

---

**GLG**

---

Global Legal Group

# The International Comparative Legal Guide to: Pharmaceutical Advertising 2011

A practical cross-border insight  
into pharmaceutical advertising

Published by Global Legal Group  
with contributions from:

Adams & Adams  
Advokatfirmaet Grette DA  
Arnold & Porter (UK) LLP  
Arthur Cox  
Avbreht, Zajc & Partners Ltd.  
Biolato Longo Ridola & Mori  
Bird & Bird LLP  
Borislav Boyanov & Co.  
Čermák a spol.  
Clayton Utz  
Clifford Chance  
Debarliev, Dameski & Kelesoska Attorneys at Law  
Epstein Becker & Green, P.C.  
Faus & Moliner  
Field Fisher Waterhouse LLP  
Herbst Vavrovsky Kinsky Rechtsanwälte GmbH  
Hwang Mok Park P.C.  
Jones Day  
Jusmedico Advokatanpartsselskab  
M. & P. Bernitsas Law Offices  
Mannheimer Swartling Advokatbyrå  
Marić & Co Law Firm  
McMillan LLP  
Molitor, Avocats à la Cour  
NautaDutilh  
Nishimura & Asahi  
Olivares & Cia., S.C.  
PDG Avocats  
Pinheiro Neto Advogados  
Roschier, Attorneys Ltd.  
Schellenberg Wittmer  
Sołtysiński Kawecki & Szlęzak (SK&S Legal)  
Taylor Wessing LLP  
Tilleke & Gibbins  
Tonucci & Partners  
YükselKarkınKüçük Attorney Partnership

# GLG

Global Legal Group

#### Contributing Editor

Ian Dodds-Smith,  
Arnold & Porter (UK) LLP

#### Account Managers

Monica Fuentes,  
Dror Levy, Florjan Osmani,  
Oliver Smith, Rory Smith,  
Toni Wyatt

#### Sub Editors

Jodie Mablin  
Suzie Kidd

#### Senior Editor

Penny Smale

#### Managing Editor

Alan Falach

#### Deputy Publisher

George Archer

#### Publisher

Richard Firth

#### Published by

Global Legal Group Ltd.  
59 Tanner Street  
London SE1 3PL, UK  
Tel: +44 20 7367 0720  
Fax: +44 20 7407 5255  
Email: info@glgroup.co.uk  
URL: www.glgroup.co.uk

#### GLG Cover Design

F&F Studio Design

#### GLG Cover Image Source

iStockphoto

#### Printed by

Ashford Colour Press Ltd.  
June 2011

Copyright © 2011  
Global Legal Group Ltd.  
All rights reserved  
No photocopying

ISBN 978-1-908070-02-9  
ISSN 1743-3363



#### Preface:

■ Preface by Tom Spencer, Counsel, GlaxoSmithKline Plc.

#### General Chapters:

1	<b>Control of Advertising of Borderline Products: Medical Devices, Foods and Cosmetics - Jackie Mulryne &amp; Elizabeth Driver, Arnold &amp; Porter (UK) LLP</b>	1
2	<b>Private Actionability of Mis-advertising of Pharmaceutical Products - Jarste Akkermann &amp; Ulf Grundmann, Bird &amp; Bird LLP</b>	9
3	<b>Pharmaceutical Promotion and the UK Bribery Act - Alison Dennis &amp; Tony Lewis, Field Fisher Waterhouse LLP</b>	15
4	<b>Social Media and Pharma in the UK: a Review of the Pitfalls and the Latest Guidance - Tim Worden &amp; Anna Furness, Taylor Wessing LLP</b>	20

#### Country Question and Answer Chapters:

5	<b>Albania</b>	Tonucci & Partners: Enkelejda Muçaj & Itena Ndroqi	26
6	<b>Australia</b>	Clayton Utz: Colin Loveday & Greg Williams	33
7	<b>Austria</b>	Herbst Vavrovsky Kinsky Rechtsanwälte GmbH: Sonja Hebenstreit & Isabel Funk-Leisch	43
8	<b>Belgium</b>	NautaDutilh: Liesbeth Weynants & Christel Brion	54
9	<b>Bosnia &amp; Herzegovina</b>	Marić & Co Law Firm: Branko Marić & Nusmir Huskić	64
10	<b>Brazil</b>	Pinheiro Neto Advogados: José Mauro Decoussau Machado & Larissa Maria Galimberti Afonso	71
11	<b>Bulgaria</b>	Borislav Boyanov & Co.: Kina Chuturkova & Radoslav Rumenov Alexandrov	82
12	<b>Canada</b>	McMillan LLP: Bill Hearn & Les Chaiet	92
13	<b>China</b>	Jones Day: Chiang Ling Li & Huang Haifeng	104
14	<b>Czech Republic</b>	Čermák a spol.: Lukáš Lorenc	113
15	<b>Denmark</b>	Jusmedico Advokatanpartsselskab: Jan Bjerrum Bach & Peter Schött Knudsen	120
16	<b>England &amp; Wales</b>	Arnold & Porter (UK) LLP: Jacqueline Bore & Silvia Valverde	131
17	<b>Finland</b>	Roschier, Attorneys Ltd.: Mikael Segercrantz & Johanna Lilja	143
18	<b>France</b>	PDG Avocats: Paule Drouault-Gardrat & Juliette Peterka	152
19	<b>Germany</b>	Clifford Chance: Dr Peter Dieners & Marc Oeben	158
20	<b>Greece</b>	M. & P. Bernitsas Law Offices: Yannis G. Chryssospathis & Nektaria G. Venaki	169
21	<b>Ireland</b>	Arthur Cox: Declan Hayes & Colin Kavanagh	178
22	<b>Italy</b>	Biolato Longo Ridola & Mori: Linda Longo & Andrea Moretti	187
23	<b>Japan</b>	Nishimura & Asahi: Somuku Iimura & Yoko Kasai	198
24	<b>Korea</b>	Hwang Mok Park P.C.: Kun Su Mok & Hye Yeon Lim	207
25	<b>Luxembourg</b>	Molitor, Avocats à la Cour: Laurent Fisch & Claire Leonelli	214
26	<b>Macedonia</b>	Debarliev, Dameski & Kelesoska Attorneys at Law: Elena Miceva & Emilija Kelesoska Sholjakovska	223
27	<b>Mexico</b>	Olivares & Cia., S.C.: Alejandro Luna & Juan Luis Serrano	229
28	<b>Netherlands</b>	NautaDutilh N.V.: Carla Schoonderbeek & Hein van den Bos	237
29	<b>Norway</b>	Advokatfirmaet Grette DA: Felix Reimers & Erik Helstad	246
30	<b>Poland</b>	Sołtysiński Kawecki & Szlęzak (SK&S Legal): Ewa Skrzydło-Tefelska & Agnieszka Jurcewicz	255
31	<b>Slovenia</b>	Avbreht, Zajc & Partners Ltd.: Andrej Kirm	262
32	<b>South Africa</b>	Adams & Adams: Alexis Apostolidis	271
33	<b>Spain</b>	Faus & Moliner: Jordi Faus & Rodrigo Osorio	279
34	<b>Sweden</b>	Mannheimer Swartling Advokatbyrå: Helén Waxberg & Fredrik Lundegårdh	288
35	<b>Switzerland</b>	Schellenberg Wittmer: Andrea Mondini & Christine Beusch-Liggenstorfer	297
36	<b>Turkey</b>	YükselKarkınKüçük Attorney Partnership: Murat Karkın & İbrahim Yamakoğlu	307
37	<b>USA</b>	Epstein Becker & Green, P.C.: Kathleen A. Peterson & Benjamin S. Martin	316
38	<b>Vietnam</b>	Tilleke & Gibbins: Tra Thanh Nguyen & Dung Thi Kim Vu	332

Further copies of this book and others in the series can be ordered from the publisher. Please call +44 20 7367 0720

#### Disclaimer

This publication is for general information purposes only. It does not purport to provide comprehensive full legal or other advice. Global Legal Group Ltd. and the contributors accept no responsibility for losses that may arise from reliance upon information contained in this publication. This publication is intended to give an indication of legal issues upon which you may need advice. Full legal advice should be taken from a qualified professional when dealing with specific situations.

# Denmark



Jan Bjerrum Bach



Peter Schøtt Knudsen

## Jusmedico Advokatanpartsselskab

### 1 General - Medicinal Products

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

Chapter 7 of the Danish Medicines Act No. 1180 of 12 December 2005, effective from 17 December 2005 (the “Act”) and Executive Orders Nos. 1244 of 12 December 2005, 272 of 21 March 2007, the latter as amended by executive orders Nos. 393 of 27 April 2007 and 181 of 12 March 2008 (the “Advertising Order”), and 105 of 28 January 2010 (collectively the “Orders”) govern the advertising of medicinal products in Denmark, including sample distribution and advertising on the radio or television.

In addition to the Act and the Orders, the National Board of Health has issued guidance notes Nos. 15250 and 15225, both of 30 August 1979, on the use and pre-approval of use of approved indications for advertising purposes, whereas the Danish Medicines Agency (the “Agency”) has issued guidance note No. 29 of 24 May 2007 on the advertising of pharmaceuticals (the “Agency Guide”).

The Danish Marketing Practices Consolidated Act No. 839 of 31 August 2009, as amended, (the “Marketing Act”), 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 guidance notes, the Agency Guide and the Marketing Act (collectively the “Legislative Basis”) are enforced by the Agency and the Consumer Ombudsman.

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

From 01 April 2008 to 31 March 2011, advertising initiatives addressing doctors, dentists, veterinaries, pharmacists, nurses, veterinary nurses and/or students of such professions (“Health Professionals”) were monitored by the Legal Board of Self-Regulation concerning Pharmaceuticals (“NSL”), whose members were: a) The Danish Medical Association (“LF”); b) The

Association of Danish Pharmacies (“DA”); c) The Danish Association of the Pharmaceutical Industry (“LIF”); d) The Danish Generic Medicines Industry Association (“IGL”); and e) The Association of Parallel Importers of Medicinal Products (“PFL”), collectively the “Organisations”. Effective as from and including 01 April 2011, NSL was dissolved and replaced by ENLI, whose members comprise LIF, IGL and PFL, whereas LF and DA are enforcing ethical rules applicable for their respective members only, leaving enforcement of advertising initiatives involving their members to the Agency on the basis of the Legislative Basis.

Going forward, ENLI will be operating under Statutes and Procedural Rules dated 28 March 2011. The rules and standards to be enforced by ENLI (the “ENLI Rules”) comprise the Legislative Basis as well as a range of ethical rules and codices instituted by LIF and consisting of: i) an Advertising Codex of 04 February 2011, amended on 28 March 2011, governing advertising *vis-à-vis* Health Professionals (the “Advertising Codex”), incorporating among other norms the WHO’s ethical criteria for medicinal drug promotion; ii) rules on the relationships between the industry and patient organisations of 01 April 2007, amended on 26 March 2008 (the “Patient Organisation Codex”); iii) rules on the relations between the industry and the Danish hospital sector of 23 February 2010 (the “Sector Codex”); and iv) rules for dialogue and negotiations between the industry, politicians and regulatory authorities of January 2010 (the “Lobby Codex”). The Advertising Codex, the Patient Organisation Codex, the Sector Codex and the Lobby Codex are hereinafter referred to as the “Codices”.

#### 1.2 How is “advertising” defined?

The Agency Guide defines “advertising” to include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, including, without limitation: promotion of medicinal products to the general public and Health Professionals; visits by sales representatives; supply of samples; any benefit or bonus except when their intrinsic value is minimal; sponsorship of promotional meetings or scientific congresses attended by Health Professionals; and payment of travelling and accommodation expenses for Health Professionals attending such meetings or conferences.

The definition excludes the labelling and the accompanying package leaflets comprising the information provided in the approved Summary of Product Characteristics (the “SmPC”), correspondence (possibly accompanied by material of a non-promotional nature) needed to answer a specific question about a particular medicinal product, factual, informative announcements

and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general medicinal product precautions (safety), trade catalogues and price lists, provided that they do not include any product claims or names of competing products, and information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products. In addition to the definition in the underlying directive the Agency Guide excludes patient information leaflets distributed by Health Professionals in connection with the prescription of medicinal products, subject to such leaflet containing SmPC-based information only.

The Marketing Act, which governs advertising in general, is construed to expand the scope of the advertising definition to include presentations made in order to promote the supply of goods; advertising which may affect the economic behaviour of the addressee or is likely to injure a competitor (misleading advertising) and advertising comparing competing goods (comparative advertising).

---

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

---

Art. 68 of the Act requires the marketing authorisation holder, or the one placing the advertising on the market if different from the marketing authorisation holder, to keep documentation of all advertisement material on file, physically or electronically. The documentation must be kept for at least two years and must be made available to the Agency on request. Advertising material includes not only printed advertisements, but also documentation for non-printed advertisements, such as electronic advertisements made available on the Internet. The filing requirements can be complied with electronically by maintaining files in generally used and acknowledged formats such as, but not limited to, .pdf, .tiff or .jpeg.

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

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

The access for the Agency to request copies for enforcement purposes is very broad as the Agency may address anybody who has been involved in the campaign, incl. advertising agencies.

Otherwise the companies are not formally required to have compliance programmes in place. Considering, however, that sanctioned non-compliance will be published by ENLI, it is recommendable for companies to institute and operate an Advertising Rule Compliance Programme across the group.

---

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

---

There are no legal or code requirements for companies to have specific SOPs governing advertising activities. Considering, however, that companies having breached the norms are required to represent to ENLI that all necessary precautions to avoid repetition

have been taken, it would seem a prudent step to implement and operate compliance SOP'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 ENLI at [www.enli.dk](http://www.enli.dk), in case of an ENLI subject:

- a) hosting or co-hosting an arrangement (meetings, congresses, symposia, etc.) partially or wholly addressing Health Professionals;
- b) sponsoring *litra a*) arrangements;
- c) acquiring access to a sales pitch at a congress in Denmark; and/or
- d) publishing, whether in physical media or electronically, advertising materials addressing Health Professionals.

Notification deadlines for each kind of initiative are set out in the Advertising Codex. 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. If pre-approved, the advertiser cannot be fined, merely reprimanded, by ENLI for non-compliance, provided however that the information on 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 Interior and Health (the “Minister”) is authorised by § 70, par. 2 of the Act to require the Agency to offer pre-assessment of intended advertising initiatives. Until the Minister may do so the Agency is precluded from offering such service. Consequently, the Agency cannot require an undertaking to submit an intended advertising campaign for pre-approval. On a more general basis, the Agency has issued guidance notes No. 15225 of 8 February 1979 pre-approving advertisements for certain veterinary medicinal products, vitamin and mineral preparations.

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.

In 2010, 2,608 advertising initiatives were notified to ENLI's predecessor, NSL, and 47 applications for pre-approvals were submitted.

---

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

---

Both the Agency and the Consumer Ombudsman have the powers to require that an advertisement be stopped, a corrective statement be issued and to take or to require appropriate corrective action to be taken. The Agency Guide authorises decisions to be appealed to the Minister, whereas action taken by the Consumer Ombudsman may be brought before the ordinary courts of justice. However,



decisions related to radio or television broadcasted advertisements may be appealed to the Board on Radio and Television Commercials, which may involve the Agency and / or the Consumer Ombudsman in the complaint. Alternatively, or normally as a next step, the decision may be brought before the competent courts of justice.

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

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

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

The self-regulated bodies enforce their statutes and rules on the basis of their contractual authority. According to the ENLI "Regulations for Sanctions and Charges" (the "Sanctions"), and ENLI's "Procedural Rules" (the "Procedures"), both of 28 March 2011, ENLI may impose sanctions ranging from reprimands, fines, corrective statements addressing / recall of illegal advertising material, publication of corrective statements in relevant periodicals, and cancellation of the advertising arrangement in question (conferences, congresses, etc.) and must for a period of no less than 2 years make the names of companies in breach public via the ENLI homepage. Due to data protection legislation, names of individuals involved will not be published.

By authority of the Sanctions, ENLI may impose fines for breach of rules governing advertising material in the range from DKK 15,000 (approx. EUR 2,000 for minor formal errors such as a cover letter not having been dated, incorrect INN or incorrect API composition) to DKK 75,000 for misleading product claims, which may compromise public health. Breaches of the Codices on other counts other than incorrect advertising material may trigger fines in the range of DKK 30,000 (approx. EUR 4,000 for minor formal errors such as meal allowance at arrangements lasting less than 2 hours, inexpensive gifts, which the sponsor has had reason to believe was professionally justified, although ENLI disagrees, etc.) to DKK 150,000 for arrangements which have been held outside Denmark without justification (such as excessive wining and dining or gifts worth more than DKK 1,000, but holding no value to the trade of the Health Professional). If several norms have been breached, ENLI may impose an accumulated fine considering all breaches. Individual fine levels for given breaches are predefined in the Sanctions. Under aggravating circumstances, such as repetition of the same breach within any current 2-year period, the fines which are otherwise applicable may be doubled. If a company has been sanctioned, the company is required to represent to ENLI that the illegal activity has been terminated and that all necessary precautions to avoid repetition have been taken. All decisions made by ENLI, whether in the 1st instance Scrutiny Board or by the 2nd instance Appeal Board, will be submitted to the Agency for information.

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

A decision made by a self-regulatory body cannot be suspended or prejudiced by appeal to the Agency. However, a party can bring a case before the Agency even though the case has been or is being handled by a self-regulatory body, whose position may be considered by the Agency assessing the case. Over the recent years the NSL sanctioned several companies for having offered to Health Professionals SMS-services for use by patients, enhancing drug consumption compliance. The NSL was of the opinion that the companies, by offering such service, in effect relieved the doctors from work normally vested in the Health Professionals, implying that the services partly constituted financial support to the doctor and partly impacted on the independency of the Health Professional from the service provider. On request by the NSL, the Agency scrutinised this practice and reached the conclusion that SMS compliance services were a service rendered to the patients on a voluntary basis and that the doctors were not relieved of any work load as they are not normally involved in day-to-day compliance monitoring. On the basis thereof NSL changed its practice, allowing for SMS compliance services to be offered to patients, although through the prescribing doctor. In principle such scrutiny by the Agency can be initiated not only by the NSL, now ENLI, but also by any interest holding *locus standi*.

ENLI may *ex officio* take up cases regarding companies, which are subject to ENLI jurisdiction. As per 01 April 2011, the number of companies subject to ENLI jurisdiction was 52, comprising the members of LIF (35), IGL (14) and PFL (3). In addition, non-members of said organisations may submit to ENLI jurisdiction. Prior to the formation of ENLI, 7 non-member companies had submitted to the NSL jurisdiction. Considering the number of subjects, ENLI is in a strong position to enforce ENLI rules against every relevant player on the Danish market.

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

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

## 2 Providing Information Prior to Authorisation of Medicinal Product

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

The Act prohibits the advertising of medicinal products for which a marketing authorisation has not been obtained in Denmark.

Unauthorised medicinal products may only be discussed at scientific meetings, subject to the content of the information provided not being caught by the advertising definition.

It will not, in our opinion, be possible for a company to sponsor or participate in a meeting the subject matter of which is a discussion of unauthorised medicinal products with independent Health Professionals. The sponsorship will imply that the discussion is automatically caught by the advertising definition as the purpose of such meeting can hardly be argued to be anything else other than awareness-creating and hence promotional. To include Health Professionals in such discussions would require a relationship with such Health Professional to be established, e.g. by including the Health Professional on an Advisory Board, which will be subject to Agency approval.

In the early stage of a product lifecycle, the availability of scientific references may be limited. The ENLI Rules therefore accept information – for products newly authorised – based on “data on file”, subject to such information having been pre-approved by ENLI. The ENLI Rules define “data on file” to comprise a final and signed study report describing study results and containing a statistical analysis of the data generated in accordance with the protocol. Detailed results, including individual data, must be included and a synopsis of the report must briefly but exhaustively describe design, treatment, subjects, and significant results. The reference must include the full report title, study code, name of principal investigator, investigator, year and name of company. The “data on file” exception, however, addresses the post-marketing authorisation period and does not authorise presentations of unauthorised products, including unauthorised indications.

Providing off-label information promoting claims outside the scope of the SmPC will *per se* qualify as advertising for a medicinal product not having received the relevant marketing authorisation and is hence prohibited.

### 2.2 May information on unauthorised medicines be published? If so, in what circumstances?

The Act and ENLI Rules reflect the requirements of Art. 87 of directive 2001/83/EC, as amended, prohibiting the advertising of medicinal products which have not been licensed in Denmark. However, informational material produced by public entities promoting rational drug consumption and scientific articles, which may comprise comparative investigations of drug properties, circulated uncommented to Health Professionals on an “as are” basis, are not considered advertising.

Previously, information provided by sources independent from the marketing authorisation holder was not necessarily considered

advertising (see the Ter Voort-case (C-219/91)). This is no longer the case (see the Damgaard-case (C-421/07)), in which the ECJ has ruled that statements about the properties of a pharmaceutical product may be considered advertising, even if the source is acting on its own initiative and independently, *de jure* and *de facto*, of interests holding a commercial interest in the product advertised. The ECJ ruling was an Article 234 ruling following an appeal to the Danish High Court (Western District) by Mr. Damgaard, who in the first instance was fined DKK 15,000 by the Danish Magistrates Court for having advertised a product which due to the product claims made was considered being a (unlicensed) medicinal product. Based on the ECJ ruling, the first instance verdict and the fining of Mr. Damgaard was upheld, although then reduced to DKK 10,000 (approx. EUR 1,333).

### 2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

The Agency Guide exempts press releases containing abbreviated information on a medicinal product from the advertising rules, provided that: i) the information offered holds general news value; ii) the release is addressing the press; and iii) the release is targeting a plurality of journalists or reporters only for the purpose of having such information assessed and elaborated upon prior to publication by such recipients.

Subject to these conditions being met the press release will be falling outside the scope of the advertising rules and hence it is irrelevant whether the medicinal product referenced is authorised or not. Considering, however, the Damgaard case (C-421/07) above, the gentlemen of the press need to be cautious, when drafting articles on the basis of press releases received. Moreover the companies must not use the press releases for any other purpose; were they to be made generally available at the homepage, the press release exception is inapplicable.

With respect to annual reports submitted to the stock market, such reports have been seen to include texts referencing medicinal products and indications being developed, but not yet authorised. By including such information in the annual reports, the companies are walking on a thin line, which basically comprises the argument that such information in the given context is not promotional in relation to the concrete product; see question 6.5 below.

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

Product information, but not press releases, may be sent to Health Professionals and others having made a specific enquiry to the company regarding the product properties. Submission on an unsolicited basis to Health Professionals of scientific articles containing information on unauthorised products is in principle possible, but such must be submitted 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 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Only to the extent that such informational material is produced by public entities promoting rational drug consumption or comprises scientific articles being submitted as per the above requirements.

As information relevant for budgeting will require information on the pricing and reimbursement status, which will not be available prior to authorisation, such information cannot be provided.

---

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

---

Medicinal doctors (human & vet.), dentists and pharmacists, but not other Health Professionals, must apply to the Agency for permission if they, while being authorised to prescribe medicinal products, wish to render services, including through membership of Advisory Boards, to enterprises holding a manufacturing authorisation, including local sales subsidiaries of such enterprises, whether or not the activity envisaged is related to a specific medicinal product and whether or not that medicinal product is authorised. Applications will be denied if the Agency finds that the services to be rendered may influence the prescription pattern of the applicant, which as per Agency practice will be the case if the services relate to the preparation of marketing material.

For many years the obligation to apply for permission has not been actively enforced. Over the last years, however, this has changed dramatically; reference is made to question 9.3 below. The Agency has issued guidelines on the subject on 13 January 2010 (No. 9011 for pharmacists and No. 9012 for doctors and dentists).

---

## 3 Advertisements to Health Professionals

---

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

---

Advertisements targeting Health Professionals must contain the following essential information:

1. Trade and generic (INN) product name(s), i.e. all INN names if a combination.
2. Name of marketing authorisation holder.
3. Indications for use consistent with the SmPC.
4. Contra-indications.
5. Side effects and cautions.
6. Dosage.
7. Product forms (strengths, methods of administration).
8. Package sizes.
9. Pharmacy purchase price + pharmacy margin (p.t. 8.5%) + DKK 6.11, incl. VAT, for pharmacy monopoly products, in spite of this price not being the consumer price.
10. Supply classification.
11. Reimbursement options.
12. Advertisement version and date.

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

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

If the advertisement is intended solely as a reminder the advertisement may comprise the trade name and the generic name of the product, the licence holder and the manufacturer only.

---

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

---

Information comprising “abstracts” cannot be used as documentation for claims made in an advertisement, whereas “data on file” can be used as documentation for claims made in an advertisement subject, however, to ENLI scrutiny and pre-approval and only for the shorter of: i) 18 months from marketing authorisation having been granted; ii) the data having been published in an acknowledged independent scientific periodical; and iii) the data having been rejected for publication by a periodical. The latter will be construed to imply that the data are invalid.

The study synopsis, the full clinical study report and any amendment thereto must be made available to any interest holding *locus standi*, including competing enterprises having submitted to ENLI jurisdiction.

On the other hand it is not – in principle – a condition that the “data on file” study is referenced in the SmPC. However, ENLI will not be granting permission to use of “data on file” if the claims intended are not solidly founded in the study material and any use must be fully compatible with the SmPC.

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

---

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

---

The prohibition against including Health Professional endorsements in campaigns addressing the general public does not apply to campaigns addressing Health Professionals. However, such endorsements are obviously also required to be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his own opinion on the therapeutic value of the product, implying that endorsements must be qualified.

---

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

---

No, the advertiser must observe the rules on comparative advertising, which, however, do not require that the products have been clinically compared.

---

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

---

Rules governing comparator advertisements are set out in the Marketing Act, the Orders, in the Agency Guide and in the NMI Rules of 10 February 2001, which latter rules are being applied by ENLI.

Comparative advertisements must be based on the SmPC’s, comply with general advertising rules, compare all relevant and available treatment alternatives, avoid product confusion, be loyal to the comparator products, be objective, and must not take unfair advantage of the reputation of a competitor brand. However, it is permitted to use such brand name.



The data provided for the promoted product must include the essential information listed in question 3.1 above, whereas data for comparator products can be limited to therapeutically relevant differences.

It is not possible to refer to a competitor's product which has not yet been authorised in Denmark as such product does not represent a treatment alternative.

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

Distribution of scientific papers, whether or not at congresses, must adhere to the advertising rules and may only be distributed if they fall outside the scope of the advertising material definition (see questions 1.2 and 2.1 *i.f.*). In addition, companies may reply to unsolicited enquiries made by Health Professionals, e.g. in connection with congresses where independent opinion leaders give presentations.

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

Neither the Legislative Basis nor the ENLI Rules prohibit the use of teasers, provided however that they do not comprise an advertisement of medicinal products. For all practical purposes, teasers should meet the conditions set out in question 1.2 above and be restrained to include general information relating to human health or diseases without indicating product names.

## 4 Gifts and Financial Incentives

### 4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

Dispensation of product samples is regulated by executive order No. 1244 of 12 December 2005, setting out the following dispensation conditions:

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

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

### 4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

The Legislative Basis provides that the granting to Health Professionals of financial benefits, including discounts, bonus payments etc. and goods is prohibited, unless the gift, whose intrinsic value must be minimal, can be used professionally by the Health Professional or is granted in connection with a personal red-letter day, which latter exception is not authorised by the Advertising Codex, i.e. that ENLI subjects cannot avail themselves of this exception. It is also prohibited to hold competitions or award prizes to Health Professionals.

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

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

The objective behind the restrictions on giving Health Professionals gifts is to avoid irrelevant criterions from impacting the prescription pattern. Donations to institutions such as hospitals do not cause the same concern. As long as nothing is promised or given in return, industry financing of medical equipment supplied to institutions is not considered inappropriate sponsoring notwithstanding, in principle at least, the value of the donation. As per Agency practice, the current distinction as to whether a donation is legal or not has to be based on whether the recipient is: i) a public hospital; or ii) a group of, or a society comprising Health Professionals. In case of the former, donations can freely be made, whereas donations, in case of the latter, must only be made in the form of professional educational arrangements such as congresses, conferences, etc. The distinction has been challenged by ENLI's predecessor arguing that it may encourage evasion and the Agency is considering whether to amend the Advertising Order to accommodate ENLI's concern.

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

If provided within the scope of permitted donations as in question 4.2 above, the donation will be legal even if it may lead to a change in the prescription pattern or in the allotment of market shares among the marketing authorisation holders.



**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?**

The purchasing of medicinal products by hospitals takes place via public tenders organised by Amgros, which is owned by the regional hospital owners. Amgros purchases approx. 98% of all medicines used at the hospitals. The Ministry of Health and LIF have entered into a price-cap and price reduction agreement related to all medicines restricted to be dispensed by hospitals in Denmark, implying that prices of hospital medicines (official price list) were reduced by 5% as of 1 January 2010 and that the prices of hospital medicines are not to be increased in the excess of these prices in the period to 31 December 2012. For the primary sector, the parties have entered into a price-cap agreement that is in force until the end of 2011. The agreement covers all medicines subject to general reimbursement. Outside the hospital sector, discounts may be granted to the retailer on the basis of cost savings realised by the supplier (cost-related discounts). Cost-related discounts must follow the individual product or the individual consignment and constitute a price reduction reasonably proportionate to the cost saving. Cost-related discounts offered to pharmacies must reflect savings realised by the wholesaler as a result of the wholesaler customer having increased the cost-effectiveness of the trade between the wholesaler and the customer.

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

Discounts may have competition law implications. A template for the auditor's report concerning suppliers' cost-related discounts has been laid down in Executive Order No 181 of 12 March 2008.

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

If offered in response to a tender, such offer would be inconsistent with the tender terms and unacceptable by Amgros. In relation to retailers, § 30 of the Advertising Order requires rebates based on cost savings to be granted in the form of price reductions and not in the form of other services or benefits. Rebates, as well as the calculation basis for same must be indicated in the invoice. Replacing the grant of a rebate by invoicing for services rendered separately will constitute a *quid pro quo* arrangements implying a breach of § 30 and hence comprise an illegal kick-back.

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

A refund scheme can be and has been offered for certain products. The supply status is irrelevant in this relation. The refund principle is fairly new and reflects that some patients may not enjoy the envisaged benefits of taking the prescribed medicinal products in spite of the medicinal product being contractual.

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

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

In June 2004 the Agency announced that Novartis had launched a "pay back" scheme for Diovan® noting that the Agency, while not approving the campaign, which the Agency cannot, did not consider the campaign being a breach of the Act *per se*. However, the Agency noted that such campaigns represent a challenge to the reimbursement system.

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

Continued medical education for individual Health Professionals will comprise a financial benefit to such recipient exceeding the limits set out in question 4.2 above and cannot be offered to Health Professionals.

## 5 Hospitality and Related Payments

**5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?**

The offering of hospitality to Health Professionals is governed by the Orders and the Codices.

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

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

Hospitality expenses must be kept at a reasonable level and be subordinate – with respect to finance as well as time – to the professional purpose of the event, which – for food (other than sandwiches, fruit and low cost beverages) to be served – must exceed two hours' duration.

Full transparency is required with respect to identification of the meeting organiser, the purpose of the arrangement, any financial support given and by whom.

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

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

In general, organisations should benefit from sponsorships rather than individuals. If, however, a Health Professional teaches at the meeting, reasonable cash remuneration may be offered, whereas the offering of values in kind is prohibited by § 23 par. 2 of the Advertising Order and the offering of reimbursement of lost earnings is prohibited as per question 4.2 above.

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

However, such expenses must be “reasonable” and must be offered solely to the extent relevant for the permitted advertising activity and solely in close connection with the same timing-wise. In any event, the Health Professional must observe the Agency guidelines of 13 January 2010 (No. 9011 for pharmacists and No. 9012 for doctors and dentists, see question 2.6 above).

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

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

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

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

**5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?**

Subject to Agency approval, doctors, dentists and pharmacists may become members of Advisory Boards, directors or assume other positions, which in theory may impact the prescription pattern. Companies engaging Health Professionals must report such engagements to the Agency. On a stand-alone basis, Health Professionals can be paid for providing expert services such as

being a lecturer at arrangements held by the pharmaceutical industry, when the payment is proportional to the work performed. Furthermore, any relevant and reasonable travel and accommodation expenses in connection with such arrangements may be paid for, whereas social activities cannot be sponsored.

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

The conduct of prospective post-marketing surveillance studies (non-interventional studies) collecting patient data are subject to a number of conditions set out in the Codices; the study must have a scientific objective, all contractual relations among participating resources must be stipulated in writing, remuneration levels must be reasonable, a study plan must be submitted to the Agency for guidance, personal data must be protected, the study must not *per se* impact on the prescription patterns otherwise applicable, a study protocol must be prepared and submitted to sponsors' R&D function for approval, a study report must be prepared and made generally available and - if risk/benefit findings - made available to the Agency, and sales representative and the sponsoring company may only be involved administratively. In contradiction to the Codices, the Act stipulates that non-interventional studies do not require notification to the Agency. In this light it is less likely that the Agency will allocate significant resources to discussing proposed study plans with the sponsoring companies.

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

Medical practitioners may not be offered gifts or other financial benefits in return for their participation in market/questionnaire surveys, unless the pecuniary benefit is within the scope of a minimal intrinsic value (see question 4.2 above) and the survey has certain merits.

Only where a practitioner is requested to render an actual service the practitioner may legally receive a fee or other remuneration, which must naturally be proportionate with the service rendered.

## 6 Advertising to the General Public

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

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

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

When advertising on film and radio the second requirement regarding package sizes and pricing may be excluded.

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 teletext pages of the TV channel concerned, and to look up the website of the

marketing authorisation holder.

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

---

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

---

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

---

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

---

Disease awareness campaigns are not considered as advertising if no medicinal product is identified. To avoid disease awareness campaigns falling within the scope of the advertisement definition, the campaign must focus on the disease, whereas neither the cure nor products should be mentioned.

Disease awareness campaigns are extremely frequent, especially via the internet. The Danish Consumer Council published a list on 15 March 2007; reference is made to <http://www.forbrugeraadet.dk/breve/alle/brev234>, showing that at that point in time the Council knew about 24 internet-based campaigns addressing the Danish general public. The list has not been updated since, but there is no reason to believe that the number has been reduced; on the contrary, it being considered that more and more patient organisations are being set up, which presumably increases the potential value of awareness campaigns.

---

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

---

Releases to the press can only be made subject to the conditions listed under question 2.3, above. If the conditions are met, it is not relevant whether the recipient is a scientific journal or not. However, the industry needs to act responsibly considering the risks represented by the Damgaard case, if the recipients of press releases are not familiar with pharmaceutical advertising. It might be worth while for the industry to consider adding a disclaimer to their releases summarising the key findings of the Damgaard case.

---

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

---

Product information in corporate brochures and annual reports may in principle be caught by the advertising definition.

However, corporate brochures and annual reports are normally distributed to analysts and stock exchanges for non-promotional purposes. Under these circumstances and subject to product information given being proportionate to the alleged aim, neither the Agency nor ENLI will interfere.

In this respect, ENLI is currently considering adopting the EFPIA Code guidelines on website content (October 2007, Annex B). The

content of Section 2 of said Annex B describes the kind and the amount of information that may be published via a homepage without violating the EFPIA Code by having a promotional purpose. In our view, the same route should be considered with the view of authorising a certain content of Annual Reports and similar documents.

---

### 6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

---

As of 08 April 2011, some 223 patient group associations were in existence, ref. <http://www.netpatient.dk/patientforeninger.htm>. The Patient Organisation Codex requires transparency by stipulating that all sponsorships must be in writing, identify the project sponsored, the names of the parties, the type of projects (contributions to general activities / specific arrangements, informational campaigns, etc.), objective, the roles of the parties involved, period of time for the sponsorship, support budget, costs that can be covered and non-financial support, if any. All contracts must be publicly accessible via the homepages of the sponsors for the duration of the co-operation (at least 6 months) and via the homepage of the patient organisation, unless the organisation does not want that, in which case the contract documentation must reflect such position. On request, a copy of the contracts must be supplied to anybody interested. LIF-companies co-operating with patient organisations must annually submit a report to LIF identifying the organisations sponsored. Further, the Patient Organisation Codex define standards applicable for companies sponsoring meetings, compliance with the Legislative Basis at all times, non-exclusivity and legal capacity.

---

## 7 The Internet

---



---

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

---

Advertising over the Internet of medicinal products is covered by §9 of the Advertising Order, which stipulates that such advertising must comply with the requirements of the Legislative Basis as were the advertisement published in physical media.

The Agency and ENLI are monitoring Internet advertising and often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark, the Agency and ENLI will address the local affiliate of the advertiser, which is normally sufficient. ENLI is at present considering adopting the EFPIA Code guidelines for Internet advertising, see question 6.5 above.

---

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

---

The Agency Guide requires sites addressing Health Professionals to be restricted in an efficient way by a unique user name in conjunction with a personal password being required for accessing the homepage.



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

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

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

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

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

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

## 8 General - Medical Devices

**8.1 What laws and codes of practice govern the advertising of medical devices in Denmark?**

Advertising of medical devices is governed by executive order No. 695 of 28 September 1998, which has been upheld by the Danish Medical Device Act No. 1046 of 17 December 2002, as amended.

A self-regulated body "Medicoindustrien", comprising Danish companies developing, manufacturing, selling or otherwise taking an interest in CE-marked medical devices, has published a code of practice, which in essence reflects the principles set out in the Legislative Basis.

**8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?**

The Code allows members to meet with and at or close to the healthcare professionals' place of business, to offer reasonable travel costs reimbursement, modest meals and hospitality.

## 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?**

As per 01 April 2011, the NSL was replaced by ENLI, whose members comprise LIF, IGL and PFL, whereas members of LF and DA are now subject to their own ethical rules and – with respect to advertising initiatives – to the Legislative Basis requirements enforced by the Agency. ENLI comprises a 1st Instance Scrutiny Board and a 2nd Instance Appeal Board. Moreover procedures and sanctions have now been determined in more detail and the Codices represent stricter norms than hitherto applied as well as increased fine levels.

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

At this juncture (12 April 2011), ENLI is not yet operational as staffs for both the 1st and the 2nd Instance are being appointed. However, ENLI is expected to become operational within the month of May 2011.

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

Although the concept of having a single board overseeing the activities of the Organisations was appreciated by all of the participating parties, the amendments of the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, and the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations on 01 July 2008, in effect required NSL to operate different sets of rules depending on who was involved in a given issue. In addition, the IFPMA (the International Federation of Pharmaceutical Manufacturers & Associations) Code of Pharmaceutical Marketing Practices (2006) had to be observed. Eventually this turned out to be too burdensome for LIF (the industry), which eventually decided to withdraw from NSL, leading to dissolution thereof, but enabling the industry to focus on the enforcement of the EFPIA and IFPMA codices via ENLI and to enforce the Codices more effectively. Hitherto the NSL operated fining levels from DKK 5,000 – 50,000, which levels – in order to reflect the importance of compliance with the Codices – will be increased by ENLI being able to impose fines from DKK 15,000 to DKK 300,000 (EUR 40,000) on interests breaching the Codices in spite of having submitted to ENLI's jurisdiction. To secure transparency all decisions made will be published. Finally, ENLI will also be enforcing the Patient Organisation Codex, the Sector Codex and the Lobby Codex, whereby all relevant activities in the market place will be covered and not only those addressing the industry and the Health Professionals.

**Jan Bjerrum Bach**

Jusmedico Advokatanpartsselskab  
 "Naesseslottet", Dronninggaards Allé 136  
 DK-2840 Holte  
 Denmark

Tel: +45 4547 5025  
 Fax: +45 4548 4449  
 Email: [JBB@jusmedico.com](mailto:JBB@jusmedico.com)  
 URL: [www.jusmedico.com](http://www.jusmedico.com)

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

Late 1991 Jan joined the Lundbeck group and was appointed General Counsel thereof in 1994. As General Counsel, Jan participated in the conclusion of numerous pharmaceutical industry transactions with cross-border implications, including acquisition and divesting of product rights, joint ventures and strategic licensing and alliance arrangements, primarily in Europe, Japan and the United States of America. In addition, Jan was responsible for the casualty insurance programmes of the group. Jan was appointed General Counsel and Executive Vice President of a globally operating reinsurance group in 1999, whose global operations, however, were put into run-off after 9/11 2001.

In 2004 Jan established Jusmedico Law Firm Ltd., which is now representing leading Danish biotech companies and R&D-based pharmaceutical operations on legal and regulatory issues, clinical testing, manufacturing, international alliances, product liability and insurance matters.

**Peter Schøtt Knudsen**

Jusmedico Advokatanpartsselskab  
 "Naesseslottet", Dronninggaards Allé 136  
 DK-2840 Holte  
 Denmark

Tel: +45 4547 5025  
 Fax: +45 4548 4449  
 Email: [PSK@jusmedico.com](mailto:PSK@jusmedico.com)  
 URL: [www.jusmedico.com](http://www.jusmedico.com)

Peter Schøtt Knudsen was born in November 1973 in Haderslev, Denmark. Having graduated from University of Copenhagen (Master of Laws) in 1998 and subsequently having been trained in the Law Firm Bech-Bruun, Peter was admitted to the bar in 2001. In addition to his legal background, Peter has taken extensive general management courses at Wharton Business School, US, and IMD, Switzerland.

In 2001 Peter joined the Novo Nordisk group as Associate General Counsel and was in mid-2004 expatriated to Zurich, Switzerland, to set up and head the legal function for the Novo Nordisk international regional sales activities. In 2006 Peter was appointed Legal Director for Novo Nordisk International Operations.

As Legal Director Peter participated in the conclusion of several pharmaceutical transactions and set-up legal and business ethic compliance programmes globally. This also included establishment and set-up companies in new markets.

Late 2007, Peter joined LifeCycle Pharma A/S, a Danish listed specialty pharmaceutical company as General Counsel and became a member of the management team in 2009, responsible for Legal, IP and Investor Relations/Communication. In that capacity Peter was involved in two rights issues, several late stages clinical trials programmes, which were executed in co-operation with Jusmedico, handling a complex royalty divestment agreement and several biotech transactions, including strategic licensing and alliance arrangements, primarily in Europe and the United States of America. In addition, Peter was responsible for the insurance programmes of the company.

In late 2010, Peter was appointed legal advisor to and member of Jusmedico's Advisory Board, concurrently with assuming the position as General Counsel of Royal Unibrew A/S, the second largest brewing group in Northern Europe.



Jusmedico® Advokatanpartsselskab ("Jusmedico") is a specialist law firm providing legal services to the biotech, pharmaceutical, medical device, dentistry, foodstuff and dietary supplement industries.

The working areas of Jusmedico include research & development, pre-clinical test and clinical trial, data protection, production & supply, labelling & packaging, licensing, co-promotion & co-marketing agreements, agent and distribution agreements, advertising & promotion, administration & renewal of third party liability insurance programmes and product liability claims.

Internationally Jusmedico operates a representative office in New York, USA.

# The International Comparative Legal Guide to: Pharmaceutical Advertising 2011

## Other titles in the ICLG series include:

- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Commodities and Trade Law
- Competition Litigation
- Corporate Governance
- Corporate Recovery & Insolvency
- Corporate Tax
- Dominance
- Employment & Labour Law
- Enforcement of Competition Law
- Environment & Climate Change Law
- Gas Regulation
- International Arbitration
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Patents
- PFI / PPP Projects
- Product Liability
- Public Procurement
- Real Estate
- Securitisation
- Telecommunication Laws and Regulations

To order a copy of a publication, please contact:

Global Legal Group  
59 Tanner Street  
London SE1 3PL  
United Kingdom  
Tel: +44 20 7367 0720  
Fax: +44 20 7407 5255  
Email: [sales@glgroup.co.uk](mailto:sales@glgroup.co.uk)