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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

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1 General - Medicinal Products

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

Chapter 7 of the Danish Medicines Act No 1180 of 12 December 2005, effective from 17 December 2005 (the "Act") and Executive Order 272 of 21 March 2007 as amended by executive orders Nos. 393 of 27 April 2007 and 181 of 12 March 2008 (collectively the "Orders") govern the advertising of medicinal products in Denmark.

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 and the Danish Medicines Agency (the "Agency") guidance on advertising of pharmaceuticals on 24 May 2007 (the "Agency Guide").

The Danish Marketing Practices Act No 1389 of 21 December 2005, 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.

Outside the scope of legislation, self-regulated bodies - proceedings before which are possible in addition to administrative and judicial proceedings - monitor advertising of medicinal products.

The bodies comprise: **1)** the Board for Self-Regulation in the Pharmaceutical Sector ("NSL"), which as from 01 April 2008 has replaced and taken over the assignments of i) the Board of; Medicinal Information Material ("NMI"), ii) the Pharmacist's Ethical Board ("AEN"), and iii) the Medical Doctor's Ethical Board ("LEN") and monitors co-operation between pharmacists and the industry related to pharmacy arrangements addressing the public; **2)** the Veterinary Marketing Practise Board; and **3)** The Health Trade Supplier Association's Ethical Board. Within the scope of their respective statutes the bodies monitor that advertising initiatives comply with ethical codes, guidance notes and collaboration agreements entered into.

Advertising initiatives addressing health professionals are monitored by NSL whose members comprise 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), hereinafter collectively referred to as the "Organisations".

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.

The rules and standards to be enforced by the NSL comprise the NSL Statutes dated 21 November 2007 and a Co-Operation Agreement entered into among NSL's members, on 31 May 2007 governing co-operation among pharmaceutical industry interests, doctors and pharmacists.

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, trade catalogues and price lists, provided they include no 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, subject to such leaflet containing SmPC based information only.

The Marketing Act, which act governs advertising in general, is construed to expand the scope of the advertising definition to include representations 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. 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. Hence, it is advisable for internet advertisements that print outs are made documenting any and all versions of the advertisement that have been released.

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

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

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

Otherwise the companies are not formally required to have compliance programs in place. Considering, however, that non-compliance may soon hit the headlines, not at least in connection with the annual reports of the NSL being published, it is recommendable for companies to institute and operate an Advertising Rule Compliance Program across the group.

1.4 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?

Neither the Legislative Basis nor the NSL Rules require the advance approval of advertising initiatives.

The Minister of the Interior and Health (the "Minister") is authorised by § 70, par. 2 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.

Finally NSL offers pre-assessment of intended campaigns. If pre-approved the advertiser cannot incur liability *vis-à-vis* NSL for non-compliance. The position of the authorities, were they to disagree with NSL, is not prejudiced hereby. However, the likelihood of an undertaking being prosecuted under such circumstances is low.

1.5 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?

The Agency has the power to require an advertisement be stopped and a corrective statement be issued. The Agency may further require publication of the decision deciding the scope and content thereof.

The Agency Guide authorises decisions to be appealed to the Minister. However, decisions related to radio or television broadcasted advertisements may be appealed to the Board on Radio and Television Commercials.

Alternatively, or normally as a next step, the decision may be brought before the competent courts of justice.

1.6 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. Sanctions imposed by the Consumer Ombudsman are subject to judicial review, if required.

The self-regulated bodies enforce their statutes and rules on basis of their contractual authority. NSL has been granted the powers to impose sanctions ranging from reprimands, fines and/or publication of corrective statements in relation to inaccurate or illegal advertising. The NSL advertising material related decisions will be published by NSL and send to the Agency enabling the Agency to consider whether additional sanctions are called for.

One of the more controversial sanctions, which may be made possible, is publication of names of doctors and pharmacists, who are not in compliance and who are being fined. The question has been considered by the Danish Data Protection Agency, the Danish Ministry of Justice and the Ministry of Health & Prevention the key question being whether such publication would infringe civil rights of doctors and pharmacists. The conclusion reached was that publication is not authorised by current legislation and that publication would require an amendment of the law.

NSL imposes fines going from DKK 5,000 (approx. EUR 650 for minor formal errors such as a cover letter not having been dated, incorrect INN or incorrect API composition) to DKK 40,000 for what may be characterised as generalised incidents of non-compliance. Under aggravating circumstances the fine may be increased to up to DKK 200,000, where the violation is of such scale that the campaign represents a health risk for the population, where the general reputation of the trade is on the line, or where legitimate competitor considerations call for extraordinary sanctions to be imposed. The fines are set out in a set of "Rules for Advertising and Other Informational Material" dated 02 February 2006, which Rules were originally issued under the authority of NMI Statutes. Under the authority of the Co-Operation Agreement entered into among NSL's members on 31 May 2007 new Statutes have taken effect as from 01 April 2008.

1.7 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 brought before 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. The decision of the self regulated body may form part of the Agency's assessment of the case. We have seen no cases where the Agency has taken up matters already decided upon by the NMI/NSL without such matter having been brought before the Agency by the claimant directly.

NSL may ex officio take up cases regarding companies, which are subject to NSL jurisdiction. As per 29 January 2009 the Organisations had 56 members and 8 companies, which are not members of the Organisations, had voluntarily submitted to the jurisdiction of the NSL. This means that NSL is in a strong position to enforce the NSL rules against every relevant player on the Danish market. If companies are not subject to NSL jurisdiction and/or do not respect the decisions of NSL, NSL may - also *ex officio* - refer the case to the Agency. If it is a matter of principle NSL may in any case decide to submit the case to the Agency and has done so in a matter regarding suspected overcharging of otherwise permitted sponsorships.

1.8 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 on his own initiative.

If the activity carried out allegedly comprises inadequate, misleading or deceptive medicinal information anybody may trigger NSL intervention.

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?

The Act prohibits 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 be possible for a company to sponsor a meeting the subject matter of which is a discussion of unauthorised medicinal products. The sponsorship will imply that the discussion is automatically caught by the advertising definition.

In the early stage of a product lifecycle the availability of scientific references may be limited. The NSL Rules therefore accept information - for products newly authorised - based on "data on file", subject to such information having been pre-approved by the NSL. The NSL 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.

The Agency Guide does not consider circulation of articles referencing clinical trial results for (yet) unauthorised medicinal products "advertising", provided that the articles have already been published in acknowledged Danish or international scientific literature. It is a condition for such circulation that no additional comments or supplementary information is offered or attached. However, the annual NMI report for 2007 released on 15 April 2008 does consider such circulation "advertising" and requires hence that such circulations comply with all advertising rules, see question 3.1 below. There have been no NMI decisions on the subject throughout 2008, so the considerations of NMI remain unclear.

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

The Act and the NSL Rules reflect the requirements of Article 87 of directive 2001/83/EC as amended prohibiting advertising of medicinal products, which have not been licensed in Denmark.

However, information provided is not considered advertising if the source is independent from the marketing authorisation holder, see the Ter Voort-case (C-219/91).

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 from the advertising rules, provided that i) the information offered comprise abbreviated information on a medicinal product, ii) the release is of relevance to the general public, iii) is targeting journalists or reporters only, and iv) is circulated to a group of journalists or media for the purpose of having such information prepared by such journalists for use in a non-promotional manner.

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.

This Agency Guide authority is in among other instances used for press releases made in connection with submission of the annual reports to the stock market.

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

Product information 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 information on unauthorised products will easily

bring even relatively neutral information within the scope of the advertising definition and should be avoided.

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?

The material, which under question 1.2 above is exempt from the advertising definition, will not be in existence prior to the product having been authorised. Hence, information relevant for budgeting cannot be distributed legally.

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.) and dentists, 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 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 practise will be the case if the services relate to preparation of marketing material.

This means that the Agency on a case by case basis considers whether an applicant's prescription pattern may be influenced by the applicant rendering the service considered, e.g. by becoming consultant or involved in research and/or development activities.

This means that if the launch of a yet unauthorised medicinal product is imminent then the Agency will not be giving its permission to such involvement.

For many years the obligation to apply for permission has not been actively enforced. Over the last year, however, this has changed dramatically, reference is made to question 9.3 below. The Agency has issued a guideline on the subject on 21 March 2007.

3 Advertisements to Health Professionals

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

"Health professionals" include medicinal doctors, dentists, veterinaries, pharmacists, nurses and students of such professions. Advertisements targeting health professionals must contain the following essential information:

1. Trade and generic product name.
2. Name of marketing authorisation holder. Indications for use consistent with the SmPC.
3. Contra-indications.
4. Side effects and cautions.
5. Dosage.
6. Product forms (strengths, methods of administration).
7. Package sizes.
8. Prices, incl. VAT, for pharmacy monopoly products.
9. Supply classification.
10. Reimbursement options.
11. 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 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.

3.3 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 have been adopted by the NSL.

Comparative advertisements must be based on the SmPC's, comply with general advertising rules, compare 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.

3.4 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. This means that distribution by interests, which are not independent as per question 2.2 above, must comply with the Legislative Basis. Only to the extent the material distributed falls outside the scope of the advertising material definition, see question 1.2 and 2.1 *i.f.*, such material may be distributed.

In addition companies may reply to unsolicited enquiries made by health professionals, e.g. in connection with congresses where independent opinion leaders given presentations.

3.5 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 NSL Rules prohibit the use of teasers. Subject to observation of the said rules, teasers are permitted.

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 pharmaceutical 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.

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 intrinsic value is minimal. 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 interpretation of which commodities that may be granted is narrow; for instance the NSL has 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. The value assessment is based on the market prices applicable if the recipient were to buy the commodity personally.

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.

However, gifts, equipment donations, funding etc. still have to be related to the medical activity at the institution and the transaction must not qualify as disguised advertising or imply a kick-back intention; the greater the value, the greater the caution. The donation must not be given to named individuals or specific departments and the use must be unrestricted.

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?

It is not possible to provide medical or educational goods and services to doctors outside the scope of question 4.2 above. In a case from 2005 NSL stated that the industry may not make devises and other equipment available to doctors, the reason being that this would imply an economic advantage for the recipient thereby being inconsistent with the Orders and the Agency Guide. NSL finds it problematic that the recipient will owe a debt of gratitude to the industry as this might influence the prescribing pattern of the practitioner.

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?

Discounts are permitted to the extent equalled by a cost saving 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.

Discounts obtained by wholesalers from their suppliers must not be credited to the pharmacy. Cost-related discounts offered to pharmacies must reflect savings realised by the wholesaler as a result of the wholesaler costumer having increased the cost effectiveness of the trade between the wholesaler and the customer.

Discounts 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?

Providing or paying for medical or technical services or equipment, when this is contingent on the purchase of medicinal products, must be evaluated in relation to the rules outlined above in regard to gifts, donations etc. and is only possible if the upside for the recipient does not exceed approximately DKK 300, incl. VAT. Even in that case, however, such model would be considered unethical and should be avoided.

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 NSL 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?

Financial benefits exceeding the limit set out in question 4.2 above must not be offered to health professionals. Continued medical education on an individual level is therefore not possible. However, the industry may sponsor scientific arrangements.

On this basis the pharmaceutical industry in Denmark sets up professional training activities contributing to medical practitioners being kept updated on the developments within the pharmaceutical field. Events sponsored must have specific professional relevance to health professionals, which means that courses or training sessions must not focus on subjects, which are irrelevant to medical care.

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 strictly regulated in the Co-Operation Agreement. The subject has also been addressed in the "Code of Practice on the Promotion of Medicines" of The European Federation of Pharmaceutical Industries and Associations (the "EFPIA Code").

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.

No company should, however, organise or sponsor an event that takes 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.

According to the Co-Operation Agreement NSL must be notified in advance, when a company organises or sponsors such an arrangement. The notification must contain information on the purpose and aim of the arrangement and who the organisers are, and it must be provided on a form provided by the NSL secretariat. The invitation to the participants must confirm that the NSL has been notified and the company must state that the arrangement complies with the rules set out in the Co-Operation Agreement.

Likewise a doctor or a pharmacist who wishes to apply for financial support from the industry must inform NSL about the application.

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 doctor teaches at the meeting, a reasonable remuneration may be offered.

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 same timing wise.

A company may also pay a health professional a reasonable fee for giving a presentation.

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?

We are not aware of cases where the Agency has enforced the rules in connection with hospitality, etc. However, companies being subject to the jurisdiction of NSL are under an obligation to notify the NSL of all meetings, sponsorships, gifts, etc. In 2007 4,088 arrangements were notified to NMI. Out of those cases, 101 notifications were investigated and in 72 cases the advertising company was fined.

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

Doctors 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 irrelevant to the arrangement 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 post marketing surveillance studies (non-interventional studies) are not regulated and can be initiated by sponsor without obtaining Agency and Ethical Committee approval. If, however, a post marketing surveillance study comprises elements, which fall within the advertising definition, the activity can be sanctioned by NSL and the Agency.

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 as part of cooperation may the practitioner legally receive a fee or other remuneration, which must naturally be reasonable in relation to 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 and dosage.

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) discuss 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 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 has published a list on 15 March 2007; reference is made to http://www.forbruger-raadet.dk/breve/alle/brev234, showing that at that point in time the Council knew about 24 internet based campaigns addressing the Danish general public. In 2007 three cases were brought before the Agency. In one case the internet page was closed before the Agency reached a decision. In the second case the Agency decided that the homepage www.influenza.dk contained advertising material conflicting with the prohibition to advertise prescription only medicines. In the third case the Agency found that general information on a home page regarding depression did not contain advertising material.

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

Press releases are in principle considered promotional if a specific medicinal product is mentioned, reference is made to question 2.3.

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 purposes different than advertising of medicinal products and not to health professionals. Under these circumstances neither the Agency nor the NSL will interfere, but depending on the circumstances the Agency may, especially if product information given seems to be out of proportion or implies an undisclosed intention.

Product information given, if any, must comply with the SmPC. If the information comprises product claims, statements, illustrations or information, which have a promotional nature, the Agency and the NSL will probably interfere.

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 February 2009, some 215 patient group associations were in existence, ref. http://www.netpatient.dk/patientforeninger.htm.

It appears to be common practice for patient groups to apply for and accept sponsorships, but the practice is not transparent. Some groups have adopted their own ethical codes, e.g. the ADHD-association; see http://www.adhd.dk/index.php?option=com_content&task=view&id=67, whereas others give no information on sponsorships although names and logos of marketing authorisation holders are used.

Guidelines for the sponsoring of patient groups have not been issued.

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 Order, which stipulates that such advertising must comply with the requirements of the Legislative Basis.

The Agency and NSL are controlling Internet advertising and often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark, the Agency and NSL will address the local affiliate of the advertiser, which is normally sufficient.

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 action 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, e.g. name, the package sizes, prices, indication, side effect and dosage.

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 health care 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?

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.

Another development is reflected by Executive Order No. 794 of 15 July 2008 implementing § 43 a of the Act requiring holders of marketing authorisations and/or manufacturing authorisations to notify the Agency about the identity of any prescribing or dispensing health professionals, who has a relation to such enterprise.

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

No significant developments in the field of pharmaceutical advertising are expected in 2009.

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

Although the NSL have considered numerous cases and imposed a

significant number of fines it appears that the breaching frequency is stabile, which may call for an adjustment of the fining levels applied.

During 2008 the NSL have considered the use of the terms "effective" and "safe" on numerous occasions deciding in line with the EFPIA code principles.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

No, the national code has not been amended.

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

Late 1991 JBB joined the Lundbeck group and was appointed General Counsel thereof in 1994. As General Counsel JBB 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 JBB was responsible for the casualty insurance programs of the group. JBB was appointed General Counsel and Executive Vice President of a globally operating reinsurance group in 1999, whose global operations were put into run-off after 9/11 2001.

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

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Line Hell Hansen ("LHH") was born in 1966. On 1 October 2006 LHH joined Jusmedico Law Firm Ltd. ("Jusmedico") taking charge of the competition law activities of the firm.

LHH graduated from University of Copenhagen and University of Hannover (Master of Laws) in 1992 and Amsterdam School of International Relations (LL.M.) in 1997.

From 1992 to 1995 LHH worked as assistant attorney at J. P. Galmond's Copenhagen office.

From 1997 to 1998 LHH worked at Stibbe Simont Monahan Duhot´s Brussels office with EU competition law and EU law issues in general.

In 1999 she joined the Danish Competition Authority where she worked until 2006 specialising in Danish and EU competition law, procurement law and EU state aid law.

LHH's main working areas comprise competition and medicinal device law, contract law issues re R&D activities and pharmaceutical advertising.