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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2016

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A practical cross-border insight into pharmaceutical advertising

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Country Question and Answer Chapters:

Kosovo

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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?

In Kosovo, the advertising of medicinal products is governed by Law no. 04/L-190, dated April 7th, 2014 "On Medicinal Products and Medical Devices" (the Law). The Law entered into force on May 10th, 2014.

The Law applies to all public authorities and public and private enterprises, as well as legal entities and natural persons engaged in manufacturing, trading and other activities that involve medicinal products and medical devices.

The Kosovo Medicines Agency (KMA) is the competent authority that supervises the implementation of the Law and issues relevant authorisations related to medicinal products and medical devices for human use.

1.2 How is "advertising" defined?

Article 19 of the Law defines the medicinal product advertising and promotion as the activity of informing on, or encouraging the use of, the medicinal product with the aim of increasing the number of prescriptions, delivery, sale or consumption of medicinal products.

In particular, advertising includes: (i) advertising of medicinal products addressed to the public; (ii) advertising of medicinal products addressed to persons qualified to prescribe or trade in medicinal products; (iii) visits by medical and sales representatives to persons qualified to prescribe or trade in medicinal products; (iv) supply of samples of medicinal products carried out pursuant to prior approval by the donor and the recipient of the sample; (v) sponsorship of promotional meetings for persons qualified to prescribe or trade in medicinal products; and (vi) sponsorship of conferences, meetings and scientific congresses for persons qualified to prescribe medicinal products or for persons trading in 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 Law provides for various arrangements that the companies should have in place to ensure compliance with the regulatory framework on advertising.

For advertising medicinal products, companies should obtain a Marketing Authorisation, consisting of the permission given by the KMA approving the release of the medicinal product on the market based on the fulfilment of quality and safety requirements and efficiency for human use in therapeutic treatment.

Any advertising of a medicinal product subject to medical prescription (POM) which is addressed to the public is strictly forbidden. The advertising or promotion of medicinal products should be approved by the KMA.

All information provided in the advertising of a medicinal product has to comply with the health conditions of the Marketing Authorisation, in particular the approved Summary of Product Characteristics (SmPC), should encourage the rational use of the medicinal product by presenting it objectively and should be in accordance with pharmaceutical industry codes of ethical marketing practice.

The advertising should not be misleading and should not involve offering or promising any indirect benefits for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no explicit requirements for companies to have in place SOPs on advertising activities.

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?

The advertising or promotion of medicinal products should be approved by the KMA. The procedure for approval may vary depending on the medicinal product for which the marketing authorisation is being granted.

The Administrative Instruction no. 01/2015 "On marketing authorisation of medicinal products" (the Administrative Instruction) provides the procedures and conditions for obtaining the marketing authorisation.

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?

Pursuant to the Administrative Instruction, the KMA is entitled to suspend the marketing authorisation, impose the withdrawal of the medicinal product from the market, cancel the marketing authorisation and impose administrative fines.

The Law provides that the Board of Appeals has the responsibility to review any appeal filed by any entity or natural person related to the decisions issued by the KMA, based on the Law and relevant secondary legislation.

Meanwhile, the provisions of the Law no. 04/L-121 "On Consumer Protection" ('Consumer Protection Law') also remain applicable.

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? To what extent may competitors take direct action through the courts?

Violation of the provisions of the Law and secondary legislation issued for its implementation and of the terms of authorisations and licences is subject to penalties. The KMA initiates civil or criminal procedures for illegal actions of natural persons or legal entities.

Among the penalties defined under the Law, it is worth noting the absolute prohibition from operating in the market for a period of three to five years, as a result of carrying out activities without an authorisation or licence.

Other breaches are subject to fines from EUR 1,000 up to EUR 50,000 depending on the responsibility of the person and potential damages caused to peoples' health.

The above penalties are imposed independently from any criminal action initiated against the breaching subject.

Furthermore, the Law provides penalties in case of advertising of a medicinal product subject to medical prescription (POM) which is addressed to the public. The penalties include punishment with a fine in the amount of EUR 5,000 or suspension of the product from circulation in the market for up to six months.

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?

When investigating matters that may constitute a breach of law, the authorities follow the procedures defined therein, acting independently from any assessment of a self-regulatory body. Any breach of codes ascertained by a self-regulatory body is sanctioned by the said self-regulatory body.

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?

The unfair competition in advertising is governed by the Consumer Protection Law, and the provisions of the Competition Protection Law are also applicable.

The Consumer Protection Law prohibits misleading and comparative advertising, and provides that interested parties have the right to require the competent inspectorate of the Ministry of Trade and Industry to stop misleading or unpermitted comparative advertising if it possesses evidence of inaccuracy of factual claims.

After receiving a request from the interested party, the inspectorate orders the prohibition of misleading and comparative advertising, upon following the below procedures,

The competent bodies for market surveillance require the publisher of advertising to submit evidence within seven days in order to confirm the accuracy of the factual claims contained in the contested advertisement.

If the publisher of the advertising does not present the required evidence within said period or the inspectorate considers that the evidence is incomplete, the advertising shall be considered as misleading, questionable and inaccurate.

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)?

Pursuant to the Law, the following activities are not considered as advertising of medicinal products:

i. information placed on packaging or enclosed in packaging of medicinal products provided that this information is in accordance with the marketing authorisation;

ii. correspondence, accompanied by information materials of non-promotional nature, required to provide answers to questions about a particular medicinal product;

iii. announcements of informative nature not addressed to the public, relating, for example, to package changes, warnings on side effects, provided that such announcements do not include any medicinal product claims;

iv. trade catalogues and price lists, containing exclusively the trade name, the usual common name, the dosage, the dosage form and the price of the medicinal product, and in the case of a reimbursable medicinal product, the official retail price, provided that the contents do not include any medicinal product claims, including therapeutic indications; and

v. information relating to human or animal health or diseases, provided that there is no reference, even indirectly, to medicinal products.

In this regard, the information can be made available to healthcare professionals before obtaining the marketing authorisation, if this would fall under the activities stipulated above.

However, sponsoring of scientific meetings, congresses and conferences for healthcare professionals falls under the definition of advertising and can be conducted only for products that have previously obtained marketing authorisation.

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

The specific legislation does not provide regulation for the publication of information on unauthorised medicinal products and/or off-label information. Only the information relating to human or animal health or diseases is allowed, provided that there is no reference, even indirectly, to medicinal products.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

Please refer to our answer to question 2.2 above.

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

Sending of information about unauthorised medicinal products to healthcare professionals is not regulated by the legal framework currently in force. However, as mentioned above, the correspondence, accompanied by information materials of non-promotional nature, required to provide answers to questions about a particular medicinal product is not considered as advertising.

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?

Kosovo is not a Member State of the EU and the rulings of cases by the ECJ have not been reflected in the legislation in Kosovo or the practical guidance applicable.

However, the Law specifically provides that trade catalogues and price lists containing exclusively the trade name, the usual common name, the dosage, the dosage form and the price of the medicinal product, and in the case of a reimbursable medicinal product, the official retail price, provided that the contents do not include any medicinal product claims, including therapeutic indications is not considered as advertising.

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?

The issues of budgets for products to be authorised in the future is not regulated by the legislation currently in force.

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?

There are neither limitations nor special regulations in the Law regarding the possibility for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications.

3 Advertisements to Healthcare Professionals

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

All information provided in the advertising of a medicinal product has to comply with the health requirements of its marketing authorisation, in particular with the approved SmPC.

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?

The printed or electronic advertising or promotional material presented to healthcare professionals should have the full text of the SmPC attached, unless a specific exemption has been granted by the KMA.

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

There are no legal provisions regarding this issue.

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?

No such requirements exist under the current legislation.

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?

Using a competitor's brand name in comparative advertisements directly or indirectly is prohibited by the Consumer Protection Law.

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

Please refer to our answer to question 3.2 above.

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?

There are no specific rules regarding "teaser" advertisements.

4 Gifts and Financial Incentives

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

Providing healthcare professionals with samples of products should be in compliance with the provisions of article 19 of the Law that regulates advertising of medicinal products.

As mentioned above under question 1.2, advertising also includes the advertising of medicinal products addressed to persons qualified to prescribe them or to persons trading them, as well as visits by medical and sales representatives to persons qualified to prescribe medicinal products or to persons trading in medicinal products.

In this regard, the supply of samples of medicinal products should be carried out pursuant to prior approval by the donor and the recipient of the sample. The number of received samples must not exceed 10 samples per year. The sample should clearly note on the external packaging "Free sample – not for sale". Such products should possess a Marketing Authorisation.

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

Pursuant to article 50 of the Code of Ethics and Medical Deontology (the Medical Code), healthcare professionals are not allowed to accept material gifts or obligations from companies, firms or individuals that trade in medicinal products and other materials, with the exclusion of financing for conferences, seminars and congresses whose purpose is professional qualification.

Further, article 64 the Code of Ethics and Medical Deontology that applies to physicians provides that physicians are prohibited from requesting or taking illegal and compromising gifts of a financial nature from a company, firm or individual engaged in the trading of medicinal products and devices, with the exception of legal financing only for accredited activities that are organised in the context of educational and training purposes for physicians.

Also, as a general remark, pursuant to article 19 paragraph 10 of the Law, medicinal product advertising shall not involve offering or promising any indirect benefits for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased.

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?

Law no. 04/L-125 "On Health" (article 57) recognises donations as one of the sources for funding healthcare services in Kosovo.

Donations of medicinal products and devices are also regulated in article 40 of the Law. The donated medicinal products and devices shall be imported and used in the Republic of Kosovo through the KMA alone, by prior approval of the Minister of Health, and should contain a clear and permanent label that states that the medicinal product and/or device is a donation and is given for free.

The authorisation for importing medicinal products and devices that have been donated should be issued if:

a. detailed information is provided for each medicinal product, including the International Non-proprietary Name (INN), or the proprietary name, amount and expiry date;

b. the type and amount of donated medicinal products and/or devices is necessary for the health protection system;

c. the medicinal product and medical device has at least one year remaining from the expiry date;

d. the medicinal product and/or device has a total use term of one year or less from the date of production, the import should be allowed if the medicinal product has 2/3 of such term remaining when imported to the Republic of Kosovo;

e. the product and device possesses a marketing authorisation in the place of origin, and its quality should be verified by the Quality Control Laboratory. If the place of origin is a third country, the product and/or device should also possess an Analysis Certificate or Product Quality Statement; and

f. for all criteria that are not included in these provisions, the criteria for donation of medicinal products defined by the World Health Organization should be taken into consideration.

The Law stipulates that conditions under (c) and (d) herein above may be reconsidered by the Donation Commission of the Ministry of Health in special circumstances when a donation is necessary and the demand for the product or device is urgent.

The KMA supervises the warehousing, labelling and distribution of donated medicinal products and devices.

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?

Please refer to our answer to question 4.2 above.

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?

The Law provides no regulations in this regard.

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?

Provisions of the Law that regulate advertising are not clear on this point. However, as a general remark, article 19 paragraph 10 of the Law provides that medicinal product advertising shall not involve offering or promising any indirect benefits for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased. Therefore, this scenario could be considered as a breach of advertising requirements provided by the Law.

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?

Refund schemes regarding medicinal products are not regulated by legislation in Kosovo. However, the general rules set by the Consumer Protection Law which provide the obligations of the seller regarding products with deficiencies or defects may be applied. In this regard, the seller is obliged to refund the money paid for the product, or, with the consent of the consumer, to reduce the price in order to compensate for the deficiencies or defects of the product.

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

In general, the Medical Code provides that financing for conferences, seminars and congresses whose purpose is professional qualification is not considered as accepting material gifts or obligations from companies, firms or individuals that trade in medical products and other materials.

However, sponsoring continuing medical education exceeds the purpose of the promotional activity and sponsorship, which is considered as advertising under article 19 paragraphs 2.5 and 2.6.

Therefore this matter should be assessed on a case-by-case basis and in cooperation of the Board for Continual Medical Education within the Ministry of Health.

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?

Other than the possibility of sponsoring conferences, meetings and scientific congresses for healthcare professionals, in the framework of advertising, based on the relevant approval, the Law does not provide further regulations regarding the offering of hospitality to healthcare professionals.

Pursuant to the Medical Code, a healthcare professional (i.e. physician) is prohibited to request or take illegal and compromising gifts of a financial nature from a company, firm or individual engaged in the trading of medicinal products and devices, with the exception of legal financing only for accredited activities that are organised in the context of educational and training purposes for physicians.

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?

The sponsoring of conferences, meetings and scientific congresses for healthcare professionals or for persons trading medicinal products is considered as a form of advertising of medicinal product, and therefore it requires the prior approval of the KMA.

On the other hand, as mentioned above, the Medical Code provides that financing by companies trading in medicinal products and devices, for conferences, seminars and congresses whose purpose is professional qualification is not prohibited. However, from the provisions of the Medical Code it is not clear whether such financing includes also payment for expenses and time.

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?

The organisation of these meetings is considered advertising. However, apart from the obligation of holding the relevant Marketing Authorisation and having the approval of the KMA for the advertising activity, there are no specific provisions regulating this issue.

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

Please refer to our answers to questions 5.1 and 5.2 above regarding payments.

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

There are no specific legal provisions regulating this issue.

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

Please refer to our answer to question 5.1 and 5.2 above.

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?

Besides the requirement that all medicinal products should have the marketing authorisation granted by the KMA, there are no other restrictions for advertising non-prescription medicinal products to the general public.

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

Advertising of a medicinal product subject to medical prescription (POM) to the general public is forbidden. In case of such advertising, the KMA is entitled to impose fines in amount of EUR 5,000 or suspension of the product from the market in duration of up to six months.

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?

Information relating to human or animal health or diseases is not considered as advertising activity, and is allowed only if there is no reference, even indirectly, to medicinal products.

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

There are no specific provisions that would apply in case of press releases concerning prescription-only medicinal products to non-scientific journals; however, if the press release would be considered as advertising, it is prohibited.

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

There are no specific provisions stipulated by the Law regarding this issue.

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

There are no specific provisions stipulated by the Law regarding this issue.

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?

The Kosovo legislation is silent on this matter.

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?

Pursuant to the Law, the sponsor shall apply for an opinion on the clinical trial at the Ethics Committee and also for the authorisation of the clinical trial at the KMA. Prior to deciding on such application, the KMA shall obtain the opinion of the Ethics Committee.

The Ethics Committee is an independent body, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial, and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of the facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

Furthermore, the KMA is also authorised to inspect clinical trials for compliance with good clinical practice.

Considering the above, the details/information regarding clinical trials will be disclosed to the KMA and Ethics Committee from the moment of application and during ongoing trials.

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, what information should be disclosed, from what date and how?

There are no such requirements.

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, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

There are no such requirements.

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?

The Kosovo legislation is silent on this matter.

8 The Internet

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

There are no specific provisions directly related to internet advertising; however, the Law foresees that the sale of medicinal products, and supplements/vitamins can be carried out through the internet too. Moreover, for prescribed medicinal products, an online prescription must exist.

The Consumer Protection Law also provides the rules regarding the sale and purchase through the internet and there are no provisions with regard to internet advertising.

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 are no legal provisions regarding this issue.

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?

There are no legal provisions regarding this issue.

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

There are no legal provisions regarding this issue.

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

There are no specific legal acts controlling the use of social media by companies.

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?

There are no significant developments in the relation to the rules relating to pharmaceutical advertising.

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

There are no significant developments in the field of pharmaceutical advertising 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 practices or enforcement trends that have been apparent and/or conducted in the recent past.

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Besarta's expertise is mainly focused on business law, including corporate law, competition law, employment law, registration of businesses, etc.

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- Trade Marks

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