PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

Advertising of pharmaceuticals is regulated by sections 50 et seq of the Austrian Pharmaceuticals Act (*Arzneimittelgesetz*, AMG).

At the self-regulatory level, the Code of Conduct (CoC) of the Association of the Austrian Pharmaceutical Industry (PHARMIG) also contains rules regarding the advertising of pharmaceuticals and the interaction between pharmaceutical companies on the one hand and health care professionals (HCPs) and health care organisations (HCOs) on the other hand. Roughly 120 pharmaceutical companies are currently members of PHARMIG (Mitgliedsunternehmen / PHARMIG) and are thus bound by this Code.

The statutory provisions governing the advertising of medical devices are contained in Sections 70-76 of the Austrian Act on Medical Devices (*Medizinproduktegesetz 2021*, MPG).

Self-regulation regarding medical devices is codified in the Code of Conduct (*Verhaltenskodex*) of AUSTROMED, the association of the manufacturers of medical devices in Austria. However, this Code only contains a very broad and unspecific stipulation regarding 'fair competition' in Section 12, but no specific rules on advertising or promotion of medical devices.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

Section 50(1) of the AMG defines 'advertising of pharmaceuticals', in line with Article 86 of Directive 2001/83/EC, as comprising all measures intended for information, market research, market development as well as to incentivise, aimed at promoting the prescription, supply, sale or consumption of pharmaceuticals. This provision thus does not distinguish between promotion and advertisement of pharmaceuticals. Pursuant to Austrian case law, the categories considered as 'advertising' of pharmaceuticals are rather broad and include also 'any measure relating to a specific pharmaceutical and serving to promote its sale' (eg, OGH, 4 Ob 75/03p – *Pro Herz*).

Section 50(2) of the AMG exempts from the application of the provisions on pharmaceutical advertising any communication and documents not serving advertising purposes that relate to specific enquiries about a particular pharmaceutical, as well as sales catalogues and price lists, and information on health or diseases, all without any mention of or reference to a pharmaceutical.

Similarly, as the AMG, the MPG does not distinguish between promotion and advertisement of medical devices either.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The statutory provisions on pharmaceutical advertising and promotion in sections 50 et seq of the AMG are controlled and supervised by the Austrian Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*, BASG) pursuant to section 56a of the AMG:

Upon request, all documents that the BASG deems necessary to monitor compliance with the AMG's advertising provisions must be submitted to the BASG (including all documents relating to sales promotion events and job-related scientific events). In the case AMG's advertising provisions are violated, the BASG shall order all measures necessary to establish conformity with the law. This supervision performed by the BASG is performed on a random basis and at irregular intervals only.

By comparison, the PHARMIG Code Adjudication and Appeal Boards deal with complaints of competitors about (alleged) infringements of the PHARMIG CoC.

In cases of advertisements that (allegedly) contravene the statutory provisions on pharmaceutical advertising, pharmaceutical companies may also be held culpable of an administrative offence by the

administrative courts. In addition, lawsuits and applications for preliminary injunctions may be filed against them, for example, by competitors, with the competent civil courts.

As to advertising and promoting medical devices, the statutory provisions are enforced by the administrative courts and, in case of any legal action filed against the manufacturers, by the civil courts as well.

Infringements of the 'fair competition' rules contained in section 12 of the AUSTROMED CoC (see Question 1 above) can be enforced by filing arbitration claims to an AUSTROMED-internal arbitral tribunal, pursuant to section 20 of the AUSTROMED Statutes (*AUSTROMED Statuten*).

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for example food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

No, section 1 of the AMG explicitly excludes other products like food and food additives, cosmetic products, etc, from the term 'pharmaceuticals'. If a product fulfils both the definition of a pharmaceutical pursuant to the AMG and the definition of a product regulated in another federal law, only the provisions of the AMG apply to this product (section 1(3a) AMG).

Pursuant to the steady case law of the OGH, products that do not have the function of a pharmaceutical but merely claim to have one according to the presentation of the product (so-called *presentation pharmaceuticals*) are also subject to the provisions of the AMG (compare OGH, 4 Ob 190/17w).

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

Austrian law provides restrictions both in relation to pharmaceuticals and to medical devices:

Advertising towards the public is, in principle, not allowed in relation to: (1) prescription-only pharmaceuticals; (2) pharmaceuticals that are not subject to prescription, but whose name contains the same invented word or the same scientific term as the name of a prescription-only pharmaceutical; and (3) registered homeopathic pharmaceuticals (section 51 AMG).

In addition, advertising towards the public must not contain any statements that go beyond the labelling, instructions for use or the summary of product characteristics (SmPC), compare Section 50a(4) of the AMG.

Also, pursuant to section 52, the presentation and contents of advertisements for pharmaceuticals directed to the public:

- must evidently express the advertising character and the product must be clearly presented as a pharmaceutical. Advertising and editorial contributions must be clearly separated;
- needs (in general) to contain, at least:
  - the name of the pharmaceutical and the usual scientific name of the active substance, if the pharmaceutical contains only one active substance;
  - the information essential for the appropriate use of the pharmaceutical; and
  - a clearly perceptible indication that pharmaceuticals can also cause undesirable effects and that the instructions for use must therefore be carefully observed or the advice of a doctor or pharmacist must be sought.

Special regulations apply to traditional herbal proprietary medicinal products and to reminder advertisements.

Furthermore, according to section 53 of the AMG, public pharmaceutical advertising must not:

- contain pictorial representations in connection with HCPs or healthcare facilities;
- make a medical examination or surgical intervention appear superfluous;
- suggest that the effect of the pharmaceutical is guaranteed without side effects or is equivalent or superior to another treatment or pharmaceutical;
- suggest that normal good health could be improved by the use of the pharmaceutical or suggest that normal good health could be adversely affected if the pharmaceutical is not used;
- be intended exclusively or mainly for children;

- refer to a recommendation by scientists, HCPs or persons who could encourage the use of pharmaceuticals due to their reputation;
- equate the pharmaceutical with a foodstuff, a cosmetic product or other consumer goods;
- suggest that the safety or efficacy of the pharmaceutical is due to the fact that it is a 'natural product';
- potentially mislead the public into a false self-diagnosis by a detailed description or presentation of the medical history;
- refer to recovery certificates in an abusive, alarming or misleading manner;
- use visual representations of changes in the human body in an abusive, alarming or misleading manner; or
- work towards obtaining prescription-only pharmaceuticals by distance selling.

Section 5 of the PHARMIG CoC on pharmaceutical advertising basically repeat and exemplify the advertising restrictions in the AMG.

Information contained in materials intended for advertising medical devices must not contradict the labelling and instructions for use pursuant to section 70 of the MPG.

Moreover, advertising of medical devices intended for consumers is not allowed regarding:

- medical devices that are subject to prescription;
- medical devices intended exclusively for use by HCPs on or for the patient; and
- medical devices which, according to the instructions for use, may only be used by consumers in connection with medical or dental treatment or monitoring,

pursuant to section 71 of the MPG.

In addition, similarly to the AMG, the MPG prohibits any elements in advertisements for medical devices directed to the public that:

- suggest that the effect of the medical device is equivalent or superior to another treatment or medical device;
- are intended exclusively or mainly for children;
- make a medical examination or surgical intervention appear superfluous;
- refer to recovery certificates; and
- use pictorial representations of changes in the human body due to diseases, injuries or disabilities or the effect of a medical device on, or in, the human body.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

No, promotion/advertising of pharmaceuticals and medical devices through the internet and social media is not regulated in Austria. However, according to case law the regulations of advertising for pharmaceuticals apply to each measure aiming to promote the pharmaceutical's sales, irrespective of the medium (4 Ob 255/03h).

As regards pharmaceuticals, the PHARMIG CoC contains, in Article 6, some exemplifications of the general pharmaceutical advertising regulations in the AMG (and in the UWG).

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

No. Please see Question 3 regarding the BASG's surveillance pursuant to section 56a of the AMG.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

In general, it is not possible to promote a product that is not registered in Austria, even to healthcare professionals. No pharmaceutical products can be advertised or promoted for indications not approved by the National Administration of Medicines, Food and Medical Technology (ANMAT), meaning that no off-label promotion of products is allowed.

Resolution No 627/2007 establishes that any promotion of not authorised for commercialisation medicines is forbidden. It also states that all the contents of the promotion of a medicinal product must match the data,

characteristics, and identifications listed on the registration certificate (marketing authorisation). ANMAT Disposition No 4980/2005 has similar provisions for the advertising of OTC products.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Advertising off-label use of pharmaceuticals is not mentioned in the AMG, and no case law exists on this aspect. However, advertising pharmaceuticals is not allowed if a required marketing authorisation (MA) is not validly in place for the respective products (section 50a(1) No 1 AMG).

In addition, public advertising pharmaceuticals must, specifically pursuant to section 50a(4) of the AMG contain any statements that go beyond the labelling, instructions for use or the SmPC.

Advertising towards HCPs in the context of scientific events whose participants are predominantly based abroad is exempted from the prohibition of advertising pharmaceuticals (compare section 50a(5) AMG).

Section 53(1) No 3 of the AMG prohibits advertising of pharmaceuticals directed to the public that suggests that the effect of the pharmaceutical is equivalent or superior to another treatment or pharmaceutical (see Question 5 above).

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

The term HCP is to be understood in a broad sense and includes, amongst others, doctors, dentists, midwives, etc.

The relevant provisions in the AMG regarding advertising to HCPs refer to persons authorised (1) to prescribe or dispense pharmaceuticals (section 50, paragraph 1 No 2 and sections 55 et seq AMG) and (2) use and dispense pharmaceuticals (section 54 AMG). While the latter is rather broad and includes, among others, members of the professional nursing service, the medical-technical services and the paramedical services, the first definition is rather narrow and refers only to doctors, dentists, pharmacies, etc. Pursuant to opinions in legal literature, HCPs should, in the context of advertisement in general, be limited (by teleological interpretation) to the authority to prescribe or dispense.

Any advertising communication directed to HCPs in publications, in electronic media, or by telecommunication regarding pharmaceuticals must be accurate, up-to-date, verifiable, and complete enough to enable the recipient to understand the therapeutic value of the product (section 55(2) and (3) AMG). Quotes, tables, or illustrations from scientific literature used must be faithfully reproduced with precise citation of the source (section 55(4) AMG).

Any such communication must include key information about the pharmaceutical; see especially section 54 of the AMG and section 74 of the MPG, respectively. Any such information must be in line with the SmPC. Advertising communication must not be misleading.

It is forbidden in the context of advertising the sale of pharmaceuticals to offer, promise, or grant gifts, pecuniary advantages, or tangible benefits to HCPs, unless these are of minor value and relevant to medical or pharmaceutical practice. The PHARMIG CoC essentially repeats these provisions.

The granting, offering, and promising of in-kind discounts to individuals authorised to prescribe or dispense pharmaceuticals is prohibited, provided that these are pharmaceuticals listed in the Reimbursement Code (*Erstattungskodex*) published by the Umbrella Association of Austrian Social Security Institutions.

Since section 53(1) No 3 of the AMG (see Question 9 above) does not relate to HCPs, comparative pharmaceutical advertising directed at HCPs is admissible if it adheres to the regulations on comparative advertising in the Gesetz gegen den Unlauteren Wettbewerb (UWG). Pursuant to Section 2a of the UWG, comparative advertising is generally admissible towards HCPs unless it is prohibited on different grounds, like, in particular, misleading phrases or elements (section 2 UWG). The OGH ruled (4 Ob 233/06b) that, regarding the comparison of a pharmaceutical with a competitor`s product, advertising of partial results of a medical study (favourable to the advertiser), may be misleading if the advertisement does not make clear which primary objectives the cited study pursued and what are the results in relation to these objectives.

Article 5.7 of the PHARMIG CoC states that pharmaceutical companies must not make reference, in their writings or promotional materials, to brands of competitors, unless they have received permission to do so or their writings or materials are in accordance with the provisions of the UWG.

The MPG similarly contains, though less detailed, provisions on the advertising of medical devices to HCPs, namely all persons who have responsibilities in the context of prescribing, dispensing, procuring for healthcare institutions (HCIs), establishment, commissioning, or application (section 75 MPG).

Under certain conditions, provisions of Austrian criminal law (such as provisions on anti-corruption) might be relevant regarding advertising of pharmaceuticals and medical devices.

See below for specific cases of advertising.

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

Austrian law does not have specific regulation on online interactions and virtual advertising activities. However, the general rules regarding advertising apply.

The PHARMIG CoC (Article 6) includes specific rules on online information and online advertising, including, among others, clear disclosure requirements regarding sponsorship and addressees of advertisements. However, there are no particular regulations concerning virtual congresses and symposia.

Regarding the payment of, for example, registration fees for online congresses and symposia, please see Question 14.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

Please see Question 5.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Yes; the provision of pharmaceutical samples to HCPs having a MA is allowed (section 58 AMG). Any such pharmaceuticals need to be labelled with '*Sample for Doctor's Use – Not for Sale*' and may only be supplied to patients free of charge. The package must be smaller than the smallest unit on the market. The number of samples that may be dispensed is staggered according to years after the first dispense of the pharmaceutical, and the numbers of patients, and of samples per patients, are limited too. Certain pharmaceuticals (eg, including addictive substances) are excluded from this authorisation to distribute samples. Specific documentation obligations apply.

Pursuant to the AUSTROMED CoC, samples of medical devices may be provided free of charge to professionally qualified staff in HCIs for (limited) demonstration purposes.

14. What rules govern the offering of hospitality to healthcare professionals?

The general principles of the AMG and MPG apply (especially section 55a(3) AMG and section 75 MPG).

It is generally permissible to cover reasonable travel, accommodation costs, and participation fees for pertinent scientific events for (individual) HCPs (see section 55a(3) AMG).

The PHARMIG CoC provides more detailed provisions such as those on covering costs and organising social programs (which are prohibited) and specific documentation requirements. Moreover, the PHARMIG CoC distinguishes between national and international events. Regarding the latter, both the CoCs of the event's location and the respective company's seat might apply. Specific regulations on hospitality of the PHARMIG CoC apply to conferences and events on pharmaceuticals, providing further guidance on the costs which can be assumed (such as, eg, the costs for a meal, which should not exceed €85).

Similarly, albeit in less detail, the MPG includes rules on advertising medical devices to HCPs. The AUSTROMED CoC imposes more detailed provisions on hospitality for conferences and events concerning medical devices, such as specific approval rights by HCIs for their employees and specific documentation requirements.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Under Austrian law, there are no specific regulations regarding the provision of gifts or donations to HCIs. No general ban on such donations is imposed.

If such donations are provided to a public official or authorised employee, anti-corruption laws (including sections 153a and 307 et seq of the Austrian Criminal Code, (StGB)) may apply.

The PHARMIG CoC allows for the specific authorisation of financial or material donations or subsidies to HCIs, solely for the purposes of training/education, research, healthcare system support, or as part of scientific or specialist activities, with specific documentation obligations applying.

The AUSTROMED CoC also specifies provisions for donations to HCIs by medical device companies. According to these, donations are only permissible if they help towards promoting research and education of scientific value, improving healthcare or patient care, education and training, or further, charitable, purposes. Moreover, specific documentation requirements apply.

Specific disclosure obligations might apply to the respective HCI, for example, pursuant to hospital law provisions.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Any such support of scientific and educational meeting has to comply with the general rules (especially section 55a(1) AMG and section 75 MGP, UWG and potentially also StGB) this applies to both, scientific and educational meetings supported by pharmaceutical laboratories as well as medical device manufacturers' or their licensees' support.

The PHARMIG CoC foresee general transparency and disclosure obligations (including the obligation to document and publish all such pecuniary advantages granted, which also covers the sponsoring of such events).

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

No specific regulations exist under Austrian law regarding the relationship with (and especially the funding of) patient organisation (POs). Section 10 of the PHARMIG CoC outlines detailed rules on advertising with the support of POs and providing support to POs including, amongst others, aims of such support, documentation and disclosure requirements, transparency, benefits provided to representatives of POs and organisation, invitations, sponsoring of events.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

Co-promotion is not specifically addressed in the AMG and the MPG; however, the general rules and regulations for advertising also apply to advertising agencies and publishers of magazines (as well as potentially other third parties), since the producer of the respective product/device and the advertiser do not necessarily have to be the same. Pursuant to the PHARMIG CoC, (pharmaceutical) companies must comply with the obligations contained in the PHARMIG CoC even if third parties act on their behalf, either directly or indirectly and with or without their approval or involvement (see Court of Justice of the European Union (CJEU) 2 April 2009, C-421/07, Damgaard).

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

As regards pharmaceuticals, the AMG does not provide for particular provisions regarding disclosure requirements regarding transfers of value. However, the PHARMIG CoC includes an obligation to disclosure cooperations of pharmaceutical companies with HCPs (also outlining the value of such contributions). Specific obligations to keep this information up-to-date apply.

No statutory transparency provisions regarding transfers of value exist regarding medical devices either. However, general guidelines regarding value transfers in connection with medical devices are provided by the AUSTROMED CoC.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Infringing the provisions on advertising pharmaceuticals in sections 50 et seq of the AMG may entail a fine of up to €25,000, or up to €50,000 in the event of a repeat offence, as an administrative offence (section 84(1) No 19 AMG). In addition, the BASG may cancel the MA of a pharmaceutical if the MA holder has been punished at least three times for the same infringement of the provisions on advertising pharmaceuticals (section 85(1) AMG).

However, the BASG very rarely imposes such fines and/or sanctions. Rather, it performs its supervisory and controlling function on a random basis pursuant to section 56a of the AMG (compare with Question 3). During a random project called 'advertising surveillance 2020' (*Projekt Werbungsüberwachung 2020*) the BASG detected, among 12 MA holders whose advertising was reviewed by the BASG, some infringements of several advertising provisions of the AMG. The information officers of the pharmaceutical companies concerned were informed about the violations of the advertising provisions of the AMG having been committed from the BASG's point of view, and they were asked to comment on them. Consequently, respective improvement measures were promised and/or implemented by the companies. Public announcement of any penalties or sanctions imposed is not provided for.

In addition, Section 85a of the AMG provides for possible actions for injunctions that may be filed against pharmaceutical companies infringing the AMG's advertising provisions, unless the respective pharmaceutical company issues a cease-and-desist declaration secured with an appropriate contractual penalty within a reasonable period following a warning by an organisation entitled to sue. The organisations entitled to sue are the Patients' Ombudsman (*Patientenanwaltschaft*), the Association for Consumer Information (*Verein für Konsumenteninformation*, VKI), PHARMIG, the Austrian Medical Association (*Österreichische Ärztekammer*) and the Austrian Chamber of Pharmacists (*Österreichische Apothekerkammer*), however not the company's competitors. Such lawsuits are not particularly frequent, and hardly any such procedures are ever taken up to the OGH (compare OGH, 4 Ob 81/07a).

Again, public announcement of any penalties or sanctions imposed following such lawsuits is not provided for; however, court hearings are generally open to the public and decisions of the OGH and partly of the Higher Regional Courts are published online, albeit in an anonymised fashion.

Competitors may file lawsuits, most notably actions for injunctions, and applications for preliminary injunctions in case of infringements of the pharmaceutical advertising regulations in the AMG and/or the advertising (comprising pharmaceutical advertising) provisions of the UWG (See also Question 21).

The Rules of Procedure of the PHARMIG Code Adjudication and Appeal Boards in section 15 provide for the following sanctions, which can be imposed alone or in combination:

- in the event of severe breaches, such as any breaches of sections 7 or 11 of the PHARMIG CoC, the imposition of a fine of at least €5,000, but not exceeding €100,000, and if the company has breached sections 7 or 11 of the PHARMIG CoC three times within 24 months, a fine of €200,000;
- announcement of the breach in a PHARMIG publication, naming the company;
- formal notice to the parent company of the company concerned of the sanctions imposed;
- formal notice to the European Federation of Pharmaceutical Industries and Associations secretary general regarding the sanctions imposed;
- expulsion from PHARMIG or termination of the PHARMIG Code Agreement entered into.

As regards medical devices, the section 80(1) No 41 of the MPG provides for fines of up to €25,000 or, in case of a repeat offence, up to €50,000, for the administrative offence of infringing the MPG's provisions regulating advertising medicinal devices in sections 70 et seq of the MPG. Imposing such fines is not announced publicly.

In addition, similarly to pharmaceutical advertising, in the case of inadmissible advertising for medical devices, competitors may file civil law actions such as, predominantly, actions for injunctions, and apply for preliminary injunctions.

The sanctions provided for infringements of the (advertising) rules of the AUSTROMED CoC are less severe: they range from issuing a reprimand to the expulsion from the AUSTROMED association, which sanctions can be imposed by the AUSTROMED's arbitral tribunal (compare section 14 of the AUSTROMED

CoC and Section 20 of the AUSTROMED Statutes). Public announcement of any sanctions imposed is not provided for.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

The enforcement measures relating to the advertising regulations in respect of pharmaceuticals taken by the responsible body, for instance the BASG, are not particularly strict, as mentioned above (see Question 3). Lawsuits and applications for preliminary injunctions filed by competitors in the case of infringements of the (pharmaceutical) advertising provisions of the AMG and/or UWG mostly aim at injunctive relief. In such cases, the Austrian civil courts have generally adopted a strict line of case law in relation to pharmaceutical advertising due to the high value of the legal interest protected, for instance, the patients' health (see OGH, 4 Ob 58/07v – Micardis). While claims for damages may also be filed in case of culpable behaviour on the part of the infringing company, the fact that the claimant has indeed incurred a damage as well as its amount are rather difficult to prove in practice.

Enforcement of the advertising regulations of the MPG regarding medical devices ultimately lies with the BASG as well. Similar to the practice relating to pharmaceutical advertising, with advertising for medical devices, too, the Austrian civil courts are the strictest enforcement authorities, mostly acting upon legal actions for injunctive relief and applications for preliminary injunctions filed by competitors.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

No significant developments are expected. To our knowledge, neither regarding the AMG nor regarding the MPG any amendments of the provisions regarding advertising are currently pending. However, actual developments regarding artificial intelligence (AI) shall be closely monitored regarding AI marketing strategies. Moreover, expanding possibilities and use cases for telehealth might also have an impact on respective advertising activities in context with pharmaceuticals and medical devices (including also complex cross-border cases) to be monitored.