# Denmark


Jan Bjerrum Bach

Martin Binzer Lind

Jusmedico Advokatanpartsselskab




## 1 General – Medicinal Products

### 1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Chapter 7 of the Danish Medicines Consolidated Act No. 99 of 16 January 2018, (the "Act"), as amended, and Executive Orders Nos 1244 of 12 December 2005 (Samples) and 1153 of 22 October 2014 (Advertising), collectively the "Advertising Order", and Executive Order No. 801 of 21 June 2013 (Television & Radio), which, together with the Advertising Order, hereinafter are referred to as the "Orders", govern the advertising of medicinal products in Denmark.

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

The Danish Marketing Practices Consolidated Act No. 426 of 3 May 2017, (the "Marketing Act"), as amended, which basically sets out fair trading standards, governs advertising in general and authorises the Consumer Ombudsman to monitor marketing activities and to sanction non-compliance.

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

In addition to said authorities, self-regulated bodies – proceedings before which are possible in addition to administrative and judicial proceedings – monitor the advertising of medicinal, borderline and dietary supplement products, and/or enforce ethical standards. The self-regulated bodies comprise: 1) the Ethical Committee for the Pharmaceutical Industry in Denmark ("*Etisk Nævn for Lægemiddelindustrien*" / "ENLI"); 2) the Marketing Board of the Association of the Veterinary Pharmaceutical Industry in Denmark, Finland, Iceland, Norway and Sweden, ViNordic ("*ViNordic's Marketing Board*" / "ViNordic"); 3) the Pharmacist's Ethical Board ("*ApotekerNævnet*" / "AEN"); 4) the Medical Doctor's Ethical Board ("*Lægeetisk Nævn*" / "LEN"); 5) the Association of Danish Vets ("*Den Danske Dyrlægeforenings Etiske Nævn*" / "DDD"); and 6) the Health Trade Supplier Association's Ethical Board ("*Helsebranchens Leverandørforenings Etiske Nævn*" / "HBL"). Within the scope of their respective statutes, the bodies monitor whether advertising initiatives comply with the Legislative Basis and ethical codes and/or that their respective members comply with applicable ethical standards.

Advertising initiatives addressing doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, midwives, laboratory technicians, clinical dieticians and radiographers, and/or students of such professions (collectively "HCPs") have been monitored by ENLI since 1 April 2011. Effective as from 1 January 2014, ENLI was transformed into a private limited company, whose entire share capital is held by The Danish Association of the Pharmaceutical Industry ("LIF"). ENLI's jurisdiction, being contractually based, covers the members of LIF, The Danish Generic Medicines Industry Association ("IGL"), The Medicinal Product Parallel Importer Association ("*Parallelimportørforeningen af lægemidler*" / "PFL"), and The Association of Medicinal Product Parallel Importers ("*Foreningen for parallelimportører af medicin*" / "FPM"), as well as corporations and associations, which could have been members of LIF, IGL, PFL or FPM, but have chosen not to be, merely to submit to the ENLI jurisdiction. Although PFL and FPM are separately registered as independent legal entities by the Danish Business Authority ("DBA"), no enterprises having submitted to the ENLI jurisdiction have been identified as FPM members. Consequently, only PFL will be referenced in this guide as the parallel importer association. The Association of Medical Doctors ("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 AEN and LEN, on the basis of the applicable ethical standards alongside the DHMA enforcing the Advertising Order. ENLI's activities are based on a Co-Operation Agreement ("COA") entered into among LIF, IGL and PFL. The current COA version is of 7 December 2018 amending the former version of 1 May 2018. The COA sets out ENLI's objective, competencies, organisation, management, organs (1st and 2nd instance) and economy, and is supplemented by a Code of Procedure of 15 May 2019 and a regulation of January 2020 on Penalties & Fees, setting out the sanctions due, were the Codices, as defined below, to be breached. The COA, the Code of Procedure and the Penalty and Fee Regulation are hereinafter referred to as the "ENLI Rules". The rules and standards to be enforced by ENLI as per the ENLI Rules comprise: i) an Advertising Codex, Version 3.0 of February 2020, governing advertising *vis-à-vis* HCPs (the "Advertising Codex") incorporating the IFPMA, EFPIA (HCP & Disclosure Codes), the Medicines for Europe ("MfE", formerly the European Generic & Biosimilar Medicine Association, EGA) and the WHO codes on advertising and amended to reflect that FPM has joined ENLI, ii) the Patient Organization Co-operation Codex Version 2.0 effective as from January 2020 incorporating the corresponding

EFPIA and MfE codices and replacing the former codex version of 23 June 2016 (the "Patient Organisation Co-operation Codex" or the "POCC"); iii) a Donation Codex Version 2.0 effective as from January 2020 addressing donations and grants to hospitals and certain institutions (the "Donation Codex"); iv) the Lobbying Codex effective as from 1 January 2017 (the "Lobbying Codex"); and v) a Joint Statement issued by the LF and LIF providing guidance on the conduct of clinical trials involving medicinal products (including non-interventional trials) in compliance with the advertising rules (the "Joint Statement") taking effect for trials commenced after 1 February 2016. The Advertising Codex, the POCC, the Donation Codex, the Lobbying Codex and the Joint Statement are hereinafter referred to as the "Codices". In addition, ENLI has issued supplementary guidance notes on: i) Advertising Codex Application Guidance Version 3.0 effective as from February 2020; ii) Donation Guidance Version 2.0 of January 2020, iii) ENLI Notification Guidance Notes of 25 June 2019, iv) Information Material and Documentation Guidance Notes, Version 1.0 of May 2019, v) Market Analysis Activities Version 1.0 of December 2018; vi) Pre-Launch Guidance Version 1.0 of April 2018; vi) Digital Media Guide Version 3,0 effective as from December 2017; vii) International Congress Guidance Version 1.1 of December 2017; and, viii) Financial Sponsorship Guidance Version 1.0 of June 2016. The ENLI guidance notes i) – viii) are hereinafter referred to as the "Guidance Notes". The Codices and the Guidance Notes are available in the Danish language, and some also in the English language, from ENLI's homepage: http://www.enli.dk/.

### 1.2 How is "advertising" defined?

The DHMA Guide defines "advertising" as any information dissemination, canvassing activity or inducement designed (intended to) promote the prescription, supply, sale or consumption of medicinal products. The ECJ's case No. C-316/09, pr. 29 (*MSD vs. Merckle*) recital 29 states that the concept of advertising is very broad. Hence, advertising includes: the promotion of medicinal products to the general public and HCPs; 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 HCPs; and payment of travelling and accommodation expenses for HCPs attending such meetings or conferences. Two types of material are not considered covered by the advertising rules, even if their content as such may be of a promotional nature, namely, a) medicinal information prepared by public institutions aiming to promote rational drug consumption, and b) submission to a HCP of a scientific article on a clinical trial, provided that the article is not commented upon, additional material is not enclosed and the article has been published in advance in a reputable and independent Danish or international journal. This exception even applies to articles summarising comparative medicinal product studies. The advertising definition excludes i) labelling and the accompanying package leaflet comprising the Summary of Product Characteristics ("SmPC"), ii) correspondence, including appendices of a non-promotional nature, needed to answer a specific question about a particular medicinal product, iii) factual, informative safety announcements and reference material, for example, packaging material changes, adverse-reaction warnings as part of general medicinal product precautions (safety) and recall announcements, iv) price lists and trade catalogues, which may comprise product names, forms, strengths, package sizes, prices and pictures of product packages, but not product claims or names of competing products, v) information brochures and homepages relating to human health or diseases, provided that there is no reference, even indirectly, to medicinal products, vi) patient information leaflets provided by a prescribing doctor or the supplying pharmacist, provided that the leaflet only contains objective information of importance to patients and their relatives, and which does not contravene the SmPC, vii) press releases believed to be of interest to the general public from the advertising rules provided that: a) the information offered holds general news value; b) the release is addressing the press; and c) the release is targeting a plurality of journalists or reporters only, for the purpose of having such information assessed and elaborated upon prior to publication by such recipients, and viii) unedited and complete reproductions of package leaflets, the approved SmPC, a publicly available evaluation report and the depiction of a medicinal product packaging, provided that the information made available in such a way that users must actively seek out the information, see ECJ's case No. C-316/09 (*MSD vs. Merckle*). This means that a company may publish, for example, a list of its medicinal products on its website with links to the SmPC and the package leaflet for each drug. For a non-HCP to access the latter, the user must make an active choice, e.g. by activating a link at the marketing authorisation ("MA") holders' homepage directing the user to the relevant document. This condition, which is inconsistent with the SmPC not being considered promotional, implies that the said documents may not be distributed directly to non-HCP users. The Marketing Act, which governs advertising in general, is construed to supplement the scope of the advertising definition to include presentations made in order to promote the supply of goods, advertising which may affect the economic behaviour of the addressee or is likely to injure a competitor (misleading advertising) and advertising comparing competing goods (comparative advertising).

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

Under the authority of para. 1–3 of Article 68 of the Act, Article 17 of the Executive Order No. 1153 on Advertising requires the marketing authorisation holder ("MAH"), or the one advertising, if different from the MAH, e.g. pharmacies, parallel distributors or even third parties without financial interests in the product sales, to store a copy of the corresponding documentation for the advertisement (reference is made to the Damgaard case ECJ C-421/07). The file must be in printed form or digital and, if the latter, in a standard format such as, but not limited to, .pdf, .tiff or .jpeg. In addition, information on the target group, how the advertisement has been distributed, a list of media used and when the advertisement was published must be stored. The documentation must be kept for at least two years and must be made available to the DHMA on request. Advertising material includes not only printed advertisements, but also documentation for non-printed advertisements, such as electronic advertisements made available on the internet. In July 2017, ENLI reached the conclusion that an MAH employee, who used her LinkedIn profile to inform her "followers" that her principal had had a new indication for an existing medicinal product granted, by such behaviour had breached the pharmaceutical advertising rules. The filing requirements can be complied with electronically by maintaining files in generally used and acknowledged formats. The obligations on the filing of the documentation related to donations, see question 4.3 below, are stricter. The DHMA has very broad powers to request copies for enforcement purposes, as it may address anybody who has been involved in the campaign, including advertising agencies. Otherwise, companies are not formally required to have compliance programmes in place.

**1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

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

Staff: Article 98 (1) of Directive 2001/83 requires that each marketing authorisation holder establishes a Scientific Service in charge of information about the medicinal products which the holder places on the market. In addition, the Advertising Codex requires that the Scientific Service takes responsibility for the approval and supervision of non-interventional studies. As per the Advertising Codex, the pharmaceutical companies are free to decide how best to establish such service(s), and whether there is one service in charge of both duties or separate services with clearly delineated duties. The Scientific Service must engage a medical doctor or, where appropriate, a pharmacist, who shall be responsible for approving any promotional material before release. This person must certify that he or she has reviewed the final form of the promotional material, and that it is in accordance with the requirements of the applicable laws and other rules, including industry regulations, is consistent with the SmPC and is a fair and truthful presentation of the facts about the medicinal product. The company must also designate staff with a corresponding background to maintain an overview of all non-interventional studies, particularly with respect to any responsibilities assumed by sales representatives. The staff must certify that he or she has reviewed the protocol for each non-interventional study and that it is in accordance with the requirements of the applicable code(s).

**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 HCPs;
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 HCPs.

As per the "Penalty & Fee List" of 1 January 2020, each notification triggers a fee of DKK 375 (approximately EUR 50). Notification deadlines for each kind of initiative are set out in § 21 of the Advertising Codex. Generally, the deadlines are 10 days before the event or, with respect to advertising materials, the same day that publication takes place. Invitations must include information that the advertising initiative complies with the above and either that it complies with the Codices applicable or has been pre-approved by ENLI (there is a pre-approval charge of DKK 6,000 + DKK 2,000 per assessment hour required in excess of two (DKK 25,000 for matters of urgency). Amendments to already pre-approved applications trigger a fee of DKK 2,000. All fees are exclusive of 25% VAT. 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, para. 2 of the Act to require the DHMA to offer pre-assessment of intended advertising initiatives. Until the Minister may do so, the DHMA is precluded from offering such service. Consequently, the DHMA cannot require an undertaking to submit an intended advertising campaign for pre-approval.

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

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

Both the DHMA and the Consumer Ombudsman have the powers to require that an advertisement be stopped, to require a corrective statement be issued and to take or require appropriate corrective action. The DHMA Guide authorises decisions to be appealed to the Minister, whereas action taken by the Consumer Ombudsman may be brought before the public courts of justice. However, decisions related to radio or television broadcasted advertisements may be appealed to the Board on Radio and Television Commercials, which may involve the DHMA and/or the Consumer Ombudsman in the complaint. The DHMA and the Ombudsman will focus on the breaches of the Legislative Basis. In the absence of such breach, the Codices and the Guidance Notes will not be enforced by the authorities acting *ex officio*. Administrative decisions may eventually be brought before the public 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? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?**

The sanctions for a breach of the advertising provisions of the Act or the Marketing Act range from fines to imprisonment for up to four months (1½ years where non-authorised medicines or fake medicines are involved). A breach of the Orders may be fined.

The DHMA enforces the Act and the Orders, whereas the Consumer Ombudsman enforces, or private interests initiate enforcement of, the Marketing Act, which is construed in

accordance with the ICC Code of Advertising and Marketing Communication Practice. Sanctions imposed by the Consumer Ombudsman are subject to judicial review, if required.

The self-regulated bodies enforce their statutes and rules on the basis of their contractual authority. According to the ENLI "Penalty & Fee List" of 1 January 2020 (the "Sanctions"), and ENLI's "Code of Procedure" (the "Procedures") of 15 May 2019, ENLI may impose sanctions ranging from reprimands and fines to public reprimands. In addition, ENLI may require a company in breach to issue corrective statements, recall and/or prohibit the use of illegal advertising material, publish a corrective statement in professional periodicals, and cancel or amend the content of arrangements (conferences, congresses, etc.) planned, including the sponsoring of such arrangement. Sanctions imposed must be publicly available for a period of no less than two years at the ENLI homepage, provided, however, that only the name of the company in breach is made public, whereas the names of any individuals involved due to data protection legislation, will not be published.

The Sanctions authorise ENLI to impose fines for the breach of rules governing i) advertising material in the range of DKK 30,000 (approximately EUR 4,000 – which has doubled since 2017) for minor, but repetitive formal errors (1st offence does not trigger a fine), such as a cover letter not being dated, an incorrect INN or API composition, to DKK 150,000 for misleading product claims (which has doubled since 2017), which may compromise public health, and ii) events in the range of DKK 30,000 for, e.g., meal allowance at arrangements lasting less than two hours, to DKK 150,000 for, e.g., meetings abroad with no professional content. Breaches of the Codices on counts other than incorrect advertising material/out of scope arrangements may trigger fines in the range of DKK 30,000 (approximately 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 moving two-year period, the fines otherwise applicable may be doubled (maximum DKK 300,000). In 2019 and 2020 fines in the amount of TDKK 30 (TEUR 4) have been imposed for extravagance in relation to use of golf resorts for HCP arrangements, unnecessary hotel stays, misleading advertising implying too-good-to-be-true physical strength improvements by intake of a given drug (alphabetically: Ibsen, Norgine, Pfizer, Servier), TDKK 40 for comparative advertising with insufficient source quotations, no indication and no identification of compared products (GSK, Nordic Drugs, Teva) and TDKK 50 for use of a 5-star hotel for an HCP arrangement, insufficient data in comparative advertising and biased drug claims (Mundipharma, Orion and Novo). In 2019 the accumulated sum of fines imposed comprised TEUR 81 against TEUR 107 in 2018.

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

A decision made by a self-regulatory body cannot be suspended or prejudiced by appeal to the DHMA. However, a party can bring a case before the DHMA, even though the case has been, or is being handled by a self-regulatory body, whose position may be considered by the DHMA assessing the case. Over recent years, ENLI's predecessor, NSL, sanctioned several companies for having offered to HCPs 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 HCPs, implying that the services partly constituted financial support to the doctor and partly impacted on the independence of the HCP from the service provider negatively. On request by the NSL, the DHMA scrutinised this practice and reached the conclusion that the SMS compliance service was a service rendered to the patients on a voluntary basis and that doctors were not relieved of any workload, as they are not normally involved in day-to-day compliance monitoring. On this basis, thereof NSL changed its practice, allowing for SMS-compliance services to be offered to patients, although through the prescribing doctor. In principle, such scrutiny by the DHMA can be initiated not only by ENLI, but also by any interest-holding *locus standi*. In a judgment (Case UfR2009-1618S) quoting Case SH2009.V-0132-05, see question 2.3 below: The Danish Maritime and Commercial Court dismissed a suit brought by MerckSerono against Ferring on the grounds that MerckSerono already had identical complaints heard by the NSL and the DHMA, whose decisions were accepted by both parties and implemented by Ferring, which was also fined by the NSL, and that MerckSerono consequently had no legitimate interest in also having the same complaints heard by the court.

ENLI may *ex officio* take up cases regarding companies that are subject to ENLI jurisdiction. As per 19 April 2020, the number of companies subject to ENLI jurisdiction are 90, comprising the members of LIF (42), IGL (13), and PFL (3), companies which are neither members of LIF, IGL nor PFL (31), and associations (1) having submitted to ENLI's jurisdiction voluntarily. ENLI remains in a strong position to enforce its rules against every relevant player on the Danish market, not at least indirectly due to ENLI having resolved to hear cases (see Annual Report 2015, pg. 2) brought by members against non-members, although it obviously cannot enforce decisions in the disfavour of non-members, rather merely hope for the DHMA to notice potential criticism expressed. In the absence of a breach of the Legislative Basis, the Codices and the Guidance Notes will not be enforced by the authorities acting *ex officio*.

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

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

## 2 Providing Information Prior to Authorisation of Medicinal Product

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

The Act, the DHMA Guide and the "*EFPIA Code of Practice*"

adopted by the EFPIA Board on 22 March 2019, and ratified by the EFPIA Statutory General Assembly of 27 June 2019 (Member Association implementation deadline 31 December 2020) prohibit the advertising of medicinal products for which a marketing authorisation has not been obtained as well as off-label advertising. As per §§ 64 and 77 of the Act, advertising is conditional not only upon a marketing authorisation having been obtained, but also – with respect to products that must only be supplied by pharmacies – on the price applicable having been notified to the DHMA.

In March 2017, however, ENLI issued a first Pre-Launch Guidance Note edition (Version 1.0 amended in April 2018), triggered by a DHMA decision passed on 28 May 2014, which latter decision set up a number of criteria determining whether an activity was to be considered scientific or promotional. On this basis, ENLI has softened its historic position, implying that, *inter alia*, the subjective intent by the "promoter" may play a role in borderline cases. On the basis of the DHMA 2014 decision, ENLI now considers a number of criteria when determining whether an activity is scientific or promotional, e.g. whether the basis for the presentation is scientific, the forum is professional, i.e. that the audience comprises a relatively selected audience, the data is purely scientific, the content and whether the presentation angle has been determined by the lecturers and not by the product proprietor. It is still a "Rule of Thumb" that information cannot be provided on drug candidates for which Phase III data have been published or data been obtained. Generally, this means that Phase I and II data may be presented (assuming that Phase III data are not available) and that an MA cannot be applied for on the basis of Phase II data only, which has been seen for a vaccine being registered under "*exceptional circumstances*" under the authority of Article 14 (8) of Regulation 726/2004 and Article 22 of Directive 2001/83, on the basis of Phase II data. The distinction implies that product information may be given in the context of a generic suitable presentation environment, e.g. at international congresses. It does not change the situation that the presentation may have been sponsored by the product proprietor. The change comprises a relaxation of the Advertising Codex rules applied in Denmark by ENLI prior to a DHMA satellite symposium decision of 28 May 2014 (the "2014 DHMA decision"), where the access to present product information prior to the MA was more limited than in most other EFPIA countries. The change of practice does not require a change of §§ 64 and 77 of the Act prohibiting advertising prior to the MA having been obtained and a price been notified, as the 2014 DHMA decision merely reflects how §§ 64 and 77 are to be construed. The change brings Denmark in line with most other European countries on this matter.

As per the Pre-Launch Guidance Note, the relaxation does not apply to off-label information in the sense that once a product has been authorised, the presentation of even early stage data on investigated new indications, will consider the promotion of the product as actually authorised. This seems to be a logical consequence of the products actually being available on the market, which creates an increased risk of off-label use, were presentation of expanded indications research to be allowed.

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

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

Having said this, the Pre-Launch Guidance Note edition (Version 1.0) referenced in question 2.1 above, authorises dissemination on unauthorised medicines, provided, however, that the criteria for the dissemination not being promotional are met. Hence, "publication" to a wider audience than the very limited number of professionals, who may be the addressees of scientific meetings, will not be allowed, especially not on off-label information, whereas very early scientific data will hardly trigger a sanction, if the sender can substantiate that promotion was not the intention. Information provided by sources independent from the MAH may be caught by the advertising rules, see the *Damgaard* case (C-421/07). As a consequence of this case ENLI has issued the Digital Media Guidance Note recommending that marketing authorisation holders (the "MAH") must monitor such social media, e.g. Facebook, Twitter, LinkedIn and YouTube, contributed to by the MAH, and remove communications, 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 to the general public (for which communication the Legislative Basis, but not the Advertising Codex applies) or is available from fora to which only HCPs have access, in which case the Advertising Codex applies. ENLI has, however, also indicated that the MAH cannot be held liable for third-party statements regarding third-party products (e.g. competing products), even if published on a MAH-controlled medium. We do believe, however, that a MAH should remove such statements, as the MAH may easily be challenged under the provisions of the Marketing Act, if not reacted to.

### 2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media) please specify.

The Advertising Codex and the DHMA Guide exempt press releases 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. Hence, a release will not be considered as a "press release", if it contains non-objective content, misleading information, appears to be advertising, if a payment, including in kind, is made for a release to be disseminated in the media, or if the release is made available only to a single journalist because of a solo agreement. Answering questions from a journalist on the basis of a press release is not covered by the exception implying that replies may be considered advertising on a stand-alone basis. If a release, subject to these conditions, is considered a press release, it would fall outside the scope of the advertising rules. If, however, the release includes an identification of named medicinal products, the release may well be considered pre-launch and hence subject to scrutiny as per the 2014 DHMA decision (and hence the ENLI Pre-Launch Guidance Note) criteria. As a press release by definition cannot address only a specific target audience and as a release to journalists can hardly meet the 2014 DHMA criteria, it is not possible for companies to issue press releases about unauthorised medicines and/or off-label information for an authorised product. This does not imply that a company cannot avail itself of the 2014 DHMA decision, but not by means of a press release defined as per the above.

As per the DHMA, press releases may be made available at the relevant company homepages for up to a maximum of three weeks, after which the press release may be considered advertising, rendering the press release exception inapplicable.

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 a DHMA resolution holding Ferring responsible for having identified medicinal products in what was classified as a press release, but, as per the DHMA, due to the identification of products in an internet-based release, was actually an advertisement addressing the general public.

On 29 August 2018, the Eastern High Court of Denmark confirmed the judgment passed on 17 March 2018 No. A-46-17 granting Sanofi-Aventis an interlocutory injunction preventing Novo Nordisk from making further use of a "press release" issued by Novo Nordisk on 15 September 2017. The "press release" described the outcome of a clinical study involving the *authorised* medicinal product Tresiba®. Although Novo Nordisk presumably had intended to describe the outcome of a clinical study named "DEVOTE" collecting data from use of both Tresiba® and Lantus® (Sanofi-Aventis), the header of the release referred to the "Tresiba®-study" rather than to the name of the study, which in combination with the comprehensive scope of the release and unsubstantiated claims made alleging reduced mortality, if severe hypoglycaemia could be avoided, implicitly by use of Tresiba®, qualified the communication as illegal comparative advertising comparing Tresiba® to Sanofi-Aventis' insulin products Lantus® and Toujeo®. The Court reached the conclusion that Novo Nordisk by means of the release had breached the Act, Executive Order No. 1153 as well as the Marketing Act and granted the injunction in combination with awarding costs to Sanofi-Aventis. ENLI's Appeals Board (case AN-2018-2631) followed up on the infringement and imposed a DKK 30,000 fine on Novo Nordisk. 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), i.e. that the medium itself is in effect advertising a drug to some extent .

**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 HCPs and others having made a specific enquiry to the company regarding the product properties. Subject to compliance with the Marketing Act's provisions on unsolicited addresses, submission to HCPs 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 your jurisdiction?**

As per § 2, No. 4 of Executive Order No. 1153 of 22 October 2014, price lists and product catalogues that do not contain information about medicinal products other than (trade) names, pharmaceutical forms, strengths, packaging sizes, prices and pictures of medicine packages published on the internet for e-commerce with drugs, do not qualify as advertising, see also question 1.2 iv) above. Hence, making price lists for named-patient/compassionate use purposes pursuant to Article 5 of the Directive available to pharmacists, without this being treated as illegal, is possible. However, the Marketing Act's provisions on unsolicited addresses should be observed together with the 2014 DHMA decision, which may render the message illegal, if the intent of the manufacturer is promotional.

**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 or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?**

As per the 2014 DHMA decision and ENLI's Pre-Launch Guidance Note, market research exercises are possible within the scope of the advertising rules implying that unlicensed products/new indications can be presented, but only to the extent the presentation is required for the HCP to render a specific service contracted. Such HCP must be a medicinal doctor (human or vet), dentist or pharmacist, but not other HCPs. The HCP must be engaged as a consultant or advisor, individually, or as part of a group, to render a specific service such as evaluating materials. The engagement must be in writing, specifying the services to be rendered and payments to be made, and the contract must be closed prior to the HCP rendering any services. Moreover, the following criteria must, to the extent applicable, be met:

a) a legitimate need for the services must be clearly identified before requesting the HCP to render the same and before closing the agreement;
b) the criteria for selecting HCP consultants should be directly related to the identified need and the persons responsible for the selection of HCP consultants must be competent to assess whether the HCPs meet the criteria;
c) the number of contracted HCPs must not exceed what is reasonably necessary for the MAH to receive the services;
d) the contracting entity shall maintain records of the services received and make proper use thereof;
e) the engagement of a HCP must not imply an incentive to recommend, prescribe, purchase, supply, sell or administer a particular drug;
f) the compensation for the services shall be proportionate and should reflect the real market value of the services provided (symbolic advisory meetings cannot justify payment of any compensations to HCPs); and
g) payment shall only be granted in the form of direct payments of money, and not by off-setting or transfer of assets or other indirect compensation.

From a HCP perspective, the consolidated Danish Health Act No. 1,286 of 2 November 2018, Chapter 61a (Co-operation

with the Industry), § 202a, prohibits medicinal doctors (human), dentists and pharmacists from operating or being affiliated with an MAH, unless the affiliation comprises i) education/training (primarily presentations of research results and treatment regimes) or research (primarily clinical research, including non-intervention studies), ii) ownership of MAH-securities, which – when purchased – did not represent a value in excess of DKK 200,000 (≈EUR 27,000) per MAH, or iii) if the MAH is a public hospital. If these conditions are met, the HCP must notify the DHMA of the affiliation, whereas the HCP must apply to the DHMA for approval if the conditions are not met. Applications will be denied if the DHMA finds that the services to be rendered may influence the prescription pattern of the applying HCP, which, as per DHMA practice, will be the case if the services relate to the preparation of marketing material. As per the Advertising Codex, the MAH is obliged to inform not only the HCPs of their obligations *vis-à-vis* the DHMA, but also the DHMA of an affiliation established between a HCP and the MAH. This double-notification system enables the DHMA to enforce the rules more easily, as the two lists can be compared and omissions identified. The DHMA, which must publish all notifications and applications received on its homepage, has on December 2016 updated its guidance notes on the relations between the industry (medicinal product or device manufacturers/marketers and i) doctors (Guidance Note No. 10360), ii) nurses (Guidance Note No. 10361), iii) dentists (Guidance Note No. 10362), iv) pharmacists (Guidance Note No. 10363), and iv) Guidance Note No. 10364 requiring medicinal product manufacturers, device manufacturers and device marketers to report annually on their relations to doctors, nurses, dentists and/or pharmacists to the extent covered by Guidelines Nos 10360–10363. Said Guidance Notes are unamended as of 1 April 2019.

## 3 Advertisements to Healthcare Professionals

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

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

1. Trade and generic ("INN") product name(s), i.e. all INN names if a combination.
2. MAH name.
3. Indications for use consistent with the SmPC.
4. Contraindications.
5. Side effects and cautions.
6. Dosage.
7. Product forms (strengths, methods of administration).
8. Package sizes.
9. The purchase price available from www.medicinpriser.dk + pharmacy margin (p.t. 7.9% compared to 8.2% in 2018) + DKK 5.46 as calculated in accordance with Executive Order No. 1,539 of 17 December 2019.
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 MAH and the logo only. On 22 May 2018, Sanofi-Aventis was reprimanded (Case KO-2018-1448 (§ 5, para. 1) for violation of the mandatory information rules, see http://www.enli.dk/media/49736/ko-2018-1448.pdf, by having invited HCPs to a meeting at which Toujeo® and Lantus® would be up for discussion, but without Sanofi-Aventis providing the product information what must accompany advertisements and without the invitation being dated.

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

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

Restrictions: Advertisements, or any other information addressing HCPs, must not contain competitions offering prizes. This prohibition is absolute regardless of whether an individual product is identified or not and regardless of the size and nature of the prize. However, prices for the best abstract or poster may be awarded at arrangements, provided, however, that the price is only used for professional purposes, such as HCP education, congress participation, etc.

Studies: 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.

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

The DHMA Guide prohibits HCP endorsements in campaigns addressing the general public, but not campaigns addressing HCPs. However, such prohibitions can be found elsewhere, e.g. in LEN's ethical rules, see question 1.1 above, as per which a medical doctor is not entitled to promote medicinal products or products making health claims. Other HCPs may make endorsements, which 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, implying that endorsements must be qualified and meet the documentation requirements applicable in general.

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

No, the advertiser may compare products by referring to parameters comprising, e.g., the respective SmPC's, while, however, observing the rules on comparative advertising.

**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 or indication, which had not yet been authorised in your jurisdiction?**

Yes, the advertiser must either ensure that the comparator products can be identified, implying that the advertiser is not only permitted, but almost required, to use a competitor's brand name in comparative advertisements, or provide data on all products available, approved for the indication. The rules governing comparative advertisements are set out in the Marketing Act, the Orders, in the DHMA Guide and in the ENLI Rules. Comparative advertisements must be based on the SmPCs and must also include supplementary data subsequently generated, provided it is SmPC compliant, complies with the general advertising rules, compares all relevant and available treatment alternatives, avoids product confusion, be loyal to the comparator products, be objective, and must not take unfair advantage of the reputation of a competitor brand. Effective as from 1 July 2015, the hitherto mandatory table comparing product properties has been abandoned for a trial period, which ended on 30 June 2016. The results achieved during the trial period have been evaluated and in the Annual Report for 2016 ENLI has announced that as no additional disloyalty issues have arisen, the comparison table has now been abandoned for an indefinite period of time. 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. Outside the scope of the Pre-Launch Guidance Note and hence outside the scope of the comparative advertising rules, it is not possible to refer to a competitor's product, which has not yet been authorised in Denmark, or to an indication of such product if not authorised in Denmark, as such product/indication does not represent a treatment alternative. As per an ENLI judgment (EN-2011-0001), the mere identification of more than one product in an address to HCPs, even addresses that the advertiser does not necessarily consider advertising, e.g. an invitation to an arrangement, will qualify as comparative advertising, requiring the sender to observe the rules applicable for such "comparisons", but it is possible that the 2014 DHMA decision may relax that position.

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

The Advertising Codex § 4, para. 3, comprises a direct translation of Article 8 of the EFPIA Code of Practice. This means that advertising materials used on exhibition stands or distributed to participants of such international events outside Denmark as per ENLI, as a minimum, must comply with sec. 2.01 in EFPIA's Code of Practice, which prescribes a set of minimum information to accompany the advertisement. Thus, there is no requirement that the compulsory information according to Article 5 accompany the advertisement, even if the event is also considered to be fully or partially targeted at Danish HCPs and therefore falls within the scope of the Advertising Codex. At international events in Denmark, the Danish legislation continues to apply, which means that only medicinal products that have a valid marketing authorisation in Denmark must be advertised. When it comes to the authority to – *in lieu* – present scientific papers to HCPs attending a congress in Denmark, it should be borne in mind that this exception cannot be found in the Act, whose §§ 64 and 77 still require that only authorised and price-notified products can be promoted. Considering, however, the 2014 DHMA decision, sponsors will in our view be able to build up a suitable presentation area meeting the criteria set out in question 2.1, para. 2 above (the presentation basis is scientific, the data is purely scientific, the forum is professional) and thereby be able to present non-authorised products/indications, if the intention is non-promotional. If the products are not registered anywhere, presentation of the scientific papers may take place subject to the 2014 DHMA criteria and the Pre-Launch Guidance Note being complied with. If, however, the sponsor is an affiliate of a Danish LIF member, ENLI may only enforce the ENLI Rules *vis-à-vis* the affiliate being a LIF member. Should the Codices and Guidance Notes be violated by an affiliated company, ENLI can, however, impose fines and a number of other strict sanctions such as withdrawal of promotional material, require public corrections or similar sanctions appropriate to the specific violation, but when the day ends, such execution of the baker *in lieu* of the blacksmith having committed the murder, will be challenging if the affiliation does not allow the LIF member any influence on what is taking place abroad implying that enforcement is subject to the LIF member agreeing to submit in its affiliated company's place. Otherwise this implies that a sponsor in reality may get away with segregating the Danish LIF member affiliate from the congress planning and execution, implying that the foreign sponsor affiliate only has to comply with the 2014-DHMA criteria, but not the Pre-Launch Guidance Note.

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

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. An address to HCPs encouraging the recipient to reserve a given date for an event "to be announced" is not considered advertising and does not need to be notified to ENLI, if the recipient cannot sign up based on the teaser and if the teaser does not include product information.

**3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?**

Part 1: Yes, a MAH holding a MA for combination product treatment of a disease may promote such combination product use irrespectively of the individual MA status for the API's incorporated in the combination product and irrespectively of whether any or different rights are held by the MAH or third-party MAH's for either API on a stand-alone basis. Of course, patent and data-exclusivity positions may prevent the combination product MAH from making such promotion, but looked upon from a pure advertising point of view, the MAH may promote any MAs that he holds within the scope of the associated SmPC granted for that specific MA. Part 2: Promotion of a pharmaceutical must take place within the limits of the SmPC

granted for the MA granted for the product itself. Usage not sustained by the SmPC comprises off-label promotion, which is not permissible. The MAH for product B must, in other words, first vary his SmPC for product B, which may be difficult considering the combination product MAH's potential patent and data-exclusivity positions.

## 4 Gifts and Financial Incentives

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

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

1. The recipient must be a HCP, authorised to prescribe the medicinal product in question, who is requesting the sample for a professional purpose that the HCP 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 HCP.
6. Dispensation is made by the MAH representative, not the pharmacy.
7. SmPC must be enclosed.
8. Narcotic/controlled medicinal product samples must not be dispensed.

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

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

### 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

As per § 22 of Executive Order No. 1153/2014, § 12 of the Advertising Codex, the latter amended to reflect the EFPIA Code of Practice of 27 June 2019 incorporating the EFPIA Code on the Promotion of POMs to, and Interactions with, HCPs of June 2014, the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations of June 2011 and the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations of June 2014, no pecuniary advantages or gifts (in cash or benefit in-kind) may be supplied, offered or promised to HCPs, except in connection with i) professional events, sponsorships and hospitality, ii) information and educational material and items of medicinal utility, and iii) donations and grants that support healthcare or research. Even the supply of so-called "leave-behind gimmicks", such as pens, post-it pads, notepads, etc., is no longer allowed, but arrangements in connection with third parties (no logos or product names) or by the sponsor itself (logos and product names allowed on pens, etc., supplied for the purpose of the HCP taking notes at a specific meeting) are permitted.

*Re* i) HCPs may receive training and professional information related to medicinal products in the form of payment of direct expenses in connection with professionally relevant courses, conferences, training and scientific events, in which the HCPs 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 HCPs, 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 and include drinks, VAT and any tips. When providing meals in other European countries, the monetary thresholds set by the pharmaceutical industry associations in such 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 HCPs 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 HCPs 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 HCPs and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA HCP Code or the POCC) 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 HCPs under which such institutions, organisations or associations provide any type of services to companies (or any other type of funding from pharmaceutical companies not covered under these ethical rules) are only allowed if such services (or other funding): a) are provided for the purpose of supporting healthcare or research; and b) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Companies which have not submitted to the ENLI Rules may still benefit from the at-present somewhat more liberal DHMA Guide, which allows HCPs, associations of HCPs or members of hospital administrations to receive gifts, provided that the market value does not exceed DKK 300 (approximately 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 HCP. From and including 1 January 2014 LIF members are, as per the ENLI Rules, no longer allowed to provide HCPs with neither "leave behinds" nor gimmicks, irrespective of the value thereof, but in connection with the execution of a conference, where note-taking tools will be permissible.

**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? If monetary limits apply, please specify.**

Yes, donations and grants that support healthcare or research may be provided, see question 4.2. Effective as from January 2020 a Version 2.0 of ENLI's initial Donation Codex made effective on 1 January 2017 took effect. Already as per Version 1.0 the scope of the Donation Codex was limited to apply to donations made to institutions, including Danish hospitals, or organisations either comprising HCPs or rendering health or research services. 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 directly or indirectly. It must be entirely up to the hospital/hospital department to manage and decide how to make use of the grant or donation. Donations to individual HCPs are not authorised by the Donation Codex. Donations and grants are authorised only if: i) the purpose is to support the rendering of health services or research; ii) the donations are registered by the sponsor; and iii) the donation is not an encouragement to consume, directly or indirectly, medicinal products. Hospital donations 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.

ENLI subjects are required to publish a schedule on their website containing the information covered by items 1–2 and 6–10 above. The schedule is to be published when the donation or grant has been made, and shall remain on the website for at least two years thereafter. During the subsequent eight years (10 years in total) the sponsors must be able to provide copies of the schedule on request. Donations made shall be reported annually via a template published by ENLI. 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, which relieve such sponsors from complying with a number of obligations, i.e. to have the donation approved by two hospital staff, compliance with the documentation requirements 1–10 above, to publish the sponsoring on their homepages and to report annually to ENLI on the scope thereof. There are no upper limits for sponsoring taking place in accordance with the Donation Codex.

**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 HCP activity funding, i.e. authorised as per an exception to the general rule that HCPs must not receive financial benefits, 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 MAHs. 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? If monetary limits apply, please specify.**

Although discounts will always comprise an economic advantage to the receiver, which as per Executive Order No. 1153/2014 § 22, para. 1 is prohibited, § 36 of the same Order exempts product discounts, which may be offered for all drugs to retail dealers, including pharmacies, provided that the discount is based on cost savings for the supplier as a direct result of volume savings or similar "cost-based discounts". No monetary limits apply, provided, however, that the rebate cannot exceed the savings realised. Permitted cost-based discounts include all drugs. The rules on access to provide cost-based discounts only apply to the relationship between supplier (whether a manufacturer, importer or wholesaler) and the retailer. Any discounts agreed between companies within the pre-retailer distribution chain, for example, between manufacturers/importers and wholesalers, are not covered by the rules on cost-based discounts. Pharmaceutical manufacturers and importers that make their own deliveries to retailers are, on the other hand, subject to these cost-based discount regulations.

Cost-based discounts should be calculated in relation to the supplier's direct and indirect costs, such as administrative expenses, payroll, inventory, transportation, 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 a 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 directly.

The discount must comprise a price reduction of the products included in the actual delivery triggering the discount. The cost-based discount must be clearly stated on the invoice, or a credit note issued immediately after delivery, to indicate how it is calculated, and it must be separate from discounts granted on products not covered by the restrictions. Bonuses must not be provided to the end-users of medicinal products, whether individuals or patient groups, neither directly nor indirectly. However, the hospital owners, the Regions, may be granted a bonus in connection with the sale of products to a hospital. If the purchaser reduces the number of deliveries by building up a bigger stock, it is possible to credit the purchaser for subsequent AIP reductions for a limited amount of medicines per every 14-day period.

**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? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?**

Whereas provision of donations and equipment may be possible under certain circumstances, see questions 4.2 and 4.3 above, making such provision contingent on the purchase of medicinal products may be illegal partly as per applicable completion law (tying/bundling) as the product markets may be narrow, and partly if the combination is construed to comprise a financial benefit to the customer. Whereas tying/bundling is not *specifically prohibited outside the scope of competition law practice, the offering of rebates are governed by § 36 of* Executive Order No. 1153/2014, which *requires rebates based on cost savings to be granted in the form of price reductions and not in the form of other services or benefits. Rebates, as well as the calculation basis for same, must be indicated in the invoice. Replacing the grant of a rebate by invoicing for services rendered separately will constitute a quid pro quo* arrangement implying a breach of § 36 and hence comprise if not a criminal kick-back, see question 4.9 below, then at least an unauthorised rebate comprising a breach of Executive Order No. 1153/2014. Were package deals to be offered, the offeror would have to consider competition law implications and the risk of the additional benefits being considered inappropriate benefits comprising rebates or gifts. If an offer was made in response to a tender, such offer would be inconsistent with the tender terms and be unacceptable to Amgros, representing the hospital owners.

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

A refund scheme can be and has been offered for certain products. The supply status is irrelevant in this situation. The refund principle reflects that some patients may not enjoy the envisaged benefits of taking the prescribed medicinal products in spite of the medicinal product being contractual. In June 2004, the DHMA announced that Novartis had launched a "pay back" scheme for Diovan®, noting that the DHMA, while not approving the campaign (which the DHMA cannot), did not consider the campaign as being a breach of the Act *per se*. However, the DHMA noted that such campaigns represent a challenge to the reimbursement system. Subsequently, the DHMA has accepted that Bayer is entitled to offer financial compensation to doctors who have to dispose of a *Mirena*® (levonorgestrel-releasing intrauterine device ("IUD")) as a result of the IUD having become unsterile. On the basis hereof, Bayer applied to the DHMA for permission to replace an unsterile IUD with a sterile one free of charge rather than providing financial compensation. The DHMA resolved that such procedure would comprise advertising and be inconsistent with Executive Order No. 1153/2014 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 GPs, without considering other replacement models.

**4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?**

As per question 4.7 above, certain indirect risk sharing schemes are in theory possible. However, prices of medicines, except for certain types of over-the-counter medicines and natural medicinal products, are fixed by the MAH and sold at the same prices from all pharmacies in Denmark. Prices of medicines are fixed for 14-day periods. The companies report changes in prices for each unit marketed every fortnight to the DHMA, which subsequently publishes the prices reported on medicinpriser.dk. When also considering § 20 of Executive Order No. 1153/2014, as per which the general public must not be offered reimbursement of meals, travelling, accommodation, or other financial benefit, the prohibition of which is absolute and independent of the scope and value of the expenditure, it is in practice difficult to implement schemes which can actually be administered; reference is made to the Novartis "pay back" scheme referred to in question 4.7 above.

**4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?**

Several models have been put in place enabling public-private co-operations. Public institutions and private companies may

join forces as development partners in innovation partnerships ("OPI") for the purpose of developing new innovative solutions to problems pre-defined by the partners. There are examples both of large well-structured OPI programmes and of small locally anchored OPI projects. At the local level, municipalities have the possibility of participating in joint public-private companies based on Act No. 548 of 8 June 2006 (L548) authorising municipalities to become minority shareholders in limited liability companies ("L548 Companies") or on the basis of municipal proxy rules. The objective of L548 Companies shall be sale of products and/or services generated on the basis of municipal or regional knowhow. If a market does not yet exist for a service considered, an L548 Company may comprise a first stepping stone for having a service, which the public expects to benefit from, rendered privately. L548 Companies are managed by a board of directors elected at a general meeting. Both OPIs and L548 Companies are to be notified to the DBA. At the end of 2013, the Minister of Health launched an action plan for co-operation between HCPs and the pharmaceutical and medical device industries aiming at introducing new legislation supporting exchange of knowledge and experience between the public healthcare system and the industry sustaining patient care. A key criterion was that the co-operation had to be carried out in a manner promoting professional benefits from such co-operation, ensuring patient confidence in the treatment they are offered in the Danish healthcare system and in a manner preventing legal incapacitation. In May 2014, the Danish Government presented an action plan aiming at increasing the number of clinical trials carried out in Denmark, whether GCP sponsored, private or public, over a period of three years in terms of number of subjects enrolled and number of trials, while securing a high-quality standard. A comprehensive co-operation has also been set up between LIF and the Danish Regions on knowledge sharing, see, e.g., http://www.enli.dk/en/collaboration-with-the-danish-regions/region-hovedstaden/.

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

The Advertising Codex § 13 authorises the sponsoring of (continued) medical education to an individual HCP carrying out a training programme, whose scope is entirely professional, whose content the sponsor is fully aware of, but does not influence in any way and which in no way whatsoever is promotional. The latter condition is also decisive for the sponsoring not being caught by § 22, para. 1 of the Act. If these conditions are met, Ph.D. projects, for example, may be sponsored directly, whereas undefined "training tuitions" cannot be paid for and training in administrative systems or organisational development cannot be sponsored.

**4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?**

Whereas no specific anti-bribery rules apply to pharmaceutical companies, HCPs and HCOs, the Danish Penal Code Consolidated Act. No. 976 of 17 September 2019 does contain two anti-bribery provisions, namely §§ 122 and 299. These provisions apply to bribery of civil servants and persons abusing fiduciary positions, respectively.

§122 stipulates that anyone who provides, gives or offers benefits or advantages to civil servants or other persons holding public offices, for the purpose of the recipient exercising public duties in a given manner, may be imprisoned for up to six years.

§299, par 2, contains a supplement as per which an administrator of third-party financial interests may be imprisoned for up to four years if the administrator – through his administration – obtains benefits or advantages for himself or others. The punishment described also applies to anybody who may have offered the administrator the benefit, etc.

Breaches of the Penal Code will be investigated by the Police, normally following receipt of a report from an aggrieved party. If the alleged breach of the Penal Code also implies that the Legislative Basis has been breached, the Prosecution Service may file suits demanding punishment not only for the breach of the Penal Code, but also for the breach of the Legislative Basis. Obviously, the Prosecution Service will not consider either the ENLI Rules or the Guidance Notes, but breaches thereof may be enforced simultaneously by ENLI, which will consider breaches thereof independently of the Penal Code breaches. There is no reason to believe that the Prosecution Service will postpone their dealing with the alleged Penal Code breaches pending a DHMA or ENLI conclusion of their investigations, as Penal Code breaches can be pursued without prejudicing the ability of the DHMA and/or the ENLI to consider the promotional advertising rules on a stand-alone basis and to impose sanctions on the offender irrespective of the results achieved by the Prosecution Service.

## 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 and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?**

Expenses in connection with promotional, educational and scientific campaigns arranged for HCPs may be sponsored, whereas non-professional activities such as entertainment, sightseeing trips, etc., may not.

Hence, support may be granted for the renting of premises, study materials, fees and travel expenses for lecturers, participant payment and hospitality costs. In cases where sponsored events are held away from the participants' normal places of work, the business may bear the costs of travelling and accommodation for the participants.

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, implying that First Class travelling will always be prohibited. Hospitality expenses must be kept at a reasonable level and be subordinate – with respect to finance, as well as time – to the professional purpose of the event, which – for food (other than sandwiches, fruit and low-cost beverages) to be served, see question 4.2 on value thresholds – must exceed two hours' duration. For accommodation at a hotel to be sponsored, the event must last at least six hours and be continued the following day.

The approved cost limits include beverages, VAT and tips. Full transparency is required with respect to identification of the meeting organiser, the purpose of the arrangement, any financial support given and by whom.

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. For events abroad, the thresholds applicable in that foreign country are applicable, i.e. that each "EFPIA country" determines the locally applicable thresholds applicable to arrangements to be held in that country. There is no requirement in the ENLI Rules that a Danish LIF member must obtain approval by its local affiliate of events taking place in that jurisdiction. However, co-ordination is recommendable as the local affiliate may be considered liable in its own right for breach of the local rules, if the local affiliate participates in the event.

As per § 202b of the Health Act, see question 2.7 above, HCPs must report sponsor contributions received for travelling abroad, to the DHMA.

As for any other arrangement, ENLI must be notified in advance of any event addressing Danish HCPs 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. In addition, notification must take place in the country in which the company affiliate offers the hospitality, if required as per national rules.

**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?**

Yes, direct expenses to a meeting participation, whether educational, scientific or promotional, as well as payment or reimbursement of expenses defrayed for meals, travelling, accommodation, and other professionally relevant activities in which a HCP participates or which a HCP is hosting, can be sponsored. However, such expenses must be "reasonable" and must be offered solely to the extent relevant for the permitted advertising activity and solely in close connection with the same timing-wise. HCP remunerations cannot be made on the basis of loss of income or time consumption as such. The criterion is the arm's length value of the service provided.

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

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

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

The DHMA does not apply *absolute maxima* for the sponsoring of HCP costs. However, the language used also calls for costs not to be excessive, so were the DHMA to consider a matter where a MAH had sponsored an event, it is likely that the DHMA would take inspiration from the Advertising Codex thresholds.

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

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

Yes, HCPs may teach at meetings or render services to the sponsor against a reasonable cash remuneration, whereas the offering of values in-kind and of reimbursement is prohibited by § 24 para. 2 of Executive Order No. 1153/2014 (reference is made to question 4.2 above). Subject to DHMA approval, doctors, dentists and pharmacists may become members of advisory boards, directors or assume other positions, which in theory may impact the prescription pattern. Companies engaging HCPs must report such engagements to the DHMA. Furthermore, any relevant and reasonable travel and accommodation expenses in connection with such arrangements may be paid for, whereas social activities cannot be sponsored. Focus groups must be used with care, as the advertising rules must be complied with when the participants are involved in the discussions required. The mere approval by the DHMA for a HCP 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 HCP may participate in a post-marketing surveillance study and may receive payment for services rendered in connection herewith, subject to observing the restrictions set out in question 2.7 above. Whereas, post-marketing non-interventional studies are subject to the ENLI Rules, clinical pre-marketing trials are subject to DHMA and ethical committee jurisdiction and hence not monitored by ENLI. However, the rules on venues, entertainment, use of consultants and transparency apply to all studies, whether pre- or post-marketing. The Joint Statement signed on 18 December 2014 clarifies the values that form the basis for HCPs and companies co-operating on trials and non-interventional studies. The Joint Statement aims at ensuring that the involved interests are independent. Although non-intervention trials do not require approval in Denmark by the DHMA or ethical committees, the Joint Statement suggests that trial plans should be submitted to the DHMA, which has undertaken to provide guidance on whether a trial is an

intervention trial or a non-intervention trial, and – in response to a specific query – render guidance on the rules on promotion and its interpretation associated with non-intervention trials.

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

Yes, HCPs may be compensated for taking part in market research within the scope of § 24 of Executive Order No. 1153/2014 and sec. 5.6.2 of the DHMA Guide, which reads as follows: "*The prohibition against providing financial benefits for healthcare personnel does not cover payment for services from individual healthcare personnel or a pharmacy if the fees are commensurate with the service provided. [] Fees may only be paid in money.*" Accordingly, HCPs may only receive payment for a service to a pharmaceutical company if the service forms part of a normal, mutually obligating agreement between the person and the company and if the service and consideration are commensurate. This might, for example, be payment for doctors' professional assistance in undertaking clinical trials or drawing up information material on medicinal products. It could also be remuneration to a HCP, who sits on an advisory board, who is to be a speaker at a professional event or who provides services in connection with market research.

ENLI introduced a guide (Version 1.0) on market research in December 2018 which, in terms of payment of HCPs, is in line with the above-cited Executive Order and the DHMA Guide.

## 6 Advertising to the General Public

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

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

Advertisements addressing the general public must inform the addressee that this is an advertisement promoting medicinal products and the advertisement must contain certain data, e.g. name, the package sizes, prices, indication, side effect, dosage, and an encouragement for the patient to check out the patient information leaflet. When advertising on film and radio, the requirements regarding package sizes and pricing do not apply.

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

The 3 April 2019 Guidelines No. 9296 of 1 April 2019 regarding Over-The-Counter medicines was issued ("The OTC Guidelines"). The OTC Guidelines instruct the MAH to include the below information in advertising directed at the general public when such advertising is placed in a pharmacy. E.g. a poster in a pharmacy containing information regarding a pharmaceutical is regarded advertising. Also, when a MAH pays the pharmacy for placing their product on a given spot in a pharmacy, the mere placing of the product in this spot results in such activity being regarded as advertising.

In order to ensure the credibility of the commercial and to avoid bringing information which could confuse ordinary consumers, the Orders contain 14 types of information that are prohibited, including: (i) statements claiming that common well-being may be reduced if the medicinal product is not used; (ii) recommendations by HCPs encouraging consumption of medicinal products; and (iii) discussions on fatal diseases or symptoms thereof. In advertisements, addressing the general public on the use of HCPs, or HCP look-a-likes, is not permitted.

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

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

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

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

**6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?**

In theory yes, in practice no. Although the pharmaceutical advertising rules do not apply to press releases containing brief, objective information on a medicinal product, which has general news value, with the press as the target group and circulated or made available to a multiplicity of journalists or the media with a view to journalistic review and processing prior to publication, a release comprising POM information will be considered advertising, as the mere mentioning of POMs will be considered promotional, even if the content is objective content and non-misleading. Also, if payment is made for a press release to be printed in the media, it is regarded as advertising irrespective of the content.

A pharmaceutical company can make a press release available to the media in the press room of its website for about three weeks. After that, it will no longer be regarded as having general news value and may, after a specific assessment, be regarded as advertising. However, the industry needs to act responsibly considering the risks represented by the *Damgaard* case and the DHMA resolution quoted above under question 2.3, if the recipients of press releases are not familiar with pharmaceutical advertising. It might be worthwhile for the industry to consider adding a disclaimer to their releases summarising the key findings of the *Damgaard* case. With respect to unauthorised medicines, press releases can be released subject to the company complying with the Pre-launch Guidance Note, whose guidance presumably will also be accepted by the DHMA, when it comes to press releases made by non LIF-members.

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

Annual Reports and other general information addressing stock market/investors, or other addressees falling outside the scope of HCPs, 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-HCPs 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 happen to qualify as HCPs, would not be entitled to receive information distributed under the exceptions otherwise applicable; see below. As per the 2014 DHMA decision, see question 2.1, it is now clear that the subjective intent of the sponsor may impact on whether published materials are considered promotional or not. As long as corporate brochures and Annual Reports are only distributed to investors, analysts and stock exchanges for the purpose of promoting investments in the company and not the individual products (to be) marketed, such documents will not be caught by the advertising definition in the Orders or the Advertising Codex.

If, however, the brochures and Annual Reports are used by the sponsor to address HCPs in their capacity as such, product information included in brochures and Annual Reports may cause the same to be caught by the advertising definition.

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

"*Danske Patienter*" (Danish Patients), http://danskepatienter.dk/about-danish-patients, is an umbrella organisation whose members comprise 20 patient organisations, representing 102 patient associations, having some 900,000 members (April 2020). As per http://netpatient.dk, a portal providing health information, the total number of patient associations is 172 (April 2020). MAHs may sponsor patient organisations subject to compliance with the POCC, which requires transparency through all sponsorships being made in a written contract identifying the parties, the project sponsored, the type of project (contributions to general activities/specific arrangements, informational campaigns, etc.), the objective, the roles of the parties involved, the period of time for the sponsorship, the support budget, the costs that can be covered and non-financial support, if any. All contracts must be publicly accessible via the homepages of the sponsors for the duration of the co-operation and for at least six months after. 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 POCC defines standards applicable for companies sponsoring meetings, compliance with the Legislative Basis at all times, non-exclusivity and legal capacity. Representatives from patient organisations may be used as speakers and be remunerated subject to contracts to this effect being closed, fairly much as per the principles applicable to HCP Consultancy Agreements.

**6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?**

Per definition patients are considered the general public in relation to the Legislative Basis and the Advertising Code. The Advertising Code prohibits wining, dining and accommodation from being offered to the general public in connection with advertising campaigns. However, support may be granted for all activities, projects and purposes within the sphere of the organisation's work, as long as it is non-promotional. Professional activities should always be the main intention of the collaboration. Services must be proportionate to the compensatory measures. Events organised or sponsored by, or on behalf of pharmaceutical companies, must be held at a suitable location that contributes to the main purpose of the event, and which is not renowned for their entertainment facilities or is too extravagant. Catering and hospitality associated with events must be limited to expenses for transportation, meals, accommodation and fees for participation. All kinds of catering and hospitality must be reasonable in level and strictly limited to the purpose of the event. In connection with events, the company's hospitality must not include sponsoring or organising entertainment of any kind (e.g. sporting, culture, music or leisure events). Catering and hospitality may only be offered to persons who qualify as participants in their own right. In exceptional cases, catering and hospitality of an accompanying person who meets health/supporting/caring needs (e.g. as a helper) can be provided.

## 7 Transparency and Disclosure

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

All authorised clinical trials must be registered in publicly acknowledged and accessible registers such as www.clinicaltrials.gov or www.clinicaltrialsregister.eu, which is acknowledged and supported in the Joint Statement, see question 1.1 above. These requirements originate from the principle of the Helsinki Declaration that both negative, as well as positive findings, should be made public. The principle has now been re-confirmed in Article 25, para. 6 of the 536/2014 Clinical Trial Regulation. During the trial, § 89 of the Act requires a sponsor to notify the DHMA i) immediately, if unexpected serious adverse reactions occur, ii) within 15 days, if a sponsor needs to abort the trial, in which case the DHMA must be informed of the reasons, and iii) annually, of all serious adverse events incurred and subject to safety. Within 90 days from close-out the sponsor must inform the DHMA hereof and without undue delay, and in any case within one year after close-out, submit the trial result to the DHMA.

**7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?**

§ 21 of Executive Order No. 1153/2014 requires that patient organisations publish on their website all economic benefits, including financial sponsorships, whether in cash or in kind, and their value/scope, that the organisation has received from MAHs (in that case the marketing authorisation triggers the

reporting requirement). The information must be made available on the websites within one month after the patient association has received an economic advantage, and must be available on the website for at least two years.

**7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?**

By means of LIF, IGL and PFL, and hence all of their members having adopted the EFPIA Code of Practice, including its disclosure requirements, full transparency is required irrespective of whether the recipient is a HCP or a healthcare or patient organisation. As a company, to become an LIF member, it is necessary to be active in research, development, manufacturing or commercialisation of medicinal products, the transparency rules also apply to companies that have not yet been granted a marketing authorisation, and to foreign companies, provided, however, that they are actually members of LIF, IGL or PFL. The transparency principles are reiterated in § 4 of the POCC, § 10 of the Donation Codex and the introduction chapter ("General") to the financial sponsorship Guidance Note. The POCC requires that contracts meet certain minimum standards, that they are publicly accessible at all times via the internet and for at least six months after the termination of the co-operation, that copies of contracts no older than 10 years are handed out on request, and that the company annually and before 31 December submits a list to ENLI of all co-operation projects. ENLI publishes these lists. Moreover, as per § 10 of the Donation Codex, each donation made to hospitals must be published on the donor's homepage, when the donation has been granted and must remain accessible for as long as relevant, and at least two years. A copy of the list shall be handed out on request, when no longer accessible on the homepage, although donations older than 10 years do not need to be included. This list shall also be submitted to ENLI annually upon elapse of the calendar year reported. Finally, the financial sponsorship Guidance Note encourages companies to request that sponsored events are fully accounted for by the company receiving accounts for the sponsored events.

As per the EFPIA Disclosure Code, disclosures shall be made within six months after the end of the relevant reporting period, and the information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable national data privacy laws or other laws or regulations, or (ii) the recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked. The companies and interests affected will be those subject to ENLI jurisdiction. It may be noted that the reporting standards required by the Codices and the Guidance Note differ from those of the ENLI Disclosure Code.

**7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?**

If the company informs the HCP of the company's obligation as per the Advertising Codex to notify the DHMA of the affiliation established between the HCP and the company, see question 2.7 item f. above, we trust that the HCP will realise that non-disclosure is not an option.

## 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 Executive Order No. 1153/2014 and the Digital Media Codex, which stipulate 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.

ENLI issued the Guide regarding use of digital media in advertising activities (The Digital Media Guide Version 3.0 of December 2017). The Digital Media Guide, Annex D, stems from Annex B to the former EFPIA's Code on the Promotion of Prescription-Only Medicines To, and Interactions with, Healthcare Professionals, and the guidelines are supplements to this code. The Digital Media Guide has not yet been updated to reflect the consolidated EFPIA Code of Practice.

The DHMA and ENLI are monitoring internet advertising (see question 8.4 below); often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark and if the local affiliate of the advertiser has not been involved, ENLI has no jurisdiction to interfere. The DHMA, however, may be able to enforce the Legislative Basis when advertising is aimed at the Danish public or HCPs, reference is made to C-173/11, Football Dataco Ltd., *et al. vs.* Sportradar GmbH. ENLI has advised that dissemination of scientific data via electronic portals managed by an expert committee is likely to be considered promotion, as the sponsor takes the initiative to the portal and is paying the committee members. *In lieu*, ENLI recommends the use of advisory boards.

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

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

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

Advertising on the internet is subject to the same requirements as the requirements applicable to advertising in other media, and there are no special rules for references made to external links. Activities with social media that are controlled or influenced by a company must be monitored and controlled by the company, as it may otherwise incur liability for third-party statements which are not in compliance with the advertising rules. Hence, the

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

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

Advertising of non-prescription medicines to the general public is generally permitted, provided that the medicinal product can be used without diagnosing or medical supervision being required. Advertisements addressing the general public must inform the addressee that this is an advertisement promoting medicinal products and the advertisement must contain essential information; see question 6.1 above. In May 2009, the DHMA required two MAHs to withdraw advertisements released on their homepages. In the case of Pfizer, the DHMA found that information on the homepage regarding Carduran® Retard should be considered as advertising. Such advertisement could be accessed by members of the public and was therefore prohibited. In the case of GlaxoSmithKline, the DHMA resolved that, while the information on the homepage qualified as an advertisement for non-prescription medicines, the information mandatory as per question 6.1 was not indicated, implying that the DHMA required the advertisement to be withdrawn.

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

The use of social media in connection with advertising activities is now governed by the Digital Media Guide of December 2017, Version 3.0, which, however, needs to be updated as per the consolidation of the EFPIA Code of Practice. The Digital Media Guide requires advertising using digital (previously referred to as "social") media to comply with the requirements of the Legislative Basis and includes numerous practical advice on the administration.

## 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?

In 2019, approximately 428 promotional activities were self-reported to ENLI each month, as required (pre-vetting procedure). Of these, ENLI's Investigator Panel has reviewed 48.8% of the reports in a random control procedure approving 98.4% of the activities, whereas sanctions were decided in 1.6% of the evaluated reports. Three complaints were filed against an affiliated pharmaceutical company. Complaints led to sanctions in two of the decided cases. In 2019, the EFPIA Code was consolidated incorporating the EFPIA Code on the Promotion of POMs to, and Interactions with, HCPs of June 2014, the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations of June 2011 and the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations. This has called for a number of amendments to be made to the Guidance Notes and ENLI has not yet completed the work, see above about, e.g., the Digital Media Codex, but will in doing so in all likelihood be successful in complying with the 31 December 2020 deadline. Also, ENLI has published the Information Material and Documentation Guidance Notes, Version 1.0 of May 2019. These notes provide an excellent overview of a number of the most frequent questions arising in relation to pharmaceutical advertising; however, there are a great number of Codices and Guidance Notes, which also have to be read and construed in light of decisions made by ENLI on cases presented, and Annual Reports, which leads one to begin to wonder whether it would be possible for ENLI one day to simply rely on the Legislative Basis, the EFPIA Code of Practice and precedents.

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

ENLI focuses on transparency and on increasing the general knowledge about ENLI and its activities only among LIF, IGL and PFL members, as well as among other stakeholders in the pharmaceutical environment, such as patient organisations. In line herewith, ENLI has continued to prioritise preventive activities. In 2019, ENLI has published 36 decisions (including 22 administrative reprimands), seven newsletters and updates to the Advertising Codex. Moreover, ENLI has conducted eight courses on the regulation, primarily the Promotional Code, and four presentations to collaborative partners, networks, medical societies, etc. This proactive approach is expected to be continued.

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

In 2019, ENLI received 5,144 notifications, an increase from 5,056 in 2018. The ENLI panel of investigators reviewed 39.8% of the 2019 notifications against 49.7% of the 2018 notifications. 98.4% of the activities were approved against 98.6% in 2018, whereas sanctions were imposed in 1.6% of the cases against 1.4% in 2018 of the cases evaluated, triggering fines in only 0.9% of the cases in 2019 against 0.6% in 2018, which continues to reflect a high compliance ratio. Although the number of fines increased slightly, the fine income for ENLI was reduced from TEUR 107 in 2018 to TEUR 81 in 2019 due to the breaches having been fined generally being less critical. Fines are primarily imposed when notifications are not made in time or where submissions are incomplete. All decisions which impose a sanction on a company are published (in Danish) on ENLI's website, www.enli.dk. In general, ENLI is satisfied that companies subject to its jurisdiction strive to comply.

**Jan Bjerrum Bach** was born in 1963 in Copenhagen, Denmark. After graduating from the University of Copenhagen (Master of Laws) in 1987, and after having completed a training programme in the Copenhagen City Law Firm Møller, Tvermoes & Hoffmeyer, Jan was admitted to the Bar and was granted High Court advocacy rights in 1991. Thereafter 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 the acquisition and divesting of product rights, joint ventures and strategic licensing and alliance arrangements, primarily in Europe, Japan and the United States of America. In addition, Jan was responsible for the casualty insurance programmes of the group, a responsibility that led to Jan being appointed General Counsel and Executive Vice President in 1999 of a globally operating reinsurance group, whose operations were ceased in 2004 as a result of the 9/11 2001 attacks on the USA.

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

Jan primarily advises on the legal implications of R&D activities (medicinal products and devices) and cross-border co-operations, and is the secretary and treasurer of BioLawEurope. He is also the contact person for Ira Nordlicht, who is in charge of Jusmedico's New York representative office.

**Jusmedico Advokatanpartsselskab**
Klampenborgvej 248, 1. mf.
DK-2800 Kongens Lyngby
Denmark

Tel: +45 4548 4448
Fax: +45 4548 4449
Email: jbb@jusmedico.com
URL: www.jusmedico.com

**Martin Binzer Lind** was born in Rønne, Denmark in 1977. In 2013, after graduating from the University of Copenhagen (Master of Laws) in 2004, and being admitted to the Bar following completion of a training programme in Advodan Glostrup, Martin was matriculated at the University of Alicante, Spain, where he obtained an LL.M. degree in intellectual property rights in 2013.

From 2013–2015 Martin worked as a business developer for hospitals in the Capital Region of Denmark. From 2015–2017 Martin mainly served as legal counsel to a listed Danish biotech company in all matters related to research and development, intellectual property strategies and the general data protection regulation ("GDPR") in the EU and Denmark. In 2018, Martin joined Jusmedico as a Partner.

**Jusmedico Advokatanpartsselskab**
Klampenborgvej 248, 1. mf.
DK-2800 Kongens Lyngby
Denmark

Tel: +45 4548 4448
Fax: +45 4548 4449
Email : mbl@jusmedico.com
URL : www.jusmedico.com

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

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

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

Jusmedico is regulated by the Danish Bar and Law Society and audited by Ernst & Young LLP, Copenhagen.

In 2018, 2019 and in 2020, Jusmedico was awarded the Corporate INTL Global Award Price as *Biotech Law Firm of the Year in Denmark*.

**www.jusmedico.com**