inclusion of such information in material distributed to non-Healthcare Professionals to be acceptable, it has to be assumed that the capacity in which the recipient is receiving the information will determine whether the exception applies or not. Otherwise investors, who also happened to qualify as Healthcare Professionals, would not be entitled to receive information distributed under the exceptions otherwise applicable; see question 6.5 below. Whether a press release actually qualifies as such or is actually an advertisement, is a balance; see judgment No. V 132/05 passed by the Danish Maritime and Commercial court on 27 March 2009 (Case SH2009.V-0132-05), quoting an DHMA resolution holding Ferring responsible for having identified medicinal products in what was classified as a press release, but, as per the DHMA, due to the identification of products in an internet-based release, was actually an advertisement addressing the general public.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Product information, but not press releases, may be sent to Healthcare Professionals and others having made a specific enquiry to the company regarding the product properties. Submission on an unsolicited basis to Healthcare Professionals of scientific articles containing information on unauthorised products is, in principle, possible, but such must be submitted within the scope of question 2.1 above or uncommented upon, without any additional material being enclosed, and must comprise articles which have been published in an independent and acknowledged Danish or foreign scientific periodical.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in Denmark?

As per § 2, No. 4 of the Advertising Order, price lists and product catalogs that do not contain information about medicinal products other than (trade) names, pharmaceutical forms, strengths, packaging sizes, prices and pictures of medicine packages published on the internet for e-commerce with drugs do not qualify as advertising, see also question 1.2 iv) above. Hence making price lists for named-patient/compassionate use purposes pursuant to Article 5 of the Directive available to pharmacists, without this being treated as illegal, is possible. However, the Marketing Act's provisions on unsolicited addresses should be observed.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Information on indications can only be provided within the scope of question 2.1 above, whereas price information and product lists can be provided under question 2.5 above.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

From the perspective of the industry, an MAH may involve medicinal doctors (human and vet), dentists and pharmacists, but not other HCPs, as consultants or advisors, individually or as groups, for the rendering of services such as giving speeches at and chairing meetings, involvement in medicinal or scientific studies, clinical trials or training, participation in advisory board meetings and participation in market analysis, even if the MAH pays the HCP for the rendering of the services and reimburses travel expenses. However, a written contract or agreement specifying the services to be rendered and payments to be made must be closed prior to the HCP rendering any services. Moreover, the following criteria must, to the extent applicable, be met:

a) a legitimate need for the services must be clearly identified before requesting the HCP to render same and before closing the agreement with the prospective consultants;

b) the criteria for selecting consultants should be directly related to the identified need and the persons responsible for the selection of consultants must be competent to assess whether the candidates meet the criteria;

c) the number of contracted HCPs must not exceed what is reasonably necessary for the MAH to receive the services;

d) the contracting entity shall maintain records of the services received and make proper use thereof;

e) the engagement of a HCP must not imply an incentive to recommend, prescribe, purchase, supply, sell or administer a particular drug;

f) the compensation for the services shall be proportionate and should reflect the real market value of the services provided (symbolic advisory meetings can not justify payment of any compensations to HCPs); and

g) payment shall only be granted in the form of direct payments of money, and not by off-setting or transfer of assets or other indirect compensation.

From the perspective of HCPs, the consolidated Danish Health Act No. 1202 of 14 November 2014 (the "Health Act"), Chapter 61a, § 202a, prohibits medicinal doctors (human), dentists and pharmacists from operating or being affiliated with an MAH, unless the affiliation comprises i) education/training (primarily presentations of research results and treatment regimes) or research (primarily clinical research, including non-intervention studies), ii) ownership of MAH-securities, which – when purchased – did not represent a value in excess of DKK 200,000 (≈EUR 27,000) per MAH, or iii) if the MAH is a public hospital. If these conditions are met, the HCP must notify the DHMA of the affiliation, whereas the HCP must apply to the DHMA for approval if the conditions are not met. Applications will be denied if the DHMA finds that the services to be rendered may influence the prescription pattern of the applying HCP, which, as per DHMA practice, will be the case if the services relate to the preparation of marketing material. As per the Advertising Codex, the MAH is obliged to inform not only the HCPs of their obligations *vis-à-vis* the DHMA, but also the DHMA of an affiliation established between a HCP and the MAH. This double-notification system enables the DHMA to enforce the rules more easily, as the two lists can be compared and omissions identified. The DHMA must publish all notifications and applications received on its homepage.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

Advertisements targeting Healthcare Professionals must contain the following mandatory information, which must be legible:

1. Trade and generic (INN) product name(s), i.e. all INN names if a combination.
2. MAH name.
3. Indications for use consistent with the SmPC.
4. Contra-indications.
5. Side effects and cautions.
6. Dosage.
7. Product forms (strengths, methods of administration).
8. Package sizes.
9. The purchase price available from www.medicinpriser.dk, but no longer the pharmacy purchase price per package, excl. VAT, + pharmacy margin (p.t. 9.0%) + DKK 9.46 as calculated in accordance with Exec. Order No. 450 of 9 April 2015.
10. Supply classification.
11. Reimbursement options.
12. Advertisement version and date.

Information provided must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his own opinion on the therapeutic value of the product.

Information provided for veterinary products must include information on the species covered.

If the advertisement is intended solely as a reminder, the advertisement may comprise the trade name, INN, the marketing authorisation holder and the logo only. In 2014, ENLI heard nine cases regarding breach of the obligation to provide mandatory information, which have been published at: http://www.enli.dk/offentliggjorte-sager/afgoerelser-2014/.

Until 1 November 2014, the trade and generic (INN) product name had to be indicated together with the trade name not only in the header, but throughout the advertisement and by use of similar fonts for both names. These requirements have now been relaxed; the INN name only needs to be indicated once, the font needs to be legible but not necessarily the same, and logos only incorporating the trade name are allowed if the INN name is provided elsewhere in the advertisement.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Advertisements, or any other information addressing HCPs, must not contain competitions offering prizes. This prohibition is absolute regardless of whether an individual product is identified or not and regardless of the size and nature of the prize.

As per the judgment passed in Case C-249/09, *Novo Nordisk vs. Ravimiamet*, an advertisement may include information which is not necessarily included in the SmPC and/or which cannot necessarily be derived therefrom, provided, however, that the claims confirm or clarify, and are compatible with, the SmPC and that the advertisement meets the requirements of Articles 87 (3), and 92 (2) and (3) of Directive 2001/83 as amended. In our view, this judgment is compatible with the Legislative Basis as is and no amendments are necessarily required as a result of the judgment.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The prohibition against including *i.a.* HCP endorsements in campaigns addressing the general public does not apply to campaigns addressing HCPs. However, such endorsements are obviously also required to be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his own opinion on the therapeutic value of the product, implying that endorsements must be qualified and meet the documentation requirements applicable in general.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No. However, the advertiser must observe the rules on comparative advertising, which do not require that products be clinically compared.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in Denmark?

Rules governing comparative advertisements are set out in the Marketing Act, the Orders, in the DHMA Guide and in the ENLI Rules. Comparative advertisements must be based on the SmPCs and must also include supplementary data subsequently generated, provided it is SmPC compliant, comply with general advertising rules, compare all relevant and available treatment alternatives, avoid product confusion, be loyal to the comparator products, be objective, and must not take unfair advantage of the reputation of a competitor brand. When making references to other products, the advertiser must ensure that such product can be identified, implying that the advertiser is not only permitted, but almost required, to use a competitor's brand name in comparative advertisements. The data provided for the promoted product must include the essential information listed in question 3.1 above, whereas data for comparator products can be limited to therapeutically relevant differences. It is not possible to refer to a competitor's product which has not yet been authorised in Denmark, as such product does not represent a treatment alternative. As per an ENLI judgment (EN-2011-0001), the mere identification of more than one product in an address to Healthcare Professionals, even addresses that the advertiser does not necessarily consider advertising, e.g. an invitation to an arrangement, will qualify as comparative advertising, requiring the sender to observe the rules applicable for such "comparisons".

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

In general, such papers can be supplied. However, the supplier has to consider whether the product is authorised for marketing or not and whether the supply is made on a HCP's request or unsolicited. Scientific papers addressing research and development achievements on potential medicinal products for which Phase III results have not yet been published will no longer, as a rule of thumb, be considered advertising, and may hence be distributed. "Rule of thumb" means that a different result may be reached if the language is clearly promotional and/or if Phase III data is not required for a product, e.g. products registered under "*exceptional circumstances*" under the authority of Article 14 (8) of Regulation 726/2004 and Article 22 of Directive 2001/83. After publication of Phase III results, there is a presumption that the sponsor's key objective is to file for an MA and that communications are influenced by this goal. This means that communications made in-between Phase III data being published and an MA being granted may be considered advertising relatively easily. This can, however, be avoided if the communications take place in scientific fora (e.g. on an independent international congress) for knowledge-creating purposes, in which case it will not be considered advertising restricted by the Advertising Code. This position corresponds to a DHMA decision of 28 May 2014, stating that education, a professional presentation of scientific data or a professional review of studies done on a scientific basis and in a scientific forum does not qualify as advertising, unless the sponsor's goal demonstrates otherwise. If reprints are distributed unsolicited, the gift restrictions have to be complied with and the reprint is for professional use to the benefit of patients.

3.7 Are "teaser" advertisements permitted that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

Neither the Legislative Basis nor the ENLI Rules prohibit the use of teasers, provided, however, that they do not comprise an advertisement of medicinal products. For all practical purposes, teasers should meet the conditions set out in question 1.2 above and be restrained to include general information relating to human health or diseases without indicating product names. An address to Healthcare Professionals encouraging the recipient to reserve a given date for an event "*to be announced*" is not considered advertising and does not need to be notified to ENLI, if the recipient cannot sign up on the basis of the teaser.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Samples of products launched on or after 1 January 2012 may be provided only during the initial two-year period after launch, and are subject to adherence to the following restrictions set out in the executive order No. 1244 of 12 December 2005:

1. The recipient must be a Healthcare Professional authorised to prescribe the medicinal product in question and who is requesting the sample for a professional purpose that he is licensed to pursue.
2. One sample of each form and strength of a medicinal product may be dispensed per year.
3. The sample must be the smallest quantity marketed.
4. Labelling requirement: "*Free medicinal product sample – not for sale*".
5. A written, dated and signed request must be made by the receiving Healthcare Professional.
6. Dispensation is made by the MAH representative, not the pharmacy.
7. SmPC must be enclosed.
8. Narcotic/controlled medicinal product samples must not be dispensed.

The MAH must keep accounts of the quantity and type of dispensed medicinal product samples. The accounts, including the requests from the recipients of the samples, must be kept on file for at least two years. Since 2009, it has been possible for a MAH to sub-contract the obligation to keep accounts and to file requests received to wholesalers.

As LF has imposed an obligation for its members, medical doctors, to neither receive nor request supplies of samples, except in very rare circumstances, and considering that a medical doctor will have to request a product sample in a written, dated and signed request format, dispensation of product samples in Denmark will presumably soon be history.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

As per § 22 of the Advertising Order and § 12 of the Advertising Codex, the latter amended to reflect EFPIA's Disclosure Code of

24 June 2013 provisions on gifts, no pecuniary advantages or gifts (in cash or benefit in-kind) may be supplied, offered or promised to Healthcare Professionals, except in connection with i) professional events, sponsorships and hospitality, ii) information and educational material and items of medicinal utility, and iii) donations and grants that support healthcare or research. Even the supply of so-called "gimmicks" such as pens, post-it pads, notepads, etc., is no longer allowed, but in connection with arrangements with third parties (no logos or product names) or by the sponsor itself (logos and product names allowed on pens, etc., supplied for the purpose of the HCP taking notes). *Re* i) Healthcare Professionals may receive training and professional information related to medicinal products in the form of payment of direct expenses in connection with professionally relevant courses, conferences, training and scientific events, in which the Healthcare Professionals participate, or arrange, including by the MAH organising, co-organising or sponsoring events of a mere professional nature and held in "appropriate" venues. Hospitality extended in connection with such events must only be extended to persons who qualify as participants in their own right and must be limited to "reasonable" travelling, meals, accommodation and registration fees (but not to compensate for the time spent). Companies shall not provide or offer any meal (food and beverages) to Healthcare Professionals, unless, in each case, the value of such meal (food and beverages) does not exceed one of the following monetary thresholds: DKK 400 for lunch; DKK 700 for dinner; or DKK 1,200 covering all meals (food and beverages) at all-day meetings/conferences, etc. The monetary thresholds apply to meals taken in Denmark. When providing meals in other European countries, the monetary thresholds set by the pharmaceutical industry associations in these countries must be complied with. Hospitality must not include sponsoring or organising entertainment (e.g. sporting or leisure) events and the organiser must avoid using venues that are "renowned" for their entertainment facilities or are extravagant and/or luxurious. *Re* ii) assignment of informational or educational materials to Healthcare Professionals is permitted provided it is: (i) inexpensive; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Furthermore, items of medicinal utility aimed directly at the education of Healthcare Professionals and patient care can be provided if they are (i) inexpensive, and (ii) do not offset the business practices of the recipient. *Re* iii) donations, grants and benefits in-kind to institutions, organisations or associations that are comprised of Healthcare Professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA HCP Code or the Patient Organisation Co-operation Codex) are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Contracts between pharmaceutical 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 from pharmaceutical companies not covered under these ethical rules) are only allowed if such services (or other funding): a) are provided for the purpose of supporting healthcare or research; and b) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Companies which have not submitted to the ENLI rules may still benefit from the at-present somewhat more liberal DHMA Guide, which allows Healthcare Professionals, associations of Healthcare Professionals or members of hospital administrations to receive gifts, provided that the market value does not exceed DKK 300 (approx. EUR 40), including 25% VAT per calendar year, per practitioner, and provided that the benefit can be used professionally (clinical thermometers, calendars and other merchandise directly related to the relevant professional activity) by the Healthcare Professional. As per the ENLI Rules, however, Healthcare Professionals are, from and including 1 January 2014, no longer entitled to receive neither "leave behinds" nor gimmicks irrespective of the value thereof, but in connection with the execution of a conference, see this question above.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

As per question 4.2, donations and grants that support healthcare or research may be provided. The "Ethical rules for the pharmaceutical industry's donations and grants to hospitals" was last issued by LIF on 1 March 2012. The code applies to LIF members, but not to IGL and PFL members, and is supplementary to, and in some areas stricter than, the EFPIA Code on the promotion of prescription-only medicines to/interactions with, Healthcare Professionals, and advertising for medicines aimed at Healthcare Professionals, respectively. Donations, whether in-kind or pecuniary, must have a professional and/or scientific purpose, including the provision of grants/donations for health services or research, or other professional activities that benefit patient care or hospitals. It must be entirely up to the hospital/hospital department to manage and decide how to make use of the grant or donation. Donations or grants must be documented by written and signed documentation specifying at the very least the following:

1) The name of the activity, project, equipment or unit the donation or grant is to support.
2) The name(s) of the hospital/department, etc., responsible for the activity, project, equipment or unit.
3) The name(s) of the person(s) at the hospital responsible for the activity, project, equipment or unit.
4) The name(s) of the person(s) at the hospital responsible for the account (money) or unit (in-kind) to which the donation or grant has been transferred.
5) The name of the competent person, manager, director, etc., at the hospital who has given approval for the hospital/department to receive the donation or grant.
6) The types of activity/project/equipment/unit for which the donation or grant is being given.
7) The purpose of the activity/project/equipment/unit for which the grant or donation is being made.
8) The timeframe (if available).
9) The amount of funding provided.
10) The scope, content and estimated value of benefits in-kind.

LIF members are required to publish a schedule on their website containing the information covered by items 1, 2 and 6-10 above. The schedule is to be published when the donation or grant has been made, and shall remain on the website for at least two years thereafter. During the subsequent eight years (10 years in total) the donating LIF member, but not members of IGL and PFL, must be able to provide copies of the schedule on request. Donations made shall be reported annually via a template published by LIF.

The sponsor must monitor that the funding granted is actually spent as agreed in the written documentation that must be signed by the parties. Certain calendar year *de minimis* thresholds of DKK 5,000 for specific activities or purposes and DKK 20,000 if identical in-kind contributions (needles, refrigerated transportation boxes, etc.) are provided, relieve such sponsors from complying with a number of obligations otherwise following from the rules.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

If provided within the scope of permitted Healthcare Professional activity funding, the donations will be legal even if they may lead to a change in the prescription pattern or in the allotment of market shares among the marketing authorisation holders. As sponsorships are limited to costs associated with strictly professional and scientific activities, and to activities whose content cannot be influenced by the sponsoring company (unless the sponsoring company is (co-) organising itself, in which case corresponding limitations apply), potential changes in the prescription pattern as a result of the arrangements will *per se* be the result of acceptable training and presentation of material, which is balanced.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Although discounts will always comprise an economic advantage to the receiver, product discounts may be offered to Healthcare Professionals, provided that the discount is based on cost savings for the supplier as a direct result of volume savings or similar "cost-based discounts". Permitted cost-based discounts include all drugs and cover all retail dealers, including pharmacies. The rules on access to provide cost-based discounts only apply to the relationship between supplier (whether a manufacturer, importer or wholesaler) and the retailer. Any discounts agreed between companies within the pre-retailer distribution chain, for example between manufacturers/importers and wholesalers, are not covered by the rules on cost-based discounts. Pharmaceutical manufacturers and importers that make their own deliveries to retailers are, on the other hand, subject to these cost-based discount regulations.

Cost-based discounts should be calculated in relation to the supplier's direct and indirect costs, such as administrative expenses, payroll, inventory, vans, etc., associated with the delivery of the drugs to pharmacies or other retail outlets. Cost-based discounts may comprise arrangements implying a reduced supply frequency/higher volumes per delivery, which imply supplier savings as a result of lower costs per delivery and reduced administrative/handling costs. If a retailer, for example, goes from five weekly deliveries to one weekly delivery, a discount may be offered if the supplier's standard terms are five weekly deliveries.

The retailer may also show flexibility in delivery times. Thus, a pharmacy holding its own stock of medicines may accept a certain irregularity in relation to the supplier delivery times, enabling the supplier to arrange an appropriate and cost-effective delivery and hence to offer rebates reflecting such logistical improvements.

Cost-based discounts cannot be justified by unilateral introduction of new general cost-saving technology at the wholesale level, but need to reflect savings achieved through retailing outlets rationalising their purchasing behaviour.

Voluntary associations of pharmacies – pharmacy chains – may negotiate agreements on cost-based discounts on behalf of all chain members. The discount obtained must not, not even partially, be accumulated in the association, but must benefit the members only.

The discount must comprise a price reduction of the products included in the actual delivery triggering the discount. The cost-based discount must be clearly stated on the invoice, or a credit note issued immediately after delivery, to indicate how it is calculated, and it must be separate from discounts granted on products not covered by the restrictions. Bonuses must not be provided to the end users of medicinal products, whether individuals or patient groups, neither directly nor indirectly. However, hospital owners may be granted a bonus in connection with the sale of products to a hospital.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

If offered in response to a tender, such offer would be inconsistent with the tender terms and be unacceptable by Amgros. In relation to retailers, § 36 of the Advertising Order requires rebates based on cost savings to be granted in the form of price reductions and not in the form of other services or benefits. Rebates, as well as the calculation basis for same, must be indicated in the invoice. Replacing the grant of a rebate by invoicing for services rendered separately will constitute a *quid pro quo* arrangement implying a breach of § 36 and hence comprise if not an illegal kick-back then at least an unauthorised rebate comprising a breach of the Advertising Order.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

A refund scheme can be and has been offered for certain products. The supply status is irrelevant in this situation. The refund principle reflects that some patients may not enjoy the envisaged benefits of taking the prescribed medicinal products in spite of the medicinal product being contractual. In June 2004 the DHMA announced that Novartis had launched a "pay back" scheme for Diovan®, noting that the DHMA, while not approving the campaign (which the DHMA cannot), did not consider the campaign as being a breach of the Act *per se*. However, the DHMA noted that such campaigns represent a challenge to the reimbursement system. Subsequently the DHMA has accepted that Bayer is entitled to offer financial compensation to doctors who have to dispose of a Mirena® (levonorgestrel-releasing intrauterine device ("IUD")) as a result of the IUD having become unsterile. On the basis hereof, Bayer applied to the DHMA for permission to replace an unsterile IUD with a sterile one free of charge rather than providing financial compensation. The DHMA resolved that such procedure would comprise advertising and be inconsistent with the Advertising Order in spite of no competing products, but parallel-imported Mirena® IUDs being available in the market place. The decision was appealed, but upheld by the Ministry of Health in a decision made on 12 November 2013. It

appears that Bayer has now decided to cease the replacement policy applied, which was greatly appreciated by the GPs, without considering other replacement models.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Continued medical education may only be sponsored through funds granted to a hospital having applied for funding of, e.g. a Ph.D. project. However, the sponsor cannot exercise any control of who the grant is allocated to, as the company is not permitted to benefit individual HCPs through hospital donations. An MAH may sponsor an individual HCP carrying out a training programme. However, such programme must have a professional content and the sponsoring company must know the exact content of the sponsored activities. If these conditions are met, e.g. Ph.D. projects may be sponsored directly, whereas undefined "training tuitions" cannot be paid for and training in administrative systems or organisational development cannot be sponsored.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The Legislative Basis is only enforced by the DHMA with respect to promotional activities carried out in Denmark, including internet advertising taking place from servers situated in Denmark. The Advertising Code stipulates that advertising undertaken, sponsored or organised by or on behalf of a company that is located outside Denmark, but still in Europe, is subject to the national codes of the country where such business is located. If the company is located outside Europe, the EFPIA Code must, in conjunction with any national code applicable, be applied. In the case of conflicting codes, the most restrictive version shall be applied, unless otherwise stated in that code. As a consequence of the above, the scope of acceptable hospitality that may be offered to HCPs is determined as per national rules, implying that the thresholds applicable will vary from country to country.

Pharmaceutical businesses may bear and/or sponsor expenses related to meals provided to a healthcare professional with relevance only. Hence, support may be granted for the renting of premises, study materials, fees and travel expenses for lecturers, participant payment and hospitality costs. In cases where events are held or supported by a pharmaceutical business and held away from the participants' normal places of work, the business may bear the costs of travelling and accommodation for the participants. Travel expenses are, however, only to be reimbursed upon presentation of an invoice and travelling should take place by reasonable means of transportation. Endeavours shall thus always be made for the mode of transport and accommodation standards to be reasonable.

However, no company should organise or sponsor an event taking place outside Denmark unless justified by logistics, i.e. that the majority of the invitees are from abroad and/or the event, for reasons outside the control of the company, takes place abroad. Non-professional activities such as entertainment, sightseeing trips, etc., may not be sponsored.

Hospitality expenses must be kept at a reasonable level and be subordinate – with respect to finance, as well as time – to the professional purpose of the event, which – for food (other than sandwiches, fruit and low-cost beverages) to be served, see question 4.2 on value thresholds – must exceed two hours' duration. For accommodation at a hotel to be sponsored, the event must last at least six hours and be continued the following day. Expenditures allowed are set by each "EFPIA country" individually and are applicable for arrangements held in that country. The approved cost limits include beverages, VAT and tips. Full transparency is required with respect to identification of the meeting organiser, the purpose of the arrangement, any financial support given and by whom.

As for any other arrangement, ENLI must be notified in advance of any event addressing Danish Healthcare Professionals and sponsored by a member, any sponsorships and a member's lease of a stand at a congress.

The notification must contain information on the purpose and aim of the arrangement and who the organisers are. The invitation to the participants must confirm that ENLI has been or will be notified prior to the arrangement being held and the company must state that the arrangement complies with the Codices or has been pre-approved by ENLI.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

If a Healthcare Professional teaches at a scientific meeting or renders services to the sponsor, reasonable cash remuneration may be offered, whereas the offering of values in-kind and of reimbursement is prohibited by § 24 par. 2 of the Advertising Order (reference is made to question 4.2 above).

However, payment or reimbursement of direct expenses defrayed for meals, travelling, accommodation, etc., in connection with advertising for medicinal products or professional training related to medicinal products, as well as direct expenses defrayed to courses, congresses and other professionally relevant activities in which a Healthcare Professional participates or which a Healthcare Professional is hosting, is in principle authorised.

However, such expenses must be "reasonable" and must be offered solely to the extent relevant for the permitted advertising activity and solely in close connection with the same timing-wise. HCP remunerations cannot be made on the basis of loss of income or time consumption as such. The criterion is the arm's length value of the service provided.

Companies must make sure that any financial support is used for the purpose intended, and – if the support is given to private individuals – that all expenses are accounted for.

Social activities, expenses in connection with the entertainment of spouses and other arrangements falling outside the approved objective of the arrangement cannot be sponsored.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

To comply with its ENLI notification obligations, the company must act prudently in ensuring that the arrangement and the scope of the hospitality to be offered lies within what is acceptable under the Codices. Whether the meeting is directly sponsored or the sponsorship is a contribution to a third party arrangement, the company must make sure that the scope of the intended sponsorship is proportional to the arrangement as arranged or described. If the sponsored arrangement breaches the Codices by means of excessive hospitality or the like, the company will, in principle, be exposed to liability even if the sponsorship is indirect. The Codices do not make a distinction based on a degree of guilt assessment. Hence, companies also sponsoring third party arrangements have to make sure that the Codices are complied with.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

Subject to DHMA approval, doctors, dentists and pharmacists may become members of Advisory Boards, directors or assume other positions, which in theory may impact the prescription pattern. Companies engaging Healthcare Professionals must report such engagements to the DHMA. On a stand-alone basis, Healthcare Professionals can be paid for providing expert services such as being a lecturer at arrangements held by the pharmaceutical industry, when the payment is proportional to the work performed. Furthermore, any relevant and reasonable travel and accommodation expenses in connection with such arrangements may be paid for, whereas social activities cannot be sponsored. Focus groups must be used with care, as the advertising rules must be complied with when the participants are involved in the discussions required. The mere approval by the DHMA for a Healthcare Professional to render their services in connection with serving as a focus group member does not relieve the sponsoring company from the obligation to comply with the advertising rules.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

A Healthcare Professional may participate in a post-marketing surveillance study and may receive payment for services rendered in connection herewith, subject to observing the restrictions set out in question 2.7 above. Whereas, post-marketing non-interventional studies are subject to the ENLI Rules, clinical pre-marketing trials are subject to DHMA and ethical committee jurisdiction and hence not monitored by ENLI. However, the rules on venues, entertainment, use of consultants and transparency apply to all studies, whether pre- or post-marketing. On 18 December 2014, LIF, LF and a number of scientific associations signed an updated "Joint Declaration" clarifying the values that form the basis for HCPs and companies co-operating on trials and non-interventional studies. The Joint Declaration aims at ensuring that the involved interests are independent. Although non-intervention trials do not require approval in Denmark by the DHMA or ethical committees, the Joint Declaration suggests that trial plans should be submitted to the DHMA, which has undertaken to provide guidance on whether a trial is an intervention trial or a non-intervention trial, and – in response to a specific query – render guidance on the rules on promotion and its interpretation associated with non-intervention trials.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Medical practitioners may not be offered gifts or other financial benefits in return for their participation in market/questionnaire surveys, not even gifts without value. Only where a practitioner is requested to render an actual service, may the practitioner legally receive a fee or other remuneration, which must be proportionate with the services rendered.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Advertising of non-prescription medicines to the general public is in general permitted, provided that the medicinal product can be used without diagnosing and/or no medical supervision is required.

Advertisements addressing the general public must inform the addressee that this is an advertisement promoting medicinal products and the advertisement must contain certain data e.g. name, the package sizes, prices, indication, side effect, dosage, and an encouragement for the patient to check out the patient information leaflet.

When advertising on film and radio, the requirements regarding package sizes and pricing do not apply.

The Orders provide that TV commercials must contain certain information to be announced on the screen or by a speaker, including the name and effects of the medicinal product and significant side effects. In addition, the addressee must be encouraged to read the package leaflet, to read more about the application of the pharmaceutical product on the tele-text pages of the TV channel concerned, and to look up the website of the marketing authorisation holder.

In order to ensure the credibility of the commercial and to avoid bringing information which could confuse ordinary consumers, the Orders contain 14 types of information that are prohibited, including: (i) statements claiming that common wellbeing may be reduced if the medicinal product is not used; (ii) recommendations by Healthcare Professionals encouraging consumption of medicinal products; and (iii) discussions on fatal diseases or symptoms thereof.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No, the Act prohibits advertising of prescription-only medicines to the general public.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Disease awareness campaigns are not considered as advertising if no medicinal product is identified, which was confirmed by ENLI on 31 January 2012 in case AN-2011-2486. To avoid disease awareness campaigns falling within the scope of the advertisement definition, the campaign must focus on the disease, whereas neither the cure nor products should be mentioned.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

It is possible to issue press releases concerning prescription-only medicines, but not to address them to non-scientific journals. Press releases must address the press as such and should be drafted in a manner that calls for an independent journalistic assessment and working up. Further, the conditions listed under question 2.3 above must be met. If the conditions are met, it is not relevant whether the actual recipient is a scientific journal or not. However, the industry needs to act responsibly considering the risks represented by the *Damgaard* case and the DHMA resolution quoted above under question 2.3, if the recipients of press releases are not familiar with pharmaceutical advertising. It might be worthwhile for the industry to consider adding a disclaimer to their releases summarising the key findings of the *Damgaard* case.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

If the reports, etc., are sent on an unsolicited basis to Healthcare Professionals in their capacity as such, product information included in brochures and annual reports will, in principle, be caught by the advertising definition. However, corporate brochures and annual reports are normally distributed to investors, analysts and stock exchanges for the purpose of promoting investments in the company and not the individual products (to be) marketed. Under these circumstances, and subject to the product information given being proportionate to the alleged aim, both the Advertising Codex and the Orders consider press releases as falling outside their scope.

In this respect, ENLI has included an amended version of the EFPIA Code guidelines on website content (Annex B to the EFPIA Code) in the Advertising Codex. As per Section 2, websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmes, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicine advertising law. This exemption allows the publication of annual reports, which often contain descriptions of development programmes and expected product claims, and will have an impact on the scope of the information allowed in announcements to investors that is exempt from the Advertising Codex.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

Based on 2011 numbers, there are approx. 225 patient organisations in Denmark. A number of these are members of the umbrella organisation "*Danske Patienter*" (Danish Patients), http://danskepatienter.dk/about-danish-patients, which represents some 870,000 Danish patients in total through memberships subscribed by 17 member organisations and 79 patient organisations. MAHs may sponsor patient organisations subject to compliance with the Patient Organisation Codex, which requires transparency through all sponsorships being made in a written contract identifying the parties, the project sponsored, the type of project (contributions to general activities/specific arrangements, informational campaigns, etc.), the objective, the roles of the parties involved, the period of time for the sponsorship, the support budget, the costs that can be covered and non-financial support, if any. All contracts must be publicly accessible via the homepages of the sponsors for the duration of the co-operation and for at least six months after, and via the homepage of the patient organisation, unless the organisation does not want that, in which case the contract documentation must reflect such position. On request, a copy of the contracts must be supplied to anybody who is interested. LIF companies co-operating with patient organisations must annually submit a report to LIF identifying the organisations sponsored. Further, the Patient Organisation Codex defines standards applicable for companies sponsoring meetings, compliance with the Legislative Basis at all times, non-exclusivity and legal capacity.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

§ 89 of the Act requires a sponsor to notify the DHMA i) immediately, if unexpected serious adverse reactions occur during the trial, ii) within 15 days, if a sponsor needs to abort the trial, in which case the DHMA must be informed of the reasons, and iii) annually, of all serious adverse events incurred and subject safety. Within 90 days from close-out the sponsor must inform the DHMA hereof and without undue delay, and in any case within one year after close-out, submit the trial result to the DHMA.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

As per § 21 of the Advertising Order, patient organisations must publish on their website all economic benefits, including financial sponsorships, whether in cash or in-kind, and their value/scope, that the organisation has received from MAHs. The information must be made available on the websites within one month after the patient association has received an economic advantage, and must be available on the website for at least two years. As HCPs are not entitled to receive financial benefits, no disclosure requirements apply other than the notification/application requirements set out in question 2.7 above.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Information on medicinal products and their use that is sponsored by a company must contain a disclosure that the information has been sponsored by a company, whether it qualifies as advertising or not. In addition, the Advertising Codex stipulates that LIF, IGL and PFL and their respective members have joined the EFPIA Disclosure Code, implying that Danish member companies are required to comply with the Legislative Basis, which is scarce on this point, and also with the Codices, which must be construed to imply that the EFPIA Disclosure Code is directly applicable, although the implementation model seems to be circular. This means that transfer of values to HCPs and Healthcare Organisations ("HCOs"), including patient organisations, must be disclosed for the first time in 2016 in respect of transfers of value for the calendar year 2015. From then, disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. Disclosures shall be made within six months after the end of the relevant reporting period and the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable national data privacy laws or other laws or regulations, or (ii) the recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked. The companies and interests affected will be those subject to ENLI jurisdiction. The Advertising Codex has not yet implemented the EFPIA Disclosure Code in detail, including by defining the information to be disclosed and the potential use of a central platform.

8 The Internet

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Advertising over the internet of medicinal products is covered by § 9 of the Advertising Order, which stipulates that such advertising must comply with the requirements of the Legislative Basis, as must advertisements published in physical media. Unless internet-based campaigns are password-protected, they are considered to be addressing the general public.

The DHMA and ENLI are monitoring internet advertising (see question 8.4 below); often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark, the DHMA and ENLI will address the local affiliate of the advertiser, which is normally sufficient. ENLI has adopted the EFPIA Code guidelines for internet advertising; see question 6.5 above.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The DHMA Guide requires sites addressing Healthcare Professionals to be restricted in an efficient way by a unique username, in conjunction with a personal password being required for accessing the homepage. If such precautions are not taken, the information provided will be considered as having been made available to the general public, i.e. illegal advertising.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Advertising on the internet is subject to the same requirements as the requirements applicable to advertising in other media and there are no special rules for references made to external links.

Activities with social media that are controlled or influenced by a company must be monitored and controlled by the company as it may otherwise incur liability for third party statements which are not in compliance with the advertising rules. Hence, the company must, on a regular basis, monitor the site and remove all illegal or non-compliant statements. It is unlikely that a company will be made liable for the content of independent websites whose content is not controlled or inspired by the company in question. However, it is nevertheless recommended that the company incorporates a disclaimer which positively informs the reader that the homepage contains links to external sites over which the company has no control and for which the company consequently is not willing to assume responsibility. Placing such disclaimers on the homepage, however, will not relieve the company from the requirement to verify that external links referred to maintain a certain standard. If sites referred to are persistently sub-standard and perhaps even subject to legal or other actions initiated by authorities, competitors or other third parties in the market, the upholding of references to such may expose the company to negative public exposure.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Advertising of non-prescription medicines to the general public is generally permitted, provided that the medicinal product can be used without diagnosing or medical supervision being required.

Advertisements addressing the general public must inform the addressee that this is an advertisement promoting medicinal products and the advertisement must contain essential information; see question 6.1 above. In May 2009, the DHMA required two marketing authorisation holders to withdraw advertisements released on their homepages. In the case of Pfizer, the DHMA found that information on the homepage regarding Carduran® Retard should be considered as advertising. Such advertisement could be accessed by members of the public and was therefore prohibited. In the case of GlaxoSmithKline, the DHMA resolved that, while the information on the homepage qualified as an advertisement for non-prescription medicines, the information mandatory as per question 6.1 was not indicated, implying that the DHMA required the advertisement to be withdrawn.

8.5 Are there specific rules, laws or guidance controlling the use of social media by companies?

On 19 February 2015, ENLI released Version 1.3 of the guide on the use of social media in connection with advertising activities, see http://www.enli.dk/media/36699/Sociale-medier.pdf, but

has simultaneously stipulated that the guide is being updated. Advertising using social media, other than homepage facilities, is not covered by the Advertising Order, but there is no doubt that such advertising must comply with the requirements of the Legislative Basis – as must advertisements published in physical media.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

On 1 November 2014, an update of the Advertising Order took effect. This caused ENLI to review all of the Codices and guidelines, bringing same in line with the Advertising Order and the Health Act on HCP affiliation. Key developments comprise: i) the INN name is no longer required to be used more than once in an advertisement; ii) the INN name does not have to be in the same font and size as the trade name, as long as it is legible; iii) previously the mandatory information to be provided included a specific purchase price per product – such requirement has been relaxed to the effect that a mere reference to a homepage is sufficient; iv) the prohibition of arranging competitions for advertising purposes has been reinstated after having been, by mistake, left out of the Advertising Codex for 2013; v) the prior requirement that (permitted) wining and dining in connection with arrangements had to be limited time-wise compared to the professional content, has been removed; vi) an obligation for the MAH to inform HCPs of the notification/application requirements as per § 202a of the Health Act has been introduced; and vii) anonymous market research activities may be executed by a third party acting on behalf of a MAH undisclosed to the participating HCP without such activity being caught by the § 202a notification requirement. A number of documents forming part of the Codices have not yet been translated from Danish to English, but will be during 2015.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The EFPIA Disclosure Code will presumably be implemented in further detail and additional practice on allowed accommodation will be developed.

9.3 Are there any general practice or enforcement trends that have become apparent in Denmark over the last year or so?

In 2014, approx. 5,400 promotional activities were self-reported to ENLI. The ENLI panel of investigators reviewed 38.9% of the reports, and approved 97% of the activities, whereas sanctions were imposed in 2.6% of the evaluated cases. All decisions which impose a sanction on a company are published (in Danish) on ENLI's website, www.enli.dk. In general, ENLI is satisfied that companies subject to its jurisdiction strive to comply, implying that the number of sanctions is decreasing.

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Jan was born in 1963 in Copenhagen, Denmark. After graduating from the University of Copenhagen (Master of Laws) in 1987 and subsequently having been trained in the Copenhagen City Law Firm Møller, Tvermoes & Hoffmeyer, Jan was admitted to the Bar and received High Court advocacy rights in 1991.

In late 1991 Jan joined the Lundbeck group and was appointed General Counsel thereof in 1994. As General Counsel, Jan participated in the conclusion of numerous pharmaceutical industry transactions with cross-border implications, including acquisition and divesting of product rights, joint ventures and strategic licensing and alliance arrangements, primarily in Europe, Japan and the United States of America. In addition, Jan was responsible for the casualty insurance programmes of the group, a responsibility that led to Jan being appointed General Counsel and Executive Vice President in 1999 of a globally operating reinsurance group, whose operations were ceased in 2004 as a result of the 9/11 2001 attacks on the USA.

In 2004 Jan established Jusmedico Law Firm Ltd. ("Jusmedico"), which now represents leading Danish biotech companies, R&D-based pharmaceutical operations and academia on legal and regulatory issues, manufacturing, clinical testing, international alliances, product liability and insurance matters. To enable the rendering of legal services on the basis of non-legal competencies, a Jusmedico Advisory Board was formed in 2007. The Advisory Board now comprises nine professionals whose individual professional competencies and experiences are complementary to each other; see www.jusmedico.com under "Advisory Board".

Jan primarily advises on the legal implications of R&D activities (medicinal products and devices) and cross border co-operations, and is the secretary of BioLawEurope. He also runs Jusmedico's New York activities.

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Lone Hertz was born in August 1957 in Aalborg, Denmark. After graduating from the University of Copenhagen (Master of Laws) in 1982, she became legal counsel of a Danish insurance company. In addition to her legal background, Lone graduated as E*MBA (Executive Master of Business Administration) in 1996 and has subsequently taken general management courses in Denmark and the USA.

In 1987 Lone joined the American insurance brokerage firm Frank B. Hall – later AON. From 1992 she served as CEO and country manager for Denmark and was a member of the boards in the Norwegian, Swedish and Finnish AON subsidiaries. The Scandinavian AON group totalled 650 employees.

In 1999 Lone left AON and set-up her own insurance brokerage firm, Hertz & Co. Insurance Consultants; see www.hertzconsult.dk. The firm specialises in advisory services to the biotech, pharma and medico industries. Lone has extensive experience in setting-up structured insurance solutions for clinical trials/product liability and she has worked with numerous sponsors and investigators worldwide.

In 2008 Lone became a member of the Jusmedico Advisory Board, which now comprises nine professionals with different competencies relevant for the rendering of services to the biotech, pharmaceutical, medical device and dentistry industries, life science investors and suppliers and service providers thereto; see www.jusmedico.com under "Advisory Board".

Jusmedico is a specialist law firm providing legal services to the biotech, pharmaceutical, medical device and dentistry industries, life science investors and suppliers and service providers thereto.

The working areas of Jusmedico include, without limitation, biotech start-ups, capital raising and re-funding activities, research & development, pre-clinical test (GLP) and clinical trial (GCP), manufacturing & supply (GMP), labelling & packaging, licensing, marketing alliances (co-promotion & co-marketing), agent and distribution agreements (GDP), advertising & promotion, pricing & reimbursement, parallel imports of pharmaceuticals and insurance issues related to all of said working areas, including product liability claims.

Internationally, Jusmedico is a founding member of the BioLawEurope F.m.b.A. alliance, comprising a network of independent European law firms and individual attorneys providing legal services in the same fields as Jusmedio. Further, Jusmedico operates a representative office in New York, USA.

Jusmedico is regulated by the Danish Bar and Law Society and audited by AP, Chartered Accountants, Copenhagen.

In 2014, as well as in 2015, Jusmedico was awarded the Corporate INTL Global Award Price as *Biotech Law Firm of the Year in Denmark*.

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