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 198 of 27 February 2013 (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 Medicines Agency (the "Agency") being a division of the Danish National Board of Health, has issued guidance note No. 29 of 24 May 2007 on the advertising of pharmaceuticals, which has been amended as per 1 February 2012 (the "Agency 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 Agency Guide and the Marketing Act (collectively the "Legislative Basis") are enforced by the Agency 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 enforces 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.

Although not reflected in the Agency Guide, advertising initiatives addressing doctors, dentists, veterinaries, pharmacists, nurses, veterinary nurses, midwives, laboratory technicians, clinical dieticians and radiographers, and/or students of such professions (collectively "Healthcare Professionals"), 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 LIF. ENLI's jurisdiction, being contractually based, covers the members of The Danish Association of the Pharmaceutical Industry ("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 Agency on the basis of the Legislative Basis.

ENLI is operating under Procedural rules dated 28 January 2013 (Version 1.3) setting out charges and sanctions of 1 January 2014 (Version 1.5). 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 instituted by LIF and consisting of: i) the Advertising Codex of March 2014, Version 1.7, governing advertising *vis-à-vis* Healthcare Professionals (the "Advertising Codex"), incorporating among other norms the EFPIA and IFPMA codes on advertising, co-operation with patient organisations and marketing practices; ii) Advertising Codex guidance notes of 10 March 2014, Version 1.12, supplemented by guidance notes of April 2012 on use of social media, Version 1.2; iii) rules on the relationships between the industry and patient organisations of January 2012 and guidance notes to same of 17 April 2012 (the "Patient Organisation Codex"); iv) rules on the relations between the industry and the Danish hospital sector of 11 February 2014 (the "Sector Codex"); v) rules for dialogue and negotiations between the industry, politicians and regulatory authorities of January 2010 (the "Lobby Codex"), and the Hospital Donation Codex of 1 March 2012, as well as guidance notes of 17 April 2012 on same. The Advertising Codex, the Patient Organisation Codex, the Sector Codex and the Lobby Codex are hereinafter referred to as the "Codices". Most of the Codices are available in the English language from ENLI's homepage: www.enli.dk/Default.aspx?ID=93.

1.2 How is "advertising" defined?

The Agency Guide defines "advertising" to include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, including, without limitation: 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.

The definition excludes regulatory assessment reports, labelling and the accompanying package leaflets comprising the information provided in the approved Summary of Product Characteristics (the "SmPC"), correspondence (possibly accompanied by material of a non-promotional nature) needed to answer a specific question about a particular medicinal product, factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general medicinal product precautions (safety), trade catalogues and price lists, provided that they do not include any product claims or names of competing products, and information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products. However, SmPCs, patient information leaflet information and regulatory assessment reports can only be made available indirectly, i.e. subject to the users being required to make an active choice, e.g. by activating a link at the marketing authorisation holders' homepage directing the user to the relevant document. This condition implies that the said documents may not be distributed directly to users on the grounds that, e.g. SmPCs are not covered by the advertising definition.

The Marketing Act, which governs advertising in general, is construed to expand 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?

Article 68 of the Act requires the marketing authorisation holder, or the one placing the advertising on the market if different from the marketing authorisation holder, to keep documentation of all advertisement material on file, physically or electronically. The documentation must be kept for at least 2 years and must be made available to the Agency 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 such as, but not limited to, .pdf, .tiff or .jpeg. The obligations on filing of documentation related to donations, see question 4.3 below, are stricter.

Apart from the advertising material itself, the marketer is obliged to keep documentation as to how the advertisement has been used, including information identifying the:

1) Advertisement target group.
2) Method of distribution of the advertisement.
3) A list identifying the media in which the advertisement has been shown.
4) Dates and periods of time during which the advertisement has been shown.

The access for the Agency to request copies for enforcement purposes is very broad, as the Agency may address anybody who has been involved in the campaign, including advertising agencies. Otherwise, the 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 represent to ENLI that all necessary precautions to avoid repetition have been taken, and that sanctioned non-compliance will be published by ENLI, it is recommendable for companies to 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.

Notification deadlines for each kind of initiative are set out in the Advertising Codex. Generally the deadlines are 10 days before the event and 21 days for making appeals of decisions passed. 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 DKK 5,000 (DKK 25,000 for matters of urgency) or, if more than 2 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 Agency to offer pre-assessment of intended advertising initiatives. Until the Minister may do so, the Agency is precluded from offering such

service. Consequently, the Agency 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 2013, 5,714 notifications were made to ENLI, out of which 2,400 related to advertising materials and 3,314 to events. 325 applications for pre-approvals 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 Agency and the Consumer Ombudsman have the powers to require that an advertisement be stopped, a corrective statement be issued and to take or to require appropriate corrective action to be taken. The Agency 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 Agency 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 breach of the advertising provisions of the Act or the Marketing Act go from fines, up to imprisonment for up to 4 months. Breach of the Orders may be fined.

The Agency 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"), of 1 January 2014 and 17 December 2013, respectively, ENLI may impose sanctions ranging from reprimands, fines, corrective statements addressing/recall of illegal advertising material, publication of corrective statements in relevant periodicals, and cancellation of the advertising arrangement in question (conferences, congresses, etc.) and must for a period of no less than 2 years make the names of companies in breach public via the ENLI homepage. Due to data protection legislation, the names of any individuals involved will not published.

By authority of the Sanctions, ENLI may impose fines for breach of rules governing i) advertising material in the range from DKK 15,000 (approx. EUR 2,000) for minor formal errors such as a cover letter not having been dated, incorrect INN or incorrect API composition) to DKK 75,000 for misleading product claims, which may compromise public health, and ii) events DKK 30,000 (meal allowance at arrangements lasting less than 2 hours) to DKK 150,000 for e.g. meetings abroad with no professional content. Breaches of the Codices on other 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 2-year period, the fines which are otherwise applicable may be doubled. If a company has been sanctioned, the company is required to represent 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 Agency 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 Agency. However, a party can bring a case before the Agency even though the case has been or is being handled by a self-regulatory body, whose position may be considered by the Agency assessing the case. Over recent years ENLI's predecessor, the 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 the Healthcare Professionals, implying that the services partly constituted financial support to the doctor and partly impacted on the independency of the Healthcare Professional from the service provider. On request by NSL, the Agency 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 the 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 Agency 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 Agency, 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, which are subject to ENLI jurisdiction. As per 1 January 2014, the number of companies subject to ENLI jurisdiction was 68, comprising the members of LIF (40), IGL (14), PFL (6), companies (8) and associations (1) having submitted to ENLI's jurisdiction voluntarily. Considering the number of subjects and that ENLI recently has resolved to hear cases brought by members against non-members, ENLI is in a strong position to enforce ENLI rules against every relevant player on the Danish market. Decisions in the disfavour of non-members can obviously not be enforced by ENLI.

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 Agency Guide and the EFPIA Code of 15 August 2013 (the "EFPIA Code"), Section 1.01 prohibits the advertising of medicinal products for which a marketing authorisation has not been obtained. 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. 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 hitherto applied in Denmark, 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 is not permitted, "data on file" may be used, provided that the data have 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 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 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 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 of which they are in control, e.g. Facebook profiles run by the MAH, and which address Healthcare Professionals only, and remove language 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 or Healthcare Professionals only, but in either case the MAH may be held liable. 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 a MHA 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 medicinal products which are not yet authorised? If so, what limitations apply?

The Advertising Codex and the Agency 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 Agency practice comprises advertising; see below. As per the Agency, press releases may be made available at the relevant company homepages for up to a maximum of 3 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). Press releases may be provided via the homepage, but only for a period not exceeding 3 weeks; thereafter the release will be considered advertising.

With respect to annual reports and other general information addressing the 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 Agency resolution holding Ferring responsible for having identified medicinal products in what was classified as a press release, but, as per the Agency, 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 information and product lists which do not contain any information but the names and the prices of medicinal products are not considered advertising. 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?

Involvement is possible. Subject to the engagement arrangements meeting a number of objective criteria, including a reasonable cash compensation being paid as per a written contract, medicinal doctors (human and vet), dentists and pharmacists, but not other Healthcare Professionals, may render services to manufacturing authorisation holders. If they are interested in doing so while being authorised to prescribe medicinal products, they must apply to the Agency for permission to render their services, including through membership of Advisory Boards. Such permission must be applied for also if the principal is a subsidiary of enterprises holding a manufacturing authorisation, whether or not the activity envisaged is related to a specific medicinal product and whether or not that medicinal product is authorised. Applications will be denied if the Agency finds that the services to be rendered may influence the prescription pattern of the applicant, which, as per Agency practice, will be the case if the services relate to the preparation of marketing material.

For many years, the obligation to apply for permission has not been actively enforced. Over the last few years, however, this has changed dramatically; reference is made in question 8.3 below. The Agency has issued guidelines No. 9485 of 11 September 2013 for pharmacists, and guidelines No. 9257 on 28 June 2011 for doctors and dentists.

Notwithstanding the above, it should be noted that on 10 April 2012, the Danish Association of Cardiologists published that the association has resolved to propose to their general assembly meeting on 11 May 2012 for members of the association to be prohibited from assuming positions, including Advisory Board memberships and/or positions with fixed salaries, with the industry, if the member also holds honorary offices in the association. This initiative has been taken to reduce the number of potential conflict of interest situations and it is our view that this initiative may well be copied by a number of other scientific associations.

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 essential information, which must be legible:

1. Trade and generic (INN) product name(s), i.e. all INN names if a combination.
2. Name of marketing authorisation holder.
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. Pharmacy purchase price + pharmacy margin (p.t. 9.3%) + DKK 9.46, incl. VAT, (Exec. Order No. 232 of 05 March 2014) for pharmacy monopoly products, in spite of this price not being the consumer price.
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 2013, ENLI has heard 16 cases published at: www.enli.dk/offentliggjorte-sager/afgoerelser-2013/.

In 2013 the trade and generic (INN) product name requirements became more restrictive, implying that the INN name must 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.

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

Advertisements, or any other Healthcare Professional address, must not contain competing products' offering prices. This prohibition is absolute regardless of whether an individual product is identified or not and regardless of the size and nature of the price.

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 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 Healthcare Professional endorsements in campaigns addressing the general public does not apply to campaigns addressing Healthcare Professionals. 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 are made?

No, the advertiser must observe the rules on comparative advertising, which, however, do not require that the products have been 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 comparator advertisements are set out in the Marketing Act, the Orders, in the Agency Guide and in the ENLI Rules.

Comparative advertisements must be based on the SmPCs and must also include supplementary data subsequently generated provided they are 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 secure 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 a Healthcare Professional address, even addresses which 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?

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. "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 the publication date, however, the information provided on such products is *per se* advertising and must therefore adhere to the advertising rules and may only be distributed if it falls outside the scope of the advertising material definition (see questions 1.2 and 2.1 above). However, companies may reply to unsolicited enquiries made by Healthcare Professionals, e.g. in connection with congresses where independent opinion leaders give presentations.

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. A Healthcare Professional address encouraging the recipient to

reserve a given date for an event to be notified is not considered advertising.

4 Gifts and Financial Incentives

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

Samples of products launched on or after 1 January 2012 may be provided only during the initial 2-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 marketing authorisation holder representative, not the pharmacy.
7. SmPC must be enclosed.
8. Narcotic/controlled medicinal product samples must not be dispensed.

The marketing authorisation holder 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 2 years. Since 2009, it has been possible for the marketing authorisation holder to sub-contract the obligation to keep accounts and to file requests received to wholesalers.

As LF has imposed an obligation for their members, the medical doctors, to neither receive nor request supply 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?

No gifts or pecuniary advantages (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. 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 courses and other professional 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 LIF's Ethical Rules for Collaboration between Patient Groups and the Pharmaceutical Industry) 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 Agency Guide, which allows Healthcare Professionals, associations of Healthcare Professionals or members of hospital administrations to receive financial benefits, including discounts, bonus payments, etc., and goods, 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. It is also prohibited to hold competitions or award prizes to Healthcare Professionals.

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 ENLI 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 2 years thereafter. During the subsequent 8 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, relieving 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.

The 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, indicate how it is calculated, and be separate from discounts granted on products not covered by the restrictions.

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, § 30 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 § 30 and hence comprise an illegal kick-back.

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 Agency announced that Novartis had launched a "pay back" scheme for Diovan®, noting that the Agency, while not approving the campaign (which the Agency cannot), did not consider the campaign as being a breach of the Act *per se*. However, the Agency noted that such campaigns represent a challenge to the reimbursement system. Subsequently the Agency 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 result of the IUD having become unsterile. On the basis hereof, Bayer applied to the Agency for permission to replace an unsterile IUD with a sterile one free of charge rather than providing financial compensation. The Agency 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 for individual Healthcare Professionals or groups thereof cannot be sponsored, unless the education is specifically related to medicinal products implying that education related to, e.g. administrative systems, organisational development cannot be sponsored. In principle, a sponsor can hence fund a Healthcare Professional's Ph.D. programme if sufficiently qualified by means of a project description.

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?

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 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 2 hours' duration. For accommodation at a hotel to be sponsored, the event must last at least 6 hours and be continued the following day.

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 is prohibited by § 23 par. 2 of the Advertising Order, and the offering of reimbursement of lost earnings is prohibited as per question 4.2 above.

In addition, 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. In any event, the Healthcare Professional must observe the Agency guidelines Nos. 9485 and 9257; see question 2.7 above.

The companies must make sure that the 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 whether 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 Agency 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 Agency. 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 Agency 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 receive payment for services rendered to a pharmaceutical company, provided that the payment is balanced and agreed upon as a natural part of a normal mutually binding agreement. This option involves the possibility of paying a doctor for his professional assistance carrying out clinical trials or development of information on drugs, all provided that the relationship between the Healthcare Professional and the company is permitted as per the guidelines identified under question 2.7. In addition to the legislation in the area, collaborations on non-intervention trials (and clinical research) are also regulated by LIF and LF's Agreement on Clinical Research, which supplements the legislation with respect to LIF and LF members. The agreement is available at www.lif.dk. ENLI only monitors compliance with the provisions set forth in these rules and LIF's other codes but not the above-identified agreement with the Danish Medical Association. In contradiction to the Codices, the Act stipulates that non-interventional studies do not require notification to the Agency. In this light, it is less likely that the Agency will allocate significant resources to discussing proposed study plans with the sponsoring companies. Non-intervention trials do not require approval in Denmark by the Agency or ethical committees. In LIF and LF's agreement on clinical trials, there is, however, a requirement to submit trial plans to the Agency, 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, it could provide 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 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 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 second requirement regarding package sizes and pricing does 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 the ordinary consumer, the Orders contain 14 types of information that are prohibited, including: (i) statements claiming that common well-being 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 has been 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 specifically 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 Agency 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 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 purposes promoting investments in the company and not the individual products (to be) marketed. Under these circumstances, and subject to 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 C to the EFPIA Code) in the Advertising Codex. The content of Section 2 of said Annex C describes the kind and the amount of information that may be published via a homepage without violating the EFPIA Code by having a promotional purpose, which description will have an impact on the construction of the scope of allowed information in announcements to investors exempt from the Advertising Codex.

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

As of 20 August 2011, some 225 patient group associations were in existence, ref. www.netpatient.dk/patientforeninger.htm. Out of these 225 associations, 79 have now joined forces in an umbrella association, "*Danske Patienter*" (Danish Patients), representing some 870,000 Danish patients in total. The Patient Organisation Codex requires transparency by stipulating that all sponsorships must be in writing, and must identify the project sponsored, the names of the parties, the type of projects (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 6 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, what information should be disclosed, and when and how?

The Act requires a sponsor to notify the Agency 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 Agency must be informed of the reasons, iii) annually of all serious

adverse events incurred, and iv) within 90 days from close-out inform the Agency hereof and within 1 year after close-out submit the trial result to the Agency.

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

As per question 5.7, LIF has resolved to implement the Disclosure Code, but awaits the principles to be reflected in legislation, which will then apply for everybody and not only for interests subject to ENLI jurisdiction.

7.3 If the EFPIA Disclosure Code has not been implemented in Denmark, is there a requirement in law and/or 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 information should be disclosed, from what date and how?

This is not applicable.

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 Agency and ENLI are monitoring Internet advertising (see question 8.4 below) and often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark, the Agency 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 Agency 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 having been made available to the general public.

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 which are controlled or influenced by a company must be monitored and controlled by the company as the company 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 disclaimer on the homepage, however, will not relieve the company from verifying that the 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 Agency required two marketing authorisation holders to withdraw advertisements released on their homepages. In the case of Pfizer, the Agency 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 Agency 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 Agency required the advertisement to be withdrawn.

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

As from April 2012 ENLI has issued guidance (Version 1.2) on the use of social media in connection with advertising activities, see http://enli.dk/Files/Filer/ENLI/DOK/sociale%20medier_guide_version%201.2.pdf.

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?

EFPIA decided on a Disclosure Code in 2013 which warranted changes also to permissible hospitality and gifts to Healthcare Professionals. The changes have all been implemented in December 2013, as required.

In 2013, hospitality was among the hot topics discussed and attempted to be clarified during the course of the year. In line with the EFPIA Healthcare Professional Code, it was decided what constitutes *reasonable* hospitality and when a venue is *renowned* for its entertainment facilities, implying that it cannot be used for promotional purposes. Member companies had much fewer violations of the hospitality provisions in 2013. Only 10 decisions involved violations of hospitality limitations, of these only four decisions related to meeting venues, whereas the numbers in 2012 were 47 and 22, respectively.

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

Implemented as per 1 January 2014, but not effective until 1 July 2014, the thresholds for hospitality (wining and dining) will take effect simultaneously with the new "gift-giving-ban", implying that Healthcare Professionals may no longer receive gimmicks such as pens, stickers, calendars, etc. Informational and training material may, however, still be provided as well as certain medical equipment whose value is negligible. In principle the restrictions are slightly less stringent for companies that have not submitted to ENLI's jurisdiction, but over time it is likely that administrative practice will close in on the EFPIA-principles and the Advertising Guide will be amended accordingly.

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

Currently, Healthcare Professionals must obtain approval from the Minister were they to acquire shares in pharmaceutical industries manufacturing medicinal products. As per March 2014, the Minister had approved 150 applications. On 5 December 2013 Bill No. 94 (the "Bill") was presented to Parliament, proposing certain amendments to the Act, the Act on Medical Devices, the Pharmacy Act, the Health Act and the promotion of healthcare services.

The Bill, which is expected to be passed and take effect on 1 October 2014, replaces this system with a new set of rules implying that certain Healthcare Professionals must not teach, carry out research or own shares exceeding the value of DKK 200,000 (approx. EUR 27,000) in the industry, unless approval from the Agency has been obtained in advance. Healthcare Professionals who already own shares exceeding said threshold will be required to notify the Agency, presumably no later than 1 March 2015. Healthcare Professionals whose shareholdings do not yet exceed the threshold must – as from 1 October 2014 – apply with the Agency for permission to own such shares, unless the threshold will not be exceeded, in which case the Healthcare Professional is only required to notify the Agency. Healthcare Professionals advising or guiding public authorities will not be allowed to own any such shares. Certain Healthcare Professionals and certain medicines and medical equipment purchase and sales chain professionals must notify the Agency if or when they receive financial support from the industry to participate in subject-related activities abroad. All permits granted and reviews executed by the Agency must be published on the Agency's website.

9.4 Has your national code been amended in order to implement the 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?

Yes, the EFPIA code was adopted in December 2013, including the Disclosure Code, which – however – is awaiting statutory regulation before taking effect. The LIF rules are not a copy of the EFPIA rules, but were the rules to be construed to set different standards, the most restrictive set will be applicable. Arrangements taking place within the EEA are governed by the local Codices applicable in the country in which the arrangement is accomplished, as well as the Codices applicable in the home jurisdiction of the sponsoring member. If an arrangement takes place outside the EEA, the EFPIA Code, as well as the Codices applicable in the home jurisdiction of the sponsoring member must be complied with. If there are inconsistencies between the applicable norms, the more demanding norm will be applied.

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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 being trained in the Copenhagen City Law Firm Møller, Tvermoes & Hoffmeyer, Jan was admitted to the Bar and received his 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 result of the 9/11 2001 attacks on the USA.
In 2004 Jan established Jusmedico Law Firm Ltd. ("Jusmedico"), which is now representing academia, leading Danish biotech companies and R&D-based pharmaceutical operations on legal and regulatory issues, clinical testing, manufacturing, international alliances, product liability and insurance matters.
Appreciating that Jusmedico clients frequently are in need of life science-related services to be rendered not only by lawyers, but also by professionals holding other competencies, a Jusmedico Advisory Board was formed in 2007. The Advisory Board now comprises 9 professionals whose individual professional competencies and experiences are complementary to each other; see www.jusmedico.com under "Advisory Board".
In 2014 Jusmedico was awarded the Corporate INTL Global Award Price as *Biotech Law Firm of the Year in Denmark*.

Lone Hertz

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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 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.hertzco.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 and has worked with numerous sponsors and investigators worldwide.
In 2008 Lone became a member of the Jusmedico Advisory Board, which now comprises 9 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".

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Jusmedico is a specialist law firm providing legal services to the biotech, pharmaceutical, medical device and dentistry industries, life science investors and to 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 operates a representative office in New York, USA, and is a member of the EuMedLex group comprising nationally-operating life science-focused law firms in Continental Europe.

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