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Practical cross-border insights into pharmaceutical advertising

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1 General – Medicinal Products

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

The most important laws, regulations and codes that include legal provisions in relation to pharmaceutical advertising are as follows:

- The Medicines for Human Use (Quality Control, Supply and Prices) Law of 2001 (70(I)/2001) (the Law).
- The Broadcasting Organisations Law of 1998 (7(I)/1998).
- The Control of Misleading and Comparative Advertising Law of 2000.
- The Cosmetic Products Law of 2017 (57(I)/2017).
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.
- The Code of Conduct of the Cyprus Association of Research and Development Pharmaceutical Companies (KEFEA), which is aligned with the relevant legislation and regulatory framework of the Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

1.2 How is "advertising" defined?

According to the definition provided in the Law, advertising of medicinal products includes any form of information intended to attract customers or promote the prescription, supply, sale or consumption of medicinal products or homeopathic medicinal products.

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?

The holder of a marketing authorisation for a medicinal product is obliged to create and maintain in operation a "Scientific Service". The role of the Scientific Service, as per the Code of Conduct of KEFEA, is to provide information on medicinal products that have been marketed. Questions (from medical sales representatives, patients or any other sources) may be put to the Scientific Service to answer.

The Scientific Service is in charge of ensuring compliance with internal and legal procedures by carrying out reviews and assessments, verifying that promotional material is in compliance with applicable laws and codes, and providing final sign off prior to dissemination of material to the public. Material should be recertified in a timely manner, in order to ensure continued compliance with the legislative regulations in force and the Code of Conduct of KEFEA.

Moreover, according to the Law, the marketing authorisation holder must send a copy of each advertisement that has been made or is about to be made to the Medicines Council, accompanied by a note indicating the recipients, the method of transmission and the date of the first transmission. Additionally, they must ensure that the advertising conducted by their business is in compliance with the Law and medical personnel are adequately trained and comply with their obligations. Finally, the marketing authorisation holder must cooperate with the Council and provide any necessary information for the control of advertising.

It must be noted that certified and accompanying material must be kept by companies for at least three years after use.

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

The compliance of pharmaceutical companies is ensured through the establishment and operation of a Scientific Service and by the procedures mentioned in the answer to question 1.3 above.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No prior approval is required for advertising. However, according to the Law, pharmaceutical companies must send a copy of each advertisement that has been made or is about to

be made to the Medicines Council, accompanied by a note indicating the recipients, the method of transmission and the date of the first transmission. This procedure takes place at the same time as the dissemination of the advertisement, so the Medicines Council can consider whether an advertisement is misleading or contrary to the Law at any time. This is done following a complaint or on its own initiative.

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

If the Medicines Council, after receiving a complaint or on its own initiative, investigates a specific advertisement and considers it misleading or contrary to the Law, it has the right to: order the offender to terminate the offence; or file an application to Court to request the issuance of a prohibition order or injunction against anyone that it believes is associated with the advertisement. The Court has the power to prohibit further publication of the advertisement and can also enforce the publication of a corrective statement. The pharmaceutical company has the right to appeal before the Supreme Court.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

The Medicines Council may impose the following sanctions, either cumulatively or alternatively:

(a) Order the offender to terminate the offence by a specified deadline and to not repeat it in future. If the infringement has been terminated before a decision has been taken, the Medicines Council may, by decision, confirm the infringement.
(b) A fine of up to €25,000.
(c) If the violation continues, an administrative fine of up to €200 for each day the violation continues.

Any affected party (natural or legal person or organisation), if they have legitimate interest (such as competitors), can appeal to the Cyprus Court and may request a prohibition or protection order.

The Medicines Council imposed a €40,000 fine on an entity that advertised a non-licensed product (other fines that have been imposed have not been made publicly available).

Pharmaceutical companies must also ensure compliance with the Code of Conduct of KEFEA. KEFEA has established a committee in charge of upholding the Code. The committee applies its own rules for submitting and examining complaints and for determining sanctions. The committee may issue a warning against a company, request that it ceases the offending activity within a prescribed time period in the event of a failure to comply or, in any other event, may impose a fine not exceeding €5,000 for a first violation and a fine not exceeding €10,000 for a second violation. It may also expel a company and may make its decision public by posting it on its website.

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

Supervising authorities (such as the Medicines Council) and self-regulating bodies (such as KEFEA) are completely separate and independent. Therefore, in the case of an adverse finding of a self-regulating body, it is not uncommon for the supervising authorities to also pursue the matter further, following an escalation of the matter by the complainant.

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

Pharmaceutical companies can take action against competitors that breach advertising rules and regulations under the ground of unfair competition. Action can be brought before the District Courts directly for injunctive relief, suspension or damage, or to the protection of competition authorities, by anyone who can establish a rightful claim.

2 Providing Information Prior to Authorisation of Medicinal Product

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

Advertising a medicinal product for which a marketing authorisation has not been granted is prohibited. Making information available to healthcare professionals about a medicine can be considered advertisement.

However, scientific information regarding recent scientific research and unauthorised medicinal products may be provided in the context of scientific events organised by the medical department of the pharmaceutical company (since this activity is not included in the concept of advertising and promotion), regardless of whether such meeting is sponsored by the company or not. Promotional material aimed at healthcare professionals may contain information contained in tables and representations derived from medical journals or scientific papers; however, such material must a) make clear that the substance in question is not approved, b) ensure that the data are presented with absolute accuracy, and c) ensure that no trade name is used.

With regard to the provision of off-label information, the same rules as above apply. Article 65 of the Law provides the information that can be contained in medicinal product advertisements, and it presupposes that the medicinal products for such advertisements have been approved.

Off label information may be used in the context of scientific events (as explained above).

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

Advertising a medicinal product for which a marketing authorisation has not been granted is prohibited under the Law.

As explained in question 2.1 above, information on unauthorised medicines and off-label information cannot be published to the general public but can be made available to healthcare professionals. Promotional material aimed at healthcare professionals can include information from medical journals or scientific papers (if the information can be faithfully reproduced and the source indicated accurately).

Whenever there is a claim based on experimental data from *in vitro* studies or studies on animals, it must be clearly indicated in the promotional material that the claim is based on experimental data.

The creative part of advertisements, including images, graphs and tables, must comply with the letter and spirit of the Code of Conduct of KEFEA. Graphs and tables must be presented in such a way as to provide a clear, fair and balanced view of the data presented, and they can only be included if they are relevant to the claims or comparisons made. Medical information leaflets cannot bear representations irrelevant to the content thereof, or that are misleading, or that imply a particular medicinal product.

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

As stated above, advertising a medicinal product for which a marketing authorisation has not been granted is prohibited. Promotional material aimed at healthcare professionals may contain information contained in tables and representations derived from medical journals or scientific papers; however, such promotional information must a) make clear that the substance in question is not approved, b) ensure that the data are presented with absolute accuracy, and c) ensure that no trade name is used.

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

The general prohibition does not apply to correspondence that may be accompanied by another non-promotional document required to answer specific questions about a particular medicinal product, if requested by healthcare professionals.

In the event that promotional material refers to data included in a particular document, the corresponding section referring to the said data must be provided, upon request, without delay, to healthcare professionals or administrative personnel.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

The *Ludwigs* case has not had a great impact on Cyprus legislation.

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

Although there are no express legislative provisions in Cyprus legislation governing this subject, in accordance with the Law, advertising a medicinal product for which a marketing authorisation has not been granted is prohibited. Therefore, sending information on unauthorised medicines to institutions may be considered advertising and is thus prohibited.

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

It is acceptable to involve healthcare professionals in market research exercises concerning unauthorised medicinal products, provided that this activity is not misused in order to promote those products.

3 Advertisements to Healthcare Professionals

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

An advertisement for a medicinal product directed to healthcare professionals must include:

(a) essential information corresponding to the brief description of the product characteristics;
(b) the classification of the medicinal product in terms of the conditions of administration; and
(c) the selling price or indicative price of the various packages and any subsidy rate by any social security organisation or general health system.

If the advertisement is addressed to persons authorised to prescribe or supply medicinal products, the name of the medicinal product, for the purpose of memorising such name, may be included.

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

Both the Law and the Code of Conduct of KEFEA prohibit the promotion of prescription-only medicines to the public. If members of the public request information on personal medical matters, they should be referred to a healthcare professional.

An advertisement directed to healthcare professionals can refer to studies not mentioned in the SmPC, e.g. information contained in tables and representations from medical journals. These, however, must be faithfully reproduced and the sources indicated accurately.

Under Appendix IX of RAA 10/2000 (Advertising Code, Telemarketing Messages and Sponsorship Programmes), the inclusion of doctors, dentists, pharmacists, nurses, midwives, etc., which may give the impression of professional advice or recommendation, in advertisements for pharmaceutical products is not permitted.

Advertisements for medicines and treatments may not include:

(i) claims for treatment of any malaise or symptoms of ill health that indicate that recovery is certain;
(ii) anything that could be construed as an offer or medicine or product or advice in connection with the treatment of serious diseases, complaints, conditions, indications or symptoms;
(iii) observations and reports that give the impression of professional advice or recommendation;
(iv) a claim for treatment or substitution of appropriate treatment or substitute treatment in connection with serious illnesses, such as ulcers, heart trouble, etc.;
(v) offers to diagnose or treat ailments by mail;
(vi) the word "stimulant" or related claims; or
(vii) any report or implication that the good health of persons may be endangered if they do not complete the dietary intake of vitamins.

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

Pharmaceutical companies are allowed to ask healthcare professionals to provide them with consulting services that are related to their specialty.

It is must be noted, however, that such provision of services must not jeopardise the clinical autonomy of the collaborating healthcare professional, who must make independent decisions and practise his/her profession in the interest of patients.

This collaboration is based on a special agreement between the company and the healthcare professional. When healthcare professionals present views or results to third parties, a statement of interest must be presented for reasons of transparency.

Under Appendix IX of RAA 10/2000, the inclusion of doctors, dentists, pharmacists, nurses, midwives, etc., which may give the impression of professional advice or recommendation, in advertisements for pharmaceutical products is not permitted.

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

Information, claims and comparisons must be correct, accurate, objective and clear, and must be based on relevant and comparable aspects of the medicinal products, as well as on an updated assessment of all data, reflecting clearly the facts. Any information, claims or comparisons must be scientifically documented. There is no specific requirement for a particular number of clinical trials to be made before comparative claims may be made.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Comparative advertising, i.e. advertising that explicitly names or implies a competitor or the goods and services offered by a competitor, is permitted as long as it is not misleading (and is therefore a legitimate means of informing consumers about an advantage).

"Misleading advertising" means any advertisement that, in any way, misleads or is likely to mislead the persons to whom it is addressed or to whom it is perceived to be addressed and, because of its misleading nature, is capable of affecting economic interests, or, for these reasons, harms or is likely to harm a competitor.

A comparative advertisement must meet the following conditions:

(i) compares goods or services that meet the same needs or have the same objectives;
(ii) refers to products with the same designation of origin;
(iii) treats in an objective manner characteristics that are essential, relevant, verifiable and representative of the goods or services in question, which may include the price; and
(iv) avoids confusion amongst healthcare professionals, and does not undervalue, imitate or unfairly benefit from competitors' trademarks or trade names.

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

The two conditions that govern the distribution of this kind of information is whether or not it has a scientific goal and whether or not it promotes sales or the inducement of prescription writing. Therefore, any information included in scientific papers and proceedings of congresses must be checked as to its scientific accuracy and integrity before distributing such material.

References to information contained in tables and representations that come from medical journals or scientific papers and used in newsletters must be reproduced faithfully and their sources indicated accurately.

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

The advertising legislation in Cyprus does not provide for any specific provision regulating "teaser" advertisements. Therefore, such advertisements are permissible as long as they comply with specific conditions and regulations regarding the advertisement of pharmaceutical products.

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

As noted above, the promotion of off-label use is prohibited. It must also be noted that it would be necessary for Product B to vary its SmPC despite the fact that the approved SmPC for Product A is authorised for a particular indication to be used in combination with Product B. As the use of Product B for Product A's indication would be off-label, the MA of Product B cannot promote the combination.

4 Gifts and Financial Incentives

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

Under article 69(1) of the Law, free samples may be provided free of charge to persons authorised to supply medicinal products or in relation to the relevant prescriptions under the following conditions:

(a) only a small number of samples per year per medicinal product and for each person authorised to prescribe are provided;
(b) each sample offered must be in response to a written request dated and signed;
(c) the supplier of the samples must have an adequate control and liability system;
(d) the samples must not be larger than the smallest commercially available package;
(e) the samples must be marked with the disclaimer: "free medical sample – sale is prohibited", or similar disclaimer;
(f) the samples must be accompanied by a copy of the brief description of the product characteristics; and
(g) no sample of a medicinal product containing psychotropic or narcotic substances within the meaning of the Single Convention on Narcotic Drugs (1969), the Protocol Amending the Single Convention on Narcotic Drugs (1973), the Convention on Psychotropic Substances (Sanctions) (1973) and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1990) can be provided.

The Medicines Council may, by reasoned decision published in the Official Gazette of the Republic, further restrict the distribution of samples of certain medicinal products.

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

According to Regulation 218/2017, healthcare professionals working in the public sector are prohibited from accepting any gifts or money given to them in their official capacity.

Under the Law, in the context of promoting the sale of medicinal products to persons authorised to prescribe the relevant prescriptions or to supply the medicinal products, it is prohibited to offer or promise to such persons a gift, monetary benefit or benefit in kind (except for items of negligible value related to the professions of doctor or pharmacist).

It is understood that hospitality, in the context of sales promotion events, is always strictly limited to the main purpose of the event and must not be extended to persons other than healthcare professionals.

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

Donations, grants and benefits in kind to institutions, organisations or associations that comprise healthcare professionals and/or that provide healthcare or conduct research are only permitted if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

In case any person/association/company intends to donate a sum of money/medical equipment or anything else to a public hospital, this intention must be notified to the public hospital where the donation is intended to be made. In case of donations to public hospitals worth over €15,000, the donor must inform the Ministry of Health through the specific hospital of the amount of the donation he intends to offer, and what medical equipment the hospital needs (for which this donation could be used). The Ministry of Health will then, once the necessary approvals are obtained, announce an open tender on behalf of the donor, provided that the product in question can be provided by more than one supplier.

It must be noted that in cases where the donor insists on purchasing the medical equipment himself (following the procedure provided in the regulations for donations), this must be approved by the Director General of the Ministry, after an internal consultation.

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

Items of medical utility aimed at educating healthcare professionals and providing patient care can be provided if they are of negligible value and do not offset the routine business practices of the recipient. Donations of items and services must not be effected in a way that constitutes an inducement to prescribe or purchase those items or services. Indicating the name of the company on the items donated to hospital institutions is permitted (however, indicating the name of a medicinal product is prohibited).

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?

Commercial measures or practices relating to prices or profit margins and discounts are permitted. Competition law must, however, be taken into consideration before deciding on establishing such measures.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

No, such practices are not encouraged, since these kinds of arrangements should only be aimed at promoting public health and for the benefit of patients and not induce sales.

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?

In Cyprus, although such schemes (pay for performance) are not prohibited in the Law, they are not currently being used. These schemes are known as "entry control agreements", which include an agreement on performance, i.e. payment for a product is not required if it does not have the expected results. Such agreements are mainly put in place for prescription-only medicines.

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

According to article 5.2 of the Directive and article 3.6 of the Law, the Medicines Council may approve the use of early access programmes enabling early patient access to new medicines, under exceptional circumstances and only for specific patients, upon request.

There are no further provisions regulating other schemes in Cyprus legislation.

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

This is permitted, but it must not have a promotion aim. With regard to the applicable rules, it depends on the public entities involved in the project and the procedures they follow, including any ethical codes. The main rules to follow are the avoidance of conflicts of interest and maintaining transparency throughout the project.

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

Yes, pharmaceutical companies may sponsor continuing medical education through events such as scientific congresses organised by government institutions and universities. With respect to scientific congresses and events for the provision of medical information and activities for the promotion of sales, when organised in Cyprus and sponsored by pharmaceutical companies (or the parent companies thereof or through any promotional or other service company established in Cyprus or abroad), and physicians established in Cyprus participate therein, before carrying out the event, a notification with a detailed programme must be submitted to the Cyprus Medical Association. Recipients of funds are jointly obliged to include in their annual accounts the relevant receipts and payments for the scientific event in accordance with the applicable laws, along with the notification mentioned above.

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

As mentioned above, healthcare professionals working in the public sector are prohibited from accepting any gifts or money given to them in their official capacity. The violation of this obligation constitutes a criminal offence, and, in such case, the Police will investigate the matter. There has been a case in Cyprus where a public-sector healthcare professional was prosecuted for this offence.

Furthermore, under the relevant law and ethical code for healthcare professionals, healthcare professionals are prohibited from using their capabilities to satisfy unfair interests.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

There are two types of healthcare professionals in Cyprus: healthcare professionals employed in the public sector; and healthcare professionals employed in the private sector. Healthcare professionals employed in the public sector are subject to the provisions of the Law on the Establishment of the State Health Services Organization (73(I)/2017) and the regulation promulgated by virtue of that legislation (namely, Regulation 218/2017). Healthcare professionals employed in the private sector are generally independent practitioners or employees, and their profession is governed by the Law regarding Doctors (Associations, Discipline and Pension Fund) (16/1967) and the internal policies of the organisations that they work for.

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

With regard to healthcare professionals working in the private sector, whether any payment to their private bank accounts is possible depends on the internal policy of the organisations they work for. As article 47 of Regulation 218/2017 forbids healthcare professionals working in the public sector from accepting any gifts or money given to them in their official capacity. There is no general prohibition in the Law to bear the travel, accommodation and hospitality (food, beverages) costs of healthcare professionals in the public sector, as long as any payment made is compatible with article 47 of Regulation 218/2017 (prohibition of gifts and bribes). With regard to healthcare professionals in the private sector, travel costs (subject to any internal policies of their organisations) can be paid for.

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

Although this is not explicitly provided, pharmaceutical companies may be held responsible for the contents of the scientific meetings they have organised. A company that only provided hospitality and did not organise or sponsor the meeting will not be held reponsible for the contents of such a meeting.

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

In relation to healthcare professionals working in the public sector, article 44(2)(b) of Regulation 218/2017 states that no employee may be paid for any publication or broadcast with reference to their duties without the prior authorisation of the Director General. With regard to healthcare professionals working in the private sector, any such remuneration will depend on the internal policy of their organisations as there is no legal obstacle.

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

Post-marketing surveillance, experience programmes and post-authorisation studies must not constitute disguised promotion. Such assessments, programmes and studies must be performed mainly for a scientific or educational purpose.

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

With regard to the private sector, there is no specific provision in Cyprus legislation regulating payment obligations to healthcare professionals to take part in market research involving promotional materials. With regard to the public sector, the abovementioned rules apply.

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?

Under article 63(1) of the Law, advertising to the public is permitted, if it is licensed.

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

Under article 63(1) of the Law, advertising to the public prescription-only medicines is prohibited. The only exception is vaccination campaigns approved by the Medicines Council.

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?

Provided that no reference is made to a specific medicine, release of information that only covers certain diseases is not considered advertising and can be conducted legally.

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

Publishing announcements in non-scientific journals is prohibited. A press release on the release of a medicine is permitted; however, promoting, advertising and providing information about it is not permitted.

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

If the information is purely informative and does not contain a hidden intention to advertise or promote the products, then such information can be included in corporate brochures and annual reports.

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

The Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organizations regulates meetings and funding of patient organisations.

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

There is no specific provision in Cyprus law regulating this matter. However, offering medical and educational goods and services (i.e. medical or diagnostic equipment, scientific publications, electronic aids (electronic systems with databases, electronically supported programs, etc.)) that improve patients' healthcare and are for the patients' benefit or for the benefit of the National Health System to private hospital institutions, healthcare centres and to general hospital institutions of the public sector, monitored by the Ministry of Health, which are directly associated with the provision of healthcare services, is permitted.

6.8 What are the rules governing company funding of patient support programmes?

Events and activities with patient associations are permitted. They are governed by the RNB (Research and Development) Code of Conduct and the Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organizations, as well as the Law. When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations they must

have a written agreement in place. This agreement must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of the significant indirect support (e.g. the donation of a public relations agency's time and the nature of its involvement) and significant non-financial support. Each pharmaceutical company must have an approval process in place for these agreements.

7 Transparency and Disclosure

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

All kinds of clinical trials are carried out but only upon approval by the competent authorities (Medicines Council) and/or the BIO Ethics Committee. The sponsor must be known to the patients participating in the trial. All data on safety and efficacy with respect to marketed products must be truthfully published on the Internet, irrespective of the outcome of the trial, at least in summary form, within the year following the grant of the marketing authorisation. Furthermore, other important clinical results must be published in the same way. In publications, lectures and other presentations, the identity of the sponsor must be known. When presenting clinical trials, the physician must make known his/her connections with all the companies of the therapeutic area covered by his/her lecture.

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

As a general obligation, each KEFEA member must document and disclose any transfers of value it makes, directly or indirectly, to or for the benefit of a recipient.

Transfers of value that are (i) solely related to over-the-counter medicines, (ii) solely related to items of medical utility, meals and drinks, medical samples, or (iii) part of ordinary course purchases and sales of medicinal products by and between a member company and a healthcare professional (such as a pharmacist) or a healthcare organisation do not fall within the scope of the disclosure obligation described in the previous paragraph. The transactions disclosed could consist of, for instance, a grant to a healthcare organisation or a consultancy fee for a healthcare professional speaking engagement.

Disclosures must be made on an annual basis and each reporting period shall cover a full calendar year, within six months after the end of each year, and the information disclosed must remain in the public domain for a minimum of three years after the time such information is first disclosed, unless the recipient's consent relating to a specific disclosure, which is required by Cyprus law, has been revoked.

Disclosures must be made in Greek or English on KEFEA's website via a link that directs to each KEFEA member company's disclosure platform, using the template provided in the Code of Conduct of KEFEA.

Disclosures are made based on the national code of the country where the healthcare professional/healthcare organisation receiving the payment or transfer of value has their principal practice. This applies regardless of whether the transfer of value occurs within or outside that country. This ensures that the patient or interested stakeholder can easily find the information regarding transfers of value to a healthcare professional/healthcare organisation he/she has an interest in. The physical address where the healthcare professional practises or healthcare organisation is located should be used to determine the country where the data must be disclosed.

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

As a member of EFPIA and in line with these initiatives at the European level, KEFEA adopted its own disclosure code that requires all KEFEA member companies to disclose details of transfers of value to healthcare professionals or healthcare organisations. The disclosure, including a general summary and/or country-specific considerations, should describe the recognition methodologies applied, and may include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of the transfers of value for the purposes of the disclosure code.

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

A pharmaceutical company that has transferred value to a healthcare professional must disclose it, irrespective of whether the healthcare professional agrees or not. In order to avoid such a situation, a written agreement should be put in place between the pharmaceutical company and the healthcare professional prior to any transfer of value.

8 Digital Advertising and Social Media

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

Cyprus does not, at present, have legislation or guidelines addressing advertising via social media and, therefore, the general rules apply. Access to promotional material available on the Internet for prescription-only medicinal products must be restricted (i.e. by a password) to healthcare professionals and the suitable administrative personnel, and the material must, in principle, have a technical, scientific or professional nature. Promotional material must include a characteristic and legible warning stating that the information contained on the web page is exclusively addressed to healthcare professionals who are authorised to prescribe or supply medicinal products and, therefore, specific training is necessary for the correct interpretation thereof.

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

There is no specific legislation in Cyprus in relation to this subject. However, measures must be taken to ensure that access to the promotional material is restricted to healthcare professionals, who can gain access by entering a password, as provided in the Code of Conduct of KEFEA.

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

As mentioned above, access to prescription-only product promotion must be limited to healthcare professionals and the corresponding administrative staff. There are no restrictions, except for the general rules for advertising non-prescription medicines.

There are no further rules or regulations for reverse linking, but the general rules apply.

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

Medicinal products for which advertising to the general public is permitted can be advertised on a website that is accessible to the general public, provided that the company complies with the applicable obligations, as mentioned above.

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

There is no specific legislation for social media. However, Codes of Conduct provide useful guidance to pharmaceutical companies in relation to their use of social media.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

There is no specific legislation for social media and, therefore, for the use of employees' personal accounts and their interactions.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There are no specific rules governing advertising and promotional activity conducted virtually. The general provisions on advertising and promotion are applicable.

9 Developments in Pharmaceutical Advertising

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

In the pharmaceutical industry, the most significant change in the last few years was the amendment of the Law in 2020 and its update in accordance with Regulation (EU) No 536/2014 and the implementation, on 31 January 2022, of the Clinical Trials Information System (CTIS) – the single entry point for clinical trial application submission, authorisation and supervision in the EU and EEA.

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

No significant developments are expected in the next year.

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

There are no general practice or enforcement trends that have become apparent in Cyprus over the last year.

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