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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2007

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 your country?

Chapter 7 of the Danish Medicines Act No 1180 of 12 December 2005, effective from 17 December 2005 (the "Act"), supplemented by executive orders No 58 of 6 February 2002, 468 of 3 June 2003 and 272 of 21 March 2007 (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 No 15250 of 30 August 1979 on the use of approved indications for advertising purposes and the Danish Medicines Agency (the "Agency") rules of 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 of Medicinal Information Material (NMI); 2) the Pharmacist's Ethical Board (PEB); 3) the Medical Doctor's Ethical Board (MDEB); 4) the Veterinary Marketing Practise Board (VMPB); 5) the Herbal Medicines Ethical Board (HMEB). 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 NMI established by the Danish Association of the Pharmaceutical Industry (LIF). The code enforced by NMI was issued on 16 January 1998 and amended by guidance notes of 9 October 1998 and 10 February 2001 (collectively the "NMI Rules"), setting out documentation requirements and comparative advertising rules, respectively.

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. However, NMI is competent to deal with most cases raised and as the bodies are mostly agreeable to the sanctions imposed by NMI, the bodies are seldom involved.

In addition to the NMI Rules the Danish Pharmaceutical Association (DPA), the Danish Medical Association (DADL), LIF, the Danish Generic Medicines Industry Association (IGL) and the Danish Association of Parallel Importers of Medicinal Products (PFL) have agreed on mutual rules (the "Co-Operation Agreement") to govern co-operation among their members.

At the same time, the parties have signed an agreement in principle on the establishment of a new joint board of ethics - the Board of Self-Regulation in the Pharmaceutical Sector (NSL). NSL will supervise Co-Operation Agreement compliance.

The Co-Operation Agreement and the self-regulation agreement took effect on 1 June, 2007. However, the NSL will not commence its work until 1 January 2008 and only subject to approval by the respective competent assemblies.

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 drug 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 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 NMI Rules require the advance approval of advertising initiatives.

The Minister of the Interior and Health (the "Minister") is authorised 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 NMI offers pre-assessment of intended campaigns. If pre-approved the advertiser cannot incur liability vis-à-vis NMI for non-compliance. The position of the authorities, were they to disagree with NMI, is not prejudiced hereby. However, the likelihood of an undertaking being prosecuted under such circumstances is low.

1.4 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.

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

The sanctions for breach of the advertising provisions of the Act or the Marketing Act go from fines up to imprisonment for up to 4 months. Breach of the Orders may be fined.

The Agency enforces the Act and the Orders, whereas the Consumer Ombudsman enforces, or private interests initiate, enforcement of the Marketing Act. 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. Under aggravating circumstances the NMI and the PEB can impose fines of up to DKK 200,000 and DKK 250,000, respectively. Refusal to comply with a decision, may lead to the member being expelled from the relevant organisation. According to the new NSL rules the NSL can impose fines on a pharmacist or a medical doctor of up to DKK 5,000.

Pharmaceutical companies are frequently being fined for non-compliance with the NMI Rules. The circumstances, the names of the fined companies and the sanctions imposed are publicly available on the NMI homepage, www.nmidk.dk, and are summarised in the annual NMI report. NMI may also decide to go public with a decision in publications addressing health professionals. All decisions made are communicated to LIF and the Agency, which may decide to take further action.

Under certain conditions, e.g. procedural, competitors may bring direct action under the Marketing Act through a court of justice. In practise, however, the self-regulated bodies are the preferred fora.

1.6 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.

NMI may ex officio take up cases regarding companies, which are subject to NMI jurisdiction. If companies are not subject to NMI jurisdiction and/or do not respect the decisions of NMI, NMI may - also ex officio - refer the case to the Agency. If it is a matter of principle NMI may decide to submit the case to the Agency.

1.7 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 NMI 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 NMI Rules therefore accept information - for products newly authorised - based on "data on file", subject to such information having been pre-approved by the NMI. The NMI 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.

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

The Act and the NMI Rules reflect the requirements of Article 87 of directive 2001/83/EC 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?

Press releases are only possible to the extent that they are not promotional and their objective is different from stimulation of the market demand for the supply of a product.

In practise information included in announcements made to stock exchanges at which the company is listed, financial reports, reports made at general meetings, etc., which information is neither provided for the purpose of stimulating a market demand for the product nor addressing health professionals, will normally be accepted.

In addition factual information about R&D expenditure, clinical activities, disease area focusing, etc. could be given, subject to product descriptions being avoided.

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.

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.
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. Prices, incl. VAT, for pharmacy monopoly products.
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 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 your country?

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.

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, 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 NMI 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 drug 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 drug 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 drug samples must not be dispensed.

The marketing authorisation holder must keep accounts of the quantity and type of dispensed drug 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, incl. 25% VAT per year, per practitioner), clinical thermometers, pens, calendars and other merchandise useful for the profession may be presented to medical practitioners. The value assessment is based on market prices.

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.

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. In a case from 2005 NMI 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. NMI 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.

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 drugs in spite of the 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 drug 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 NMI Rules.

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 to be served - must exceed 2 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 NMI 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 NMI secretariat. The invitation to the participants must confirm that the NMI has been notified and the company must state that the arrangement complies with the rules set out in the Co-Operation Agreement.

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.

However, the Orders and the Co-Operation Agreement between the medical industry and DADL authorises that a company may pay actual and reasonable travel and accommodation expenses for health professionals. 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?

According to the Co-Operation Agreement all companies being subject to the jurisdiction of NMI/NSL are under an obligation to notify the relevant board of all meetings, sponsorships, gifts, etc. In 2006 3,583 arrangements were notified to NMI. Out of those cases,

97 cases gave rise to protest and in 68 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 offering of financial benefits to health professionals is governed by the Orders and strictly regulated in the Co-Operation Agreement. However, the Co-Operation Agreement covers more general and occasional activities arranged for medical practitioners in general.

The Co-Operation Agreement does not prevent medical practitioners from being engaged as consultants by the industry in exchange for a reasonable fee. The assignment undertaken could be the conduct of a post-marketing surveillance study. As long as the remuneration of the doctor is entirely independent of his prescription pattern, there are no concerns to the conduct of such activity.

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 NMI 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 drug 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 addressee must be encouraged to contact a doctor or pharmacy if in doubt.

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 drug 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 prohibit (i) statements claiming that common well-being may be reduced if the medicinal product is not used; and (ii) recommendations by health professionals encouraging consumption of medicinal products.

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.

As provided for in question 2.2 above, independent interests are permitted to promote not only disease awareness campaigns, but also products regardless of their supply status. Obviously true independence is paramount; any kind of working relation between these interests and the medical industry may imply that the campaigns are launched by the industry.

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. If, however, the purpose of the release is legitimate, e.g. to redress incorrect product information having been given to the addressees through other sources, the rules are construed pragmatically.

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 and not to health professionals. Under these circumstances NMI will not 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 of product claims, statements, illustrations or information, which have a promotional nature, the Agency 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?

Meetings with patient support groups should only concern information on health and diseases, whereas products neither directly nor indirectly should be referred to.

Meetings serving information and safety purposes, but not marketing purposes, will be acceptable. Although disclosure requirements do not force corporate reports to go to such detail as to report on funding of patient support groups, ethical considerations suggest that such disclosure would be prudent, not at least considering that access would probably easily be granted via the patient group.

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 not separately regulated and must comply with the requirements of the Legislative Basis.

The Agency and NMI are controlling Internet advertising, often in reaction to complaints submitted by competitors to advertising companies. If the advertiser is based outside Denmark, the Agency and NMI 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 Orders require sites addressing health professionals to be restricted in an efficient way preferably by password.

A central Internet based service allowing health professionals to use a single password to access homepages of companies having joined the scheme is available.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in your country?

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?

Based on an approach from LIF in February 2006, the Ministry of the Interior and Health requested the Agency to investigate whether any new discount arrangements were introduced in 2006 contrary to the rules comprising the Legislative Basis.

In its approach, LIF drew attention to the fact that the pharmacy sector was planning initiatives for a new type of discount arrangement and that a group of pharmacists (pharmacist chain) intended to offer selling a wide range of prescription-only medicinal products and in return the pharmacists would receive a special discount on the products in question. According to LIF, these new initiatives were completely contrary to the principles that had so far governed the trade between primarily wholesalers and pharmacists, but also between wholesalers and suppliers.

Subsequently, the Agency has investigated whether the larger Danish wholesalers in the medicine area during 2006 have introduced any new discount systems and whether they violate the rules on cost-reasoned discounts as described in question 4.5. The Agency has also investigated the dispense practice at pharmacies that are part of the pharmacy chain in question and compared their dispense practice to that of other pharmacies.

The report states:

- that the authority under the Act did not give the Agency access to sufficiently detailed information for the Agency to be able to make a decision concerning the controversial discounts which wholesalers offer to pharmacies;
- that the investigation of the pharmacy dispense practice did not indicate that pharmacies that are part of the investigated chain have been affected by discounts in a way that has made them hand out fewer inexpensive and more expensive packages than other pharmacies; and
- that nothing suggests that pharmacies that are part of the investigated chain take advantage of delivery failure to dispense other packages than the least expensive package available.

Based on the Agency-report the rules on cost-limited discounts were adjusted in connection with the passing of executive order No 272 of 21 March 2007. The order intends to clarify some of the rules on pharmaceutical advertising. The clarifications concerns the rules on arrangement and sponsoring of professional activities, entertainment, gifts and other goods of insignificant value as well as the industry's advertising at pharmacies.

Further the Agency Guide on advertising of pharmaceuticals has just been revised, see question 1.1.

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

The closing of the Co-Operation Agreement and the establishment of the NSL, if adopted, will ensure that cooperation between the participating parties is not influenced by in-transparent and irrelevant considerations, which will ensure that prescription of pharmaceuticals by doctors and advice given by pharmacists when dispensing pharmaceuticals considers the patients best interests only.

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

In regard to fines the NMI rules issued on 16 January 1998 were amended by guidance notes of 1 April 2006. With this amendment fines are raised by 50 percent on average. This means that even minor formal mistakes may trigger of a fine in the range of DKR 8,000 and DKR 16,000.

As mentioned under question 5.5 above 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, there is a doubt as to whether the post marketing surveillance study comprises elements, which fall within the advertising definition, the activity may be submitted to the Agency for evaluation. Based on cases that NMI has been dealing with during 2006 it is the opinion of NMI that this present arrangement between NMI and the Agency does not, however, remove the circumvention risk. Hence, the NMI is now working on identifying procedures, which will reduce this risk further.

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