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Portugal

PHARMACEUTICAL ADVERTISING

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VdA



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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Portugal.

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PORTUGAL PHARMACEUTICAL ADVERTISING



1. What laws are used to regulate advertising on medicines in your jurisdiction?

Advertising of medicinal products in Portugal is mainly governed by Decree Law 176/2006, of 30 August, as amended (the “Medicines Code”). The Medicines Code consolidates the regime applicable to marketing authorisation, manufacture, import, export, marketing, labelling, promotion and pharmacovigilance of medicines, and transposes several directives into Portuguese law, including Directive 2001/83/EC, as amended (the “Directive”)

Decree Law 330/90, of 23 October, as amended (“Advertising Code”), establishes the rules applicable to advertising in general, and applies residually to advertising of medicinal products, in matters that are not addressed by the Medicines Code.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Yes.

The Portuguese Pharmaceutical Industry Association, Apifarma, approved and enacted the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Health Care Professionals (“Apifarma Code of Ethics”).

The regime provided for in this Code is similar to that arising from the Code approved by Efpia – the European Federation of Pharmaceutical Industries and Associations.

The Code is binding only to pharmaceutical companies

that are Apifarma members. Failure to comply with their terms constitutes a disciplinary infraction, and thus may give rise to an infringement procedure before the Association’s bodies, which in turn may result in the application of penalties.

3. Is there a statutory or generally accepted definition of “advertising”? a) What does the definition cover? - does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Yes. The definition of advertising is provided for in article 150 of the Medicines Code, going beyond the equivalent definition set-forth in the Directive. The Medicines Code considers “advertising” as any kind of information, canvassing activity or inducement which has as its object or effect the promotion of the prescription, dispensation, sale, purchase or consumption of medicines.

Contrary to the Directive, Portuguese law does not require that the conduct is designed to promote a given product to qualify it as advertising, it being sufficient that the conduct has a promotional effect.

The advertising of medicines can be performed before the general public and/or before wholesale distributors and/or healthcare professionals (“HCP”).

The following situations are expressly provided for as means of advertising:

- a. visits of medical sales representatives to HCP;
- b. granting of samples to HCP;
- c. granting, offering or promise to grant benefits (in money or in kind), except when of insignificant value;
- d. sponsorship of promotional meetings

- addressed to HCPs;
- e. sponsorship of congresses, or scientific events addressed to HCPs, including, *via* the payment of hospitality costs, either directly or indirectly; or
 - f. reference to the commercial name of the medicine concerned.

a) What does the definition cover? - does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

Despite the definition of advertising being extremely broad, the following situations, in line with what is provided for in the Directive, are expressly excluded from this notion and thus from application of promotion rules:

- i. The labelling and the information leaflet;
- ii. The correspondence required to respond to a specific question on a certain medicine, possibly accompanied by documents, provided that there is no promotional element;
- iii. Specific information, or reference documents related to changes in packaging, warnings on adverse reactions, as well as sales catalogues and price lists, provided that it does not contain any other information on the medicine.
- iv. Information related to human health or diseases, provided that it does not make any reference to a medicine, be it directly or indirectly.

The Portuguese Agency, Infarmed, has approved a Regulation which complements certain aspects of the promotion regime set-forth in the Medicines Code ("Advertising Regulation"). The Advertising Regulation sets-forth the requirements which must be complied with for sales catalogues and price lists to be excluded from the notion of promotion: these must be expressly identified as such and should only contain reference to the name of the medicine, respective composition, dosage, pharmaceutical form and presentation and the price. In addition, sales catalogues and price lists can only be disclosed before HCP, wholesale distributors, pharmacies and authorized points of sales for OTCs.

b) Does the definition apply equally to all target audiences?

Yes.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases regarding medicines are allowed to extent that these are compliant with promotion rules. Thus, press releases regarding non-reimbursed OTCs are admissible to the extent that every particular that should be included in promotion of medicines before the general public is included. In what concerns prescription drugs, press releases may be disclosed in materials accessible only by HCPs provided once more that promotion rules are complied with. Note that press releases out of scope of the respective approval are not permitted.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Yes. The Apifarma Code of Ethics requires pharmaceutical companies to have a scientific department which should include a physician or a pharmacist who are responsible for the approval of all promotional and informative materials prior to disclosure.

Amongst other aspects, said professional must ensure that the materials comply with all applicable laws and regulations as well as ethical rules, are consistent with the Summary of the Product Characteristics and constitute a faithful and truthful description of the medicinal product at stake.

6. Do companies have to have material approved by regulatory bodies prior to release?

No.

However, pharmaceutical companies must notify the Portuguese Agency, Infarmed, of all promotional materials within 10 days following publication or disclosure thereto. Such does not prevent Infarmed from requesting pharmaceutical companies to provide it with promotional materials prior to their release, and assess them before disclosure.

7. Is comparative advertising for medicines

allowed and if so, what restrictions apply?

Comparative advertising of medicines is only allowed before HCPs, not before the general public. It must therefore comply with the general requirements applicable to advertising before HCPs.

Comparative advertising is also subject to additional requirements, provided for in the Advertising Code. Amongst others, the comparison must not be misleading, and must rely on objective and scientifically proven information to compare essential, relevant and representative characteristics of the medicines.

The Apifarma's Code of Ethics further provides that comparisons between medicines (i) should be based on relevant and comparable aspects, (ii) should not be misleading or defamatory, and (iii) should only be performed by reference to the elements included in the Summary of the Product Characteristics or on credible clinical data.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

No. Advertising of unauthorised medicines or indications is strictly forbidden. Such a prohibition applies even if the information at stake is presented during a scientific conference directed at HCP or proactively sent to HCPs.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

Prescription-only medicines and reimbursed over the counter medicines cannot be advertised before the general public. They can only be advertised before HCPs. This prohibition applies also to the advertisement of discounts on the price of the said products.

Over the counter medicines that are not reimbursed, however, can be advertised before the general public, provided several requirements are met.

Firstly, the general principles applicable to the promotion of medicines apply: advertising must not be misleading, must contain elements which are consistent with the information provided for in the approved SmPC and promote the rational use of medicines, doing so in an objective manner and not exaggerating its properties.

In addition, the promotional material must be unequivocally identified as such and include:

- a. The name of the medicinal product, as well as the international non-proprietary name (if the medicine contains only one active substance), or the respective brand;
- b. The necessary information on how to correctly use the medicine, including the therapeutic indications and special precautions;
- c. A recommendation to carefully read the information contained in the information leaflet and label, and an advice to consult the physician or pharmacist in case of doubt or persistence of the symptoms.

On the other hand, advertising before the general public cannot contain elements that:

- a. Give the impression that a medical appointment or a surgical operation is unnecessary, particularly by offering a diagnosis or by advocating treatment by mail;
- b. Suggest that the effects of taking the medicine are guaranteed, without adverse reactions or secondary effects, with superior or equivalent results to other treatments or medicines;
- c. Suggest that the person's health can be improved by taking the medicine;
- d. Suggest that the person's health can deteriorate if the medicine is not taken, except when the advertisement concerns vaccination campaigns approved by the Portuguese Agency, Infarmed;
- e. Are directed exclusively or primarily at children;
- f. Refer to recommendations of scientists, HCPs or any other person who, because of their celebrity, could incite the consumption of medicinal products;
- g. Treat the medicine as a foodstuff, cosmetic or body hygiene product, or as any other consumer product;
- h. Suggest that the safety or efficacy of the medicine is due to it being a natural product;
- i. Lead or may lead to erroneous self-diagnosis through by describing, or making a detailed representation of the anamnesis procedure;

- j. Refer to claims of recovery in an abusive, scary or misleading way;
- k. Use visual representations of changes in the human body caused by disease or injury, or by the effect of a medicine on the human body or a body part, in an abusive, scary or misleading way.

In addition, and subject to what is provided for in the Apifarma Code of Ethics, the following general rules apply also to promotion of medicines before the general public:

- a. the word “safe” cannot be used to qualify a medicine;
- b. neither can the word “new” be used to qualify a medicine or presentation which is available in the market for over 1 year, or to refer to an indication which has been launched for over 1 year.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Yes.

There are restrictions both in what concerns the interactions with patients and with patient organisations.

In what the first aspect is concerned, pharmaceutical companies cannot grant or promise to grant, directly or indirectly, gifts, prizes, bonuses, pecuniary advantages or benefits in kind to patients.

As for interactions with patient organisations, sponsorship and consultation is permitted. Events may be also addressed to patient organisations provided that it is ensured that no promotion of prescription or reimbursed drugs are made. Patients and patients’ organisations are considered, for the purposes of promotion rules, as “public in general”.

The main principles and rules applying to the interaction between pharmaceutical companies and patient organisations are provided for in the Code of Conduct for the Relations Between the Pharmaceutical Industry and Patients’ Associations, Patients Advocates, Patients Experts, Patients and Caregivers approved by Apifarma – the Pharmaceutical Industry Association (“Apifarma Code on Interaction with Patient Organisations”).

Once more, this Code follows closely the regime provided for in the Efpia Code. It further incorporates

several of the rules provided for in the principles for remunerating patients, patient organisation representatives & carers for work undertaken with the Pharmaceutical Industry approved by Efpia. We recall that these rules apply only to pharmaceutical companies which are members of Apifarma.

Subject to what is provided for in the Apifarma Code on Interaction with Patient Organisations, the following rules, amongst others, must be complied with:

- a. Promotion of prescription only medicines to Patients’ Organisations, their representatives, patients, caregivers, patient advocates and patient experts is forbidden.
- b. Interactions between pharmaceutical companies and Patients’ Organisations should be drawn up in writing, the same applying to the engagement of patient advocates, patient experts, patients and caregivers for the provision of services;
- c. Pharmaceutical companies may support or sponsor events and activities organised by Patients’ Organisations and may bear the hospitality costs of the representatives of Patients’ Organisations, patients, caregivers, patient advocates and patient experts, limited to traveling, meals, lodging and registration costs. The general rule in this regard is that events should be of an institutional, scientific or educational nature, no promotion being allowed;
- d. Pharmaceutical companies should publicly disclose any and all benefits in cash or kind granted to Patient’s Organisations, their representatives, patients, caregivers, patient advocates and patient experts.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Firstly, and once more, the general principles applicable to the promotion of medicines apply also to advertising before HCP. As such, advertising must not be misleading, must contain elements which are consistent with the information provided for in the approved SmPC and promote the rational use of medicines, doing so in an objective manner and not exaggerating its properties.

In addition, advertising before HCPs should include, legibly, on the materials:

- a. The medicine's name;
- b. The essential information compatible with the SmPC, including the (i) name, (ii) qualitative and quantitative composition, (iii) pharmaceutical form, (iv) therapeutic indications, (v) posology and method of administration, (vi) contraindications and adverse reactions. Warnings and special precautions for use, and interactions with other medications, if relevant, must also be included.
- c. The medicine's classification for dispensing purposes, namely if it is subject to medical prescription, when applicable;
- d. The reimbursement regime.

These elements may only be dismissed when the advertising corresponds only to a reference to the medicine's name - the so-called name reminders.

Advertising before HCPs must also include the date in which the material was issued, and the date of the last revision.

Furthermore:

- a. Information must be accurate, current, verifiable, consistent with the SmPC, and complete enough to allow the recipient to form a correct idea of the medicine's therapeutic value;
- b. Scientific citations and mentions must be correctly reproduced and should mention their respective sources.

Information on clinical trials and copies of journals may be sent to HCPs. Caution should be taken however so as to guarantee that such does not entail off-label promotion (see reply to 8 above).

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

They may, but under very strict limitations.

Under the Medicines Code, pharmaceutical companies cannot offer or promise to offer, directly or indirectly, gifts, bonuses, benefits in money or kind to HCPs, except if of insignificant value - i.e. equal to or lower than € 60 (sixty euro) - and relevant to the HCP's practice (medicine or pharmacy).

The Apifarma Code of Ethics is more restrictive and provides for a distinction between promotional gifts and items of medical utility. Promotional gifts are only

admitted in the context of promotion of OTCs. These gifts should be in kind, relevant to the HCP's professional activity and/or involve a benefit to the patient and its value be lower than € 25.00 (twenty-five euro). As for the items of medical utility, these may be granted to HCPs if they are relevant to the practice of the HCPs professional activity and directly benefit the provision of healthcare services to patients. In addition, these items should not consist in a personal benefit for the HCP, nor to an item that the HCP would usually acquire for purposes of their daily professional activity and its value should be equal to or lower than € 60.00 (sixty euro).

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

To the exception of samples of medicines containing narcotics and psychotropic substances, free samples may be granted to physicians, on an exceptional basis, and provided the following requirements are met:

- a. The number of samples provided per physician cannot exceed the maximum yearly amount (currently four samples);
- b. The samples are provided in response to a dated and written request, signed by the physician;
- c. The samples are not larger than the smallest presentation on the market;
- d. The packaging must contain the reference «Free Sample» and «Not for sale», or similar wordings.

When granting the samples, they should be accompanied by the respective SmPC.

Samples may only be provided on the first two years after the beginning of the medicine's effective marketing.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Sponsorship of these events is allowed.

Pharmaceutical companies are only allowed to bear hospitality costs. Hospitality costs include enrolment, transportation and accommodation. The event location should be adequate from a professional and logistic

perspective and should have an appropriate financial cost. The venue should be fit to purpose – i.e., events should not be held in resorts or venues that are otherwise known for their leisure, entertainment or sports facilities.

In addition, hospitality benefits can only be paid to the attending HCP and not exceed the period between the day before and the day after the event is held (and should indeed strictly correspond to the event's duration). The event should not include social activities that should harm or prevent full participation in the scientific and professional sessions.

The Apifarma Code of Ethics sets-forth additional requirements, such as that of hospitality costs not exceeding what the HCPs would be willing to bear themselves and not being offered to compensate the time spent by the HCP in attending the event.

In what concerns events taking place abroad, the Apifarma Code of Ethics provides that these may only be organised or sponsored if the event is held on the country of origin of most of the attendees, or the event is held at the place where the resources to address the event's topic are located. In such a case, in addition to complying with the Apifarma Code of Ethics, pharmaceutical companies must also comply with the rules of conduct in force at the country where the event takes place. In case of conflict, the most stringent rules prevail. As for hospitality costs, the Code sets-forth that the costs of meals should not exceed € 90 (ninety euros) unless the respective Code of Ethics or local legislation sets-out a different cap, in which said cap should apply, even if higher.

The above rules apply to events abroad should HCPs established in Portugal be invited by a pharmaceutical company operating in Portugal.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Organising non-scientific events, regardless of their nature, is forbidden.

The Apifarma Code of Ethics explicitly sets out that no entertainment events are permitted.

16. Is it possible to pay for services

provided by healthcare professionals and if so, which restrictions apply?

Yes.

The payment, by pharmaceutical companies, of *honoraria* to HCPs in consideration for services rendered is permitted – being out of scope of the prohibition to grant benefits to HCPs.

HCPs can therefore be paid for acting as active participant (speaker) in scientific or training events or any kind of service. Naturally that payment cannot be made in return for prescription and/or dispensing of medicines and the honoraria should be reasonable and reflect the market value of the services at stake.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Pharmaceutical companies are not entitled to provide any kind of grants or donations to HCPs – be it in money or in kind. In fact, and in what the interaction with HCPs is concerned, the rule is that no benefits can be granted save if insignificant in value and relevant to the practise of medicine or pharmacy (see 12 above).

As for healthcare institutions, limitations apply to National Health Service healthcare institutions (“NHS Hospitals”), subject to what is provided for in Decree-Law 5/2017, of 6 January.

In accordance with what is provided for therein, NHS Hospitals cannot canvass, or receive, directly or indirectly, benefits in money or kind from companies operating in the pharmaceutical industry that may affect their neutrality and impartiality. They may only receive such benefits if the donation does not compromise their neutrality and impartiality and is authorised by the Ministry of Health. The Ministry of Health delegated the competence to deliver this authorisation on the Portuguese Agency, Infarmed.

Although the need for this specific authorisation should be taken into account by pharmaceutical companies, the obligation to request prior authorisation falls upon the NHS Hospital which receives the benefit.

18. Are pharmaceutical companies required to disclose details of transfers of value to

healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Pharmaceutical companies are required to notify the Portuguese Agency, Infarmed of any transfer of value (be it in kind or in money in excess of € 60) made not only to HCPs and healthcare institutions, but also, and amongst others, medical or scientific associations/organisations and patient associations. The recipient is also required to validate this notification. Should he fail to validate within a specific deadline, the notification will be deemed as correct – notwithstanding the possibility of rectifying in the future providing evidence thereto. Part of this information, including the amount of the benefit and the identity of the recipient, is published on Infarmed's website.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

As noted above, advertising is not subject to prior authorisation, notwithstanding the notification obligation to the Portuguese Agency, Infarmed (see 6 above).

Advertising of medicines the internet, including social media, is not subject to special regulation. The general rules applicable to promotion, be it before the public or HCPs, therefore apply. This being, and so as to ensure that prescription medicines and reimbursed medicines are advertised exclusively before HCPs access restrictions on websites containing advertising or other information intended for HCPs should be implemented

Apifarma has nevertheless enacted a set of guidelines devoted to the use of digital channels by pharmaceutical companies – Apifarma's Guidelines on the use of Digital Channels ("Apifarma's Guidelines"). Under the guidelines, pharmaceutical companies are responsible for all information and materials, promotional or not, disclosed through any digital channel owned by the

pharmaceutical company, sponsored or owned by a third party if the latter publishes information regarding the pharmaceutical company, its products or therapeutic areas, on its behalf. Pharmaceutical companies are also responsible for the information shared by their personnel and should provide for internal policies and procedures which assure their compliance with the applicable advertising and data protection rules.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

No specific anti-bribery rules apply to communications between pharmaceutical companies and HCPs or healthcare organizations.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The granting of benefits to HCPs is governed by article 158 of the Medicines Code and articles 14, 21 and 27 of Apifarma's Code of Ethics. Order 1542/2017, of January 31, which currently provides for the maximum value of benefits that can be granted to HCPs, also plays a pivotal role.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The Portuguese Agency, Infarmed is the regulatory authority responsible for the supervision and enforcement of the advertising rules set-forth in the Medicines Code. Infarmed is hence responsible for initiating administrative offence procedures for the infringement of advertising rules provided for in the Medicines Code, conducting these and issuing a final decision in that context. With the final decision, Infarmed will also decide on the applicable fines and ancillary sanctions.

Decisions taken by Infarmed in administrative offence procedures can be challenged before the courts.

Infringements to the Apifarma Code of Ethics are in turn analysed by Apifarma's Ethics Council, which may impose penalties to Apifarma's members, provided they

are heard in an equitable disciplinary process. The company may appeal from this decision to Apifarma's General Assembly.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Pharmaceutical companies may only initiate proceedings in exceptional circumstances. As a rule, they may only file complaints before competent authorities, based on infringement of any of the rules described above. Since the Portuguese Agency, Infarmed is the competent authority to investigate advertising infringements, complaints – either identified, or anonymous – should be directed at Infarmed.

Pharmaceutical companies may resort to industry self-regulation and file a complaint before Apifarma for breach of the advertisement rules provided on the Apifarma Code of Ethics. In case they suffer damages, pharmaceutical companies may also contemplate filing a civil claim to obtain compensation from pharmaceutical companies engaging in illegal advertising.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Infringement of the advertising and inducement provisions of the Medicines Code is considered an administrative offence punishable with a fine which may range between € 2,000 and 15% of the infringer's turnover or € 180,000, whichever is lower. Infarmed may also require the pharmaceutical company to withdraw or change the advertisement or to cease the illegal conduct immediately.

Ancillary sanctions may also apply, specific of infringement of advertising rules or general.

Ancillary sanctions specific to infringement of advertising rules are the following:

- a. Publication of the essential elements of the conviction on a newspaper, or other similar medium, at the expenses of the perpetrator;
- b. Suspension of advertising of the relevant medicine for a maximum period of two years;
- c. Exclusion of the relevant medicine from State reimbursement, if applicable;

Should the violation of the regime applicable to the visits of medical sales representatives to NHS Hospitals be at stake, the medical sales representative concerned and/or the MA Holder may be prevented from performing said visits.

The general ancillary sanctions provided for in the Medicines Code for infringement of its rules may also be imposed on the infringing pharmaceutical company, notably:

- a. Deprivation of the right to participate in public tenders for a maximum period of two years;
- b. Suspension of authorisations, licenses and of other titles for a maximum period of two years.

Should the procedure be held before Apifarma, for infringement of the Apifarma Code of Ethics, the Apifarma Ethics Council may also apply sanctions, such as:

- a. Warning;
- b. A fine (up to the amount corresponding to five years of the contribution due to Apifarma);
- c. In serious cases, propose to Apifarma's General Assembly the membership suspension or expulsion.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

Procedures before or measures taken by self-regulatory authority (Apifarma) and procedures before or measures taken by government or State authorities (Infarmed and the Court) are independent. Different authorities are responsible for the respective procedures, and they do not interact.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The strictness of Portuguese medicine advertisement law is matched by Infarmed's severity in its application. This authority generally follows a very stringent interpretation of advertisement rules, which requires pharmaceutical companies to navigate a complicated balance between the need to provide objective,

thorough, and scientific information, and the prohibition

to promote their medicines persuasively.

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