Chapter

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 Act No. 1180 of 12 December 2005, effective from 17 December 2005 (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. 338 of 16 April 2011 (Television & Radio), as amended by Exec. Order No. 864 of 23 August 2012 (Product Placement), 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 (the "Agency Guide"), which has been updated as per 1 February 2012.

The Danish Marketing Practices Consolidated Act No. 58 of 20 January 2012, (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 "Health Professionals"), have been monitored by ENLI since 1 April 2011. 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 5 March 2013 (Version 1.4). 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 22 February 2013, Version 1.6, governing advertising vis-à-vis Health 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 27 February 2013, Version 1.10, supplemented by guidance notes on use of social media, Version 1.12; 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 Organization Codex"); iv) rules on the relations between the industry and the Danish hospital sector of 23 February 2010 (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 Health 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 Health Professionals; and payment of travelling and accommodation expenses for Health 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) Way of distribution of the advertisement.
3) A list identifying the media in which the advertisement has been shown.
4) Dates at 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, incl. 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 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 Health 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 Health 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 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.

As per 10 April 2012, ENLI's first annual report covering the last 9

months of 2011, was published. During that period 4,453 notifications were made to ENLI, out of which 1,870 related to advertising materials and 2,582 to events. 94 applications for pre-approvals were submitted. This is as per March 2013 (deadline for this publication) as the 2012 report has not yet been published.

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 5 March 2013 and 28 January 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 1st instance Scrutiny Board or by the 2nd 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 the recent years, ENLI's predecessor, the NSL, sanctioned several companies for having offered to Health 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 Health Professionals, implying that the services partly constituted financial support to the doctor and partly impacted on the independency of the Health Professional from the service provider. On request by NSL, the Agency scrutinised this practise and reached the conclusion that SMS compliance services was a service rendered to the patients on a voluntary basis and that the doctors were not relieved of any work load 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 2013, the number of companies subject to ENLI jurisdiction was 65, comprising the members of LIF (34), IGL (14), PFL (6), companies (8) and associations (1) having submitted to ENLI's jurisdiction voluntarily. Considering the number of subjects, ENLI is in a strong position to enforce ENLI rules against every relevant player on the Danish market.

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 health 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's variants not authorised)?

The Act, the Agency Guide and the EFPIA Code of 5 July 2007, amended on 19 June 2008 and 14 June 2011 (the "EFPIA Code"), Section 1.01 prohibits the advertising of medicinal products for which a marketing authorisation has not been obtained. However, ENLI authorises that advertising takes place in connection with arrangements outside Denmark even if the products advertised at such arrangements are not authorised in the relevant jurisdictions, provided however that the advertiser clearly informs the addressees that the product is not locally authorised or available, that the marketing authorisation conditions may vary country to country, and that it is legal locally. This exception complies with the EFPIA code Section 9.03, but does not appear in the Advertising Order, implying that presentation in Denmark of medicinal products not authorised in Denmark will not be legal.

However, ENLI has resolved that publication of clinical trial results and data relating to what may subsequently become an authorised medicinal product, will not be considered advertising provided that such publication takes place prior to the point in time where Phase III results are published (date of publication) in an acknowledged international peer reviewed publication (e.g. ISI Web of Science media). This is an important change of policy, which opens up for the conduct of scientific meetings dealing with products under development, which has not hitherto been formally authorised in Denmark.

In the early stage of a product lifecycle, the availability of scientific references will be limited and a marketing authorisation holder therefore be challenged, 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.

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 Health Professionals on an "as are" basis, or as per question 2.1 above relates to medicines for which Phase III results have not been published, are not considered advertising.

Previously, information provided by sources independent from the marketing authorisation holder was not necessarily considered advertising (see the *Ter Voort* case (C-219/91)). This is no longer the case (see the *Damgaard* case (C-421/07)), in which the ECJ has ruled that statements about the properties of a pharmaceutical product may be considered advertising, even if the source is acting on its own initiative and independently, *de jure* and *de facto*, of interests holding a commercial interest in the product advertised. The ECJ ruling was an Article 234 ruling following an appeal to the Danish High Court (Western District) by Mr. Damgaard, who in the first instance was fined DKK 15,000 by the Danish Magistrates Court for having advertised a product which due to the product claims made was considered as a (unlicensed) medicinal product. Based on the ECJ ruling, the first instance verdict and the fining of Mr. Damgaard was upheld, although then reduced to DKK 10,000 (approx. EUR 1,333).

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 does not cover press releases to the general public, whereas the Agency Guide exempts 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 practise comprises advertising, see below. As per the Agency, practise releases may be made available at the relevant company homepages for up to a maximum of 3 weeks, where after the press release may be considered advertising rendering the press release exception inapplicable. When drafting articles on the basis of press releases received, the gentlemen of the press need 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, whereafter 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 Health 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-Health 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 Health 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 health professionals by the company? If so, must the health professional request the information?

Product information, but not press releases, may be sent to Health Professionals and others having made a specific enquiry to the company regarding the product properties. Submission on an unsolicited basis to Health 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 *Ludwig's* 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?

The Advertising Order, Section 3, item (4) prohibits the advertising of medicinal products sold or dispensed according to a special compassionate use permit according to section 29 of the Act. No specific exception addressing the provision of information on product identification (name), package size, dosages and prices under circumstances as in the *Ludwig* case apply or have been adopted and consequently submission of product lists identifying products not authorised in Denmark to Danish Health Professionals would, as a starting point, be illegal as per the Legislative Basis. Considering the *Ludwig's* case ruling it is likely that the ENLI Rules and the Orders will be amended to include an exception describing the situation where the Free Movement of Goods principles prejudice the scope of the advertising definition as set out in the Legislative Basis. The exception in the Advertising Order for price and product name lists supplied to Health Professionals from the advertising definition does not solve the *Ludwig* problem as the products listed must be authorised.

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

Only to the extent that such informational material is produced by public entities promoting rational drug consumption or comprises scientific articles being submitted as per the above requirements. As information relevant for budgeting will require information on the pricing and reimbursement status, which will not be available prior to authorisation, such information cannot be provided, save under circumstances as those prevailing in the *Ludwig's* case. See question 2.5 above.

2.7 Is it possible for companies to involve health 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 Health 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 practise 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 years, however, this has changed dramatically; reference is made in question 8.3 below. The Agency has issued guidelines No. 9011 on 13 January 2010 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 Health Professionals

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

Advertisements targeting Health 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. 8.8%) + DKK 8.61, incl. VAT, 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 sanctioned 1 LIF member for breach of the above in the case 2013-0578 (legibility). In 2012, numerous breaches of the above have been sanctioned in 25 cases published at: http://www.enli.dk/Default.aspx?ID=167.

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 Health Professional address, must not contain competitions 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 Health Professional endorsements in campaigns addressing the general public does not apply to campaigns addressing Health 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.

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 comparator 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, 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 Health 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 doctors?

Scientific papers addressing research and development achievements on potential medicinal products for which Phase III results have not yet been published will no longer be considered advertising. After the publication date, however, information provided on such products are per se advertising and must therefore adhere to the advertising rules and may only be distributed if they fall 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 Health Professionals, e.g. in connection with congresses where independent opinion leaders give presentations.

3.7 Are "teaser" advertisements permitted, which 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 Health 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 It is possible to provide health 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 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 Health 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. Written, dated and signed request must be made by the receiving Health Professional.
6. Dispensation 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, neither to receive nor to request supply of samples, but in very rare circumstances and considering that the 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 medical practitioners? If so, what restrictions apply?

The Legislative Basis and the "Ethical rules for the pharmaceutical industry's donations and grants to hospitals" of 1 March 2012, see question 4.3 below, provide that the granting to Health Professionals, associations of Healthcare Professionals or members of hospital administrations, of financial benefits, including discounts, bonus payments, etc. and goods is prohibited, unless the gift, whose intrinsic value must be minimal, can be used professionally by the Health Professional or is granted in connection with a personal red-letter day, which latter exception is not authorised by the Advertising Codex, i.e. that ENLI subjects cannot avail themselves of this exception. It is also prohibited to hold competitions or award prizes to Health Professionals.

Within the scope of a minimal intrinsic value (up to DKK 300 (approx. EUR 40), incl. 25% VAT per calendar year, per practitioner), clinical thermometers, calendars and other merchandise directly related to the relevant professional activity may be presented to medical practitioners. The value assessment is based on the market prices applicable if the recipient were to buy the commodity personally via an outlet open to the general public (market prices). The interpretation of which commodities that may be granted is narrow; for instance, ENLI's predecessor NSL decided that a sphygmometer, laser pointers and USB-sticks fall outside the scope of permitted gifts, unless said latter gifts serve a specific educational or scientific goal, which can be the case if the Health Professional is teaching on behalf of the sponsoring enterprise.

4.3 Is it possible to give gifts or donations of money to institutions 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?

The objective behind the restrictions on giving Health Professionals gifts is to avoid irrelevant criterions from impacting the prescription pattern. Donations to institutions such as hospitals do not cause the same concern. As long as nothing is promised or given in return, industry financing of medical equipment supplied to institutions, projects, activities, or hospital units is not considered inappropriate sponsoring notwithstanding, in principle at least, the value of the donation.

"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, Articles 11 and 14 of 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) Name of the activity, project, equipment or unit the donation or grant is to support.
2) Name(s) of the hospital/department, etc., responsible for the activity, project, equipment or unit.
3) Name(s) of the person(s) at the hospital responsible for the activity, project, equipment or unit.
4) 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) 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) 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) Timeframe (if available).
9) The amount of funding provided.
10) 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, 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. 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 doctors 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 Health 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 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?

On 20 December 2011, the Ministry of Health and LIF prolonged the price-cap and price reduction agreement entered into in 2008 and related all medicines subject to general reimbursement and sold via the pharmacies. Hereinafter the current price ceiling will apply until 1 April 2013 as per which date a 1.5% increase may be applied until 1 April 2014, where additionally, 1.5% may be added. The agreement covers all medicines subject to general reimbursement sold via the pharmacies. Hereinafter the current price ceiling will apply until 1 April 2013 as per which date a 1.5% increase may be applied until 1 April 2014, where additionally, 1.5% may be added.

Outside the hospital sector, discounts may be granted to the retailer on the basis of cost savings realised by the supplier (cost-related discounts). Cost-related discounts must follow the individual product or the individual consignment and constitute a price reduction reasonably proportionate to the cost saving. Cost-related discounts offered to pharmacies must reflect savings realised by the wholesaler as a result of the wholesaler costumer having increased the cost-effectiveness of the trade between the wholesaler and the customer.

Discounts obtained by wholesalers from their suppliers must not be credited to the pharmacy.

Discounts may have competition law implications. A template for the auditor's report concerning suppliers' cost-related discounts has been laid down in Executive Order No. 198 of 27 February 2013.

The purchasing of medicinal products by hospitals takes place via public tenders organised by Amgros, which is owned by the regional hospital owners. Amgros purchases approx. 99% of all medicines used at the hospitals. On 18 December 2012, the Ministry of Health, the Danish Regions (hospital owners) and LIF entered into a new price-cap and price reduction applicable from 1 January 2013 to 31 December 2015 and relating to all medicines restricted to be dispensed by hospitals in Denmark. Compared to a similar agreement entered into as of 4 June 2009, which agreement lapsed on 31 December 2012, the new agreement will be reducing the price ceilings applicable therein by 2.5% on 1 April 2013 and by another 2.5% on 1 April 2014.

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 relation. The refund principle is fairly new and reflects that some patients may not enjoy the envisaged benefits of taking the prescribed medicinal products in spite of the medicinal product being contractual.

The refund system represents therapeutic, administrative and ethical challenges.

Therapeutically and administratively, treatment goals need to be defined up front in order to enable assessment of medicinal product efficacy on a patient-by-patient basis to substantiate invocation of the refund option and ethically such scheme may influence the prescription pattern without therapeutic justification.

The latter might be considered inconsistent with both Marketing Act standards and the ENLI Rules.

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.

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

Continued medical education for individual Health 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 Health 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 health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

The offering of hospitality to Health Professionals is governed by the Orders and the Codices; see question 1.1. Pharmaceutical businesses may bear and/or sponsor expenses related to events of professional 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 place 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 – 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 Health 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 doctor 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 Health 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 Health Professional participates or which a Health 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 Health Professional must observe the Agency guidelines Nos. 9011 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 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 doctors 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 doctors to provide expert services (e.g. participating in focus groups)? 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 Health Professionals must report such engagements to the Agency. On a stand-alone basis, Health 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 Health Professional to render their services in connection with serving as focus group members does not relieve the sponsoring company from the obligation to comply with the advertising rules.

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

The conduct of prospective post-marketing surveillance studies

(non-interventional studies) collecting patient data are subject to a number of conditions set out in the Codices: the study must have a scientific objective; all contractual relations among participating resources must be stipulated in writing; remuneration levels must be reasonable; a study plan must be submitted to the Agency for guidance; personal data must be protected; the study must not per se impact on the prescription patterns otherwise applicable; a study protocol must be prepared and submitted to sponsors' R&D function for approval; a study report must be prepared and made generally available and - if risk/benefit findings - made available to the Agency; and sales representative and the sponsoring company may only be involved administratively. 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.

5.6 Is it possible to pay doctors 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, unless the gift, whose intrinsic value must be minimal, can be used professionally (see question 4.2 above) and the survey has certain merits.

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.

5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

Donations made to hospitals, see question 4.3 above, must be published in comprehensive detail on the sponsors homepage and remain there for at least 2 years. Also donations made to Patient Organizations must be publicly accessible via the homepages of the sponsors for the duration of the co-operation and remain for at least 6 months. See question 6.6 below. Otherwise, the ENLI Rules encourage, but do not require, the companies to make all information on Health Professional donations, grants and benefits in kind publicly available.

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 T.V. 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 T.V. 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, which are prohibited, including: (i) statements claiming that common well-being may be reduced if the medicinal product is not used; (ii) recommendations by Health 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.

Disease awareness campaigns are frequent, especially via the Internet. Currently, the Danish Consumer Council identifies 24 initiatives under the heading "Illegal Pharmaceutical Advertising" available at their homepage: www.taenk.dk/dokumentation/breve/ulovlige-medicinreklamer.

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 gentlemen of 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 worth while 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 Health 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 is currently considering adopting the EFPIA Code guidelines on website content (Annex B to the EFPIA Code). The content of Section 2, (i) of said Annex B 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 funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

As of 20 August 2011, some 225 patient group associations were in existence, ref. www.netpatient.dk/patientforeninger.htm. The Patient Organization Codex requires transparency by stipulating that all sponsorships must be in writing, identify the project sponsored, the names of the parties, the type of projects (contributions to general activities/specific arrangements, informational campaigns, etc.), objective, the roles of the parties involved, period of time for the sponsorship, support budget, 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 Organization Codex defines standards applicable for companies sponsoring meetings, compliance with the Legislative Basis at all times, non-exclusivity and legal capacity.

7 The Internet

7.1 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 were the advertisement 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 7.4 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 is at present considering adopting the EFPIA Code guidelines for Internet advertising; see question 6.5 above.

7.2 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 health professionals?

The Agency Guide requires sites addressing Health 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.

7.3 What rules apply to the content of independent websites that may be accessed by 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.

It is unlikely that a company will be made liable for the content of 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.

7.4 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 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 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 Developments in Pharmaceutical Advertising

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

ENLI, which comprises a 1st Instance Scrutiny Board and a 2nd Instance Appeal Board, are enforcing the Codices efficiently and have both increased fine levels and communicated more detailed guidance on when which fine levels apply. In 2012, ENLI dealt with approx. 100 published cases and in the first calendar quarter of 2013 with 8 published cases.

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

The Agency position referenced in case No. V 132/05 (see question 2.3 above) and ENLIs corresponding practise defining the mere identification of a medicinal product in an address as advertising and/or containing/identifying more than one product or API name as comparative advertising (see the ENLI EN-2011-001, AN-2011-2487, Aa-2011-2455 & 2011-56), regardless of the subjective intention lying behind the communication, has had severe consequences for certain market research companies, as an obligation to apply the advertising rules in general jeopardises the objective behind numerous market research models hitherto applied generally and internationally with the view of obtaining views and opinions from Health Professionals without having to inform the addressee up front of who the interest sponsoring the enquiry is. The construction applied has not yet been challenged by market research companies as they, even when acting on behalf of LIF members, are not themselves subject to ENLI's sanctions, which hence cannot be appealed by the market research companies, which will often find themselves being put in a place between a rock and a hard place.

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

Currently, Health Professionals must obtain approval from the Minister, were they to acquire shares in pharmaceutical industries manufacturing medicinal products. As per March 2013, the Minister had approved 178 applications. A committee under the Minister has now proposed for a threshold limit implying that certain Health Professionals must not own shares exceeding the value of DKK 300,000 (approx. EUR 40,000) in the industry. The Minister, however, believes that the mere holding of shares in the pharmaceutical industry by certain Health Professionals may impact the prescription pattern and has now proposed for a general prohibition of Health Professionals owning any shares at all in the pharmaceutical industry, i.e. a "no tolerance" criterion. Two of the three political parties in the current three-party coalition support the Minister, whereas one of the government parties, as well as the right winged opposition strongly object to the proposal arguing that full transparency on shareholdings will do. Although we do not believe that the proposal will fly, the heated discussion reflects how much concern politicians and the public have about which interests that may be driving a given prescription pattern; it being implied that the well-being of the patient is not necessarily the key driver for the Health Professionals. The debate reflects the background for the advertising rules on sponsoring, use of Health Professionals as consultants, etc. and there is no doubt that these rules continuously will be strengthened.

8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

LIF, and thereby ENLI, apply the EFPIA Codes of June 2011 on the promotion of prescription-only medicines to, and interactions with, Healthcare Professionals, and on practice on relationships between the pharmaceutical industry and patient organisations, on an as are basis and in conjunction with the Legislative Basis. If an arrangement takes place within the EEA, 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 must be complied with. 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. Having graduated 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 his High Court advocacy rights in 1991.
Late 1991, Jan joined the Lundbeck group and was appointed General Counsel thereof in 1994. As General Counsel, Jan participated in the negotiation and 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. In 1999, Jan was appointed General Counsel and Executive Vice President of a globally operating reinsurance group, whose operations were put into run-off after 9/11 2001.
In 2004, Jan established Jusmedico Law Firm Ltd. Advokatanpartsselskab ("Jusmedico"), which is now representing 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.
To accommodate the need among Jusmedico clients for life science related services to be rendered not only by lawyers, but also by professionals holding other competencies, a Jusmedico Advisory Board, now comprising 8 professionals, was formed in 2007. See www.jusmedico.com under "Advisory Board".

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Lone Hertz was born in August 1957 in Aalborg, Denmark. Having graduated from 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 member of the boards in the Norwegian, Swedish and Finnish AON subsidiaries. The Scandinavian AON group was totalling 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 has specialised 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, now comprising 8 professionals with different competencies relevant for the rendering of services to the biotech, pharmaceutical, medical device and dentistry industries, life science investors and to suppliers and service providers thereto; see www.jusmedico.com under "Advisory Board".

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ADVOKATFIRMA

Jusmedico is a specialist law firm providing legal services to the biotech, pharmaceutical and medical device 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 and development, pre-clinical test (GLP) and clinical trial (GCP), manufacturing and supply (GMP), labelling and packaging, licensing, marketing alliances (co-promotion and co-marketing), agent and distribution agreements (GDP), advertising and promotion, pricing and reimbursement, parallel imports of pharmaceuticals and insurance issues related to all of said working areas, including product liability claims.

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