Hogan Lovells

Connecting Europe

False Advertising in Life Sciences

draft/version
20/04/2018 09

Introduction

In view of the success of our first edition of "False Advertising in Life Sciences", I am proud to introduce our second edition which is even more thorough.

As you know too well, marketing of medicinal products and medical devices is highly competitive. Successful advertising often depends on making forceful statements in relation to a product's performance or in comparing a product with a competitor's product. As advertising is highly regulated, especially in the Life Sciences industry, these statements can cause legal problems and possibly invite legal sanction. Companies are keen to challenge competitors' advertising which they believe to be inaccurate or misleading, as well as to robustly defend their own marketing claims in the event of a challenge from a competitor or a regulator.

Due to the international nature of the Life Sciences sector, challenging misleading advertising statements is complex. New regulations make it easier to enforce cross-border judgments. In addition to the different options for taking action against misleading advertising before state courts and public authorities, in many countries, the role of self-regulatory bodies is becoming increasingly important.

When marketing your products, you may wish to draw comparisons with your competitors' products. Or you may want to make forceful statements about your products, but worry about them being challenged. Perhaps your competitors are making claims about the quality or efficacy of their products or services that you believe are not factual, or a competitor may have made a statement about your company or product that is false or misleading.

We can help. We have extensive experience in all facets of misleading advertising and we have handled these cases throughout Europe and across the world. We anticipate potential problems before they arise, working closely with you to clear potentially problematic marketing campaigns before you launch them. We analyse and evaluate product promotions and advertising in the light of regulatory frameworks and other restrictions. We also assist you in vigorously defending your marketing campaigns against claims of misleading advertising before the courts, the public authorities or the self-regulatory bodies and actively pursue claims against your competitors who make misleading statements about their products or yours.

Our advertising lawyers operate as an integrated international team of professionals, enabling us to provide coordinated worldwide and cross-border advice. Our understanding of the common features of advertising and marketing laws across multiple jurisdictions equips us to advise you on the legal aspects of advertising throughout the world. Not only do we have extensive experience in advertising, but our Life Sciences lawyers also have a breadth of experience in regulatory matters. This cooperation helps us to achieve the optimal results for our clients.

Only recently, we were able to defend two of our client's medical devices which our client's would not be able to market any longer had we not prevailed. We live and work for these victories.

In addition to our first version, we have included a part on the legality of advertising a medical device before a CE mark has been granted as well as on the legality of advertising unpublished study results "data on file" as clients keep asking us about both topics.

We trust that this publication is of interest to you and provides a helpful insight and overview.

Tanja Eisenblätter

Contents

Belgium

"Elisabethann Wright in Brussels is an expert inregulatory issues and advises clients on classification, authorisation and marketing of products in the EU. She is described by her peers as 'a wonderful lawyer who is very visible in the market.'"

Who's Who Legal, Life Sciences 2017

How to challenge false advertising in the Life Sciences Sector

In Belgium, complaints against false or misleading pharmaceutical advertisements can be brought before the Belgian self-regulatory body Pharma. Belgium SA (pharma.be). Pharma.be member companies can submit a complaint to pharma.be against other member companies concerning any violation of the Code of Deontology adopted by pharma.be.

The self-regulatory body can impose a number of measures against the company which has violated the Code of Deontology.

The self-regulatory body can make a reprimand or impose corrective measures. Corrective measures include:

- a correction of the infringing material
- an amendment to the advertising material in question
- publication of a corrective statement
- recall of any infringing material already distributed
- communication of their decision by letter to the members of the Belgian medical and pharmaceutical professions; and
- removal of the link to a website.

In addition, pharma.be can take supervisory measures, including for example recommendations for transparency or clarity; or submission of a detailed plan of concrete measures that the relevant party intend to undertake in order to comply with the decision. Furthermore, pharma.be is also entitled to impose financial indemnification measures.

Pharma.be can further inform the Federal Agency for Medicines and Health Products (FAMHP) of serious infringements of the Code of Deontology.

The Directorate-General Inspection of the FAMHP is responsible for enforcing the laws and regulations governing the advertising of medicinal products, including the provisions of the Medicines Act and the Information and Advertising Decree. The FAMHP has powers to investigate any alleged breach of applicable laws and regulations either on its own initiative or in response to a complaint submitted to it. Such complaints are often initiated by competitors of the pharmaceutical company under investigation.

False pharmaceutical advertising claims can be litigated in the commercial courts. Applicant companies can initiate summary proceedings before the President of the Commercial Courts by filing a request for either a 'cease-and-desist' order or a preliminary injunction.

Proceedings may be expedited depending on the urgency of the case. Dependent upon the facts of each case, summary proceedings concerning advertising litigation can be concluded within 2 months. However, proceedings could take approximately one and a half years in first instance and 2 to 3 years on appeal. The President of the Commercial Court may grant the alleged infringer a period of time to cease the infringement in a specific 'cease-and-desist' order. This proceeding is governed by the Belgian Code of Economic Law.

The limitation period for bringing a non-contractual claim is 5 years from the day on which the company becomes aware of the infringement. The decision of the court can be appealed by either party to the relevant Court of Appeal. However, the appeal must be filed within 1 month of notification of the decision of the court of first instance.

A decision of the Court of Appeal can be appealed to the Supreme Court within 3 months of the date of the decision of the Court of Appeal.

There are no fixed rules on cost budgeting.

Facts and figures

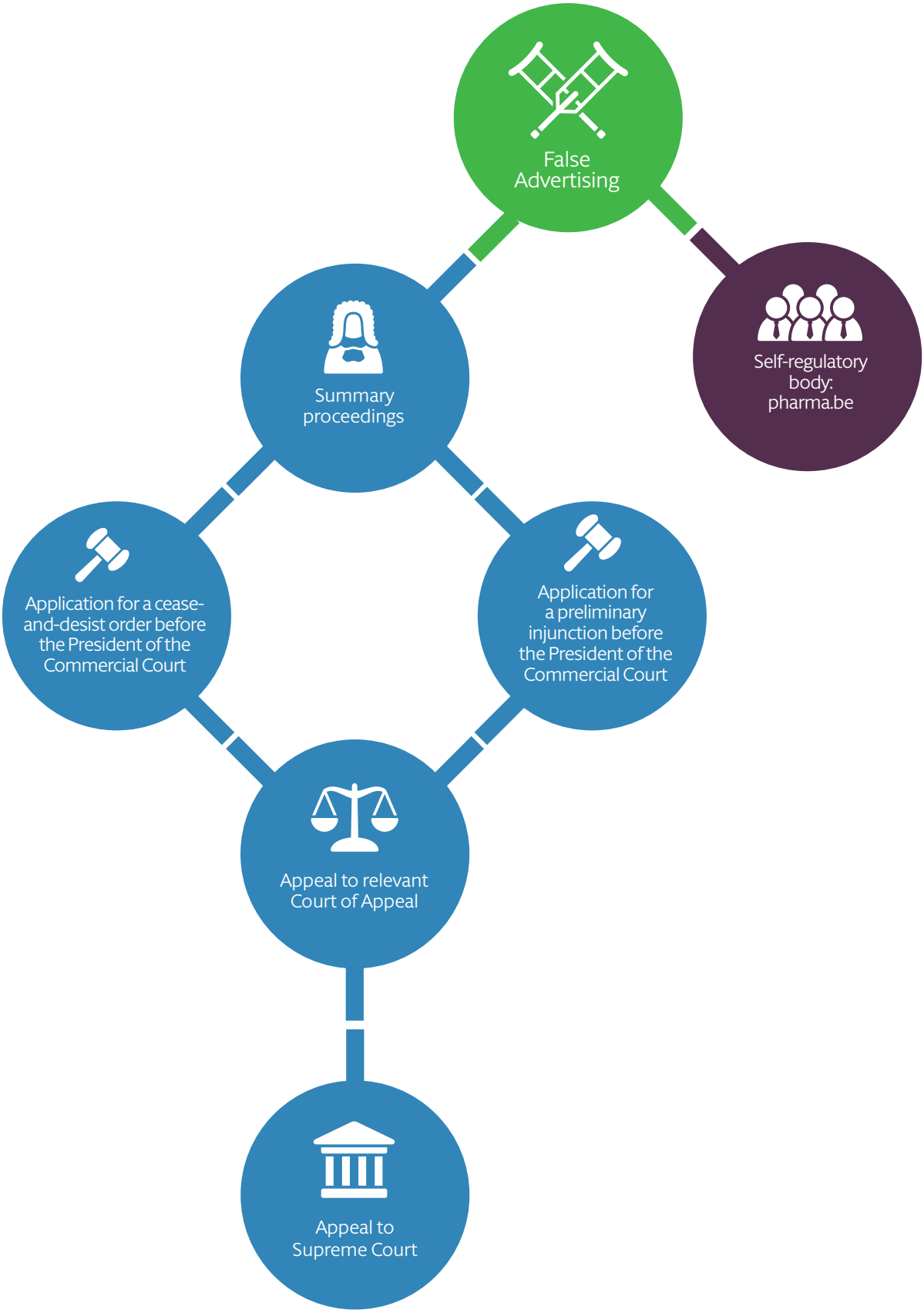
Definition of False Advertising	The applicable laws and regulations in Belgium do not define false or misleading advertising. Advertising practices could, however, be considered false or misleading if the advertisement causes confusion or deception which could negatively influence the consumer's decision to purchase a product or service. Belgian law also prohibits advertisements that are able, by their presentation or omission of information, to mislead the addressee of the advertisement.
Self-Regulatory Bodies	Pharma.be is the Belgian self-regulatory body. Member companies of pharma.be can submit complaints to the body against another member company regarding any violations of the Code of Deontology adopted by pharma.be.
Public Authorities	The Federal Agency for Medicines and Health Products (FAMHP) is responsible for the monitoring and enforcement of the applicable laws and regulations governing advertising of medicinal products in Belgium.
Possibility of Expedited Proceeding	Proceedings can be expedited if the urgency of the case requires.
Initiation of Proceedings	Applicants can initiate summary proceedings by filing a request for either: • a cease-and-desist order; or • a preliminary injunction before the President of the Commercial Courts.
Court's Decision	• The court makes its decision in an ex parte proceeding. Depending on the facts of the case, summary proceedings concerning advertising litigation can be concluded within 2 months. However, proceedings could take approximately one and a half years in the court of first instance. • Proceedings on appeal could take approximately 2 to 3 years. • Rectification can be requested. For instance, the President of the Commercial Court can order the publication of the judgment in a newspaper.
Deadlines for Initiation	The limitation period for bringing a non-contractual claim is 5 years from the day on which the company becomes aware of the infringement.
Enforcement	The President of the Commercial Court can grant the infringer a period of time to cease the infringement through a specific cease-and-desist order.
Appeal	• The decision can be appealed by either party to the relevant Court of Appeal. An appeal must be filed within 1 month of the notification of the decision of first instance. • The decision of the Court of Appeal can be appealed to the Supreme Court. The deadline for initiating the appeal is 3 months from the date of the decision of the Court of Appeal.
Costs	Costs for civil proceedings in Belgium are divided into formal costs (for filing and administrative steps) and a (limited) compensation for legal costs. A fixed indemnity, set by the Belgian legislator, can be claimed for the legal costs. The amount of this fixed indemnity varies in relation to the complexity of the dispute and the amounts involved in the dispute. The costs (within the limits described above) are, in principle, borne by the losing party. There are no fixed rules on cost budgeting.

Representation by an Outside Counsel	Representation by outside counsel is not obligatory in proceedings concerning false advertising in Belgium.

Legality of Advertising a Medical Device before a CE Mark has been granted	• The Royal Decree of 18 March 1999 on medical devices provides that advertising of medical devices that do not bear a CE Mark is prohibited.
	• However, the introduction of medical devices without a CE Mark is permitted at exhibitions, expositions and demonstrations as long as there is a visible sign that clearly indicates:
	  • the absence of conformity of the medical device and
	  • the impossibility of putting the medical device into service before compliance of the device is demonstrated by the manufacturer or its authorised representative.

Legality of Advertising Unpublished Study results ("data on file")	• Belgian applicable laws provide that advertisements based on citations, charts and illustrations from medical journals or scientific publications should indicate their precise source. Advertising of unpublished study results is contrary to the Belgian law. • Additionally, the Code of Deontology of pharma.be provides that references should clearly indicate their sources. The references should be easily traceable.

The legal system at a glance



Your contact in Belgium

Elisabethann Wright

Partner, Brussels

Elisabethann Wright is a partner in Hogan Lovells Brussels office. Her experience in European Union law includes periods in private practice and periods working with international institutions. She focuses on European Union (EU) and Belgian law relating to life sciences, with a particular emphasis on pharmaceutical law, medical devices, food law, and environmental law. Her experience includes assisting clients in the promotion and marketing of their products and in the conduct of compliance and anti-bribery investigations. She also challenges national authority and EU Institution decisions concerning the marketing of medicinal products and medical devices.

Elisabethann's practice was ranked in Band 1 by *Chambers Belgium 2017 for Life Sciences* and Band 2 by *Chambers Europe 2017 for Life Sciences*.

She is a member of the Northern Ireland Bar and has extensive experience in litigation before the European Court of Justice (the European Court of First Instance) and the European Free Trade Agreement (EFTA) Court. Elisabethann was a Référendaire at the Court of Justice of the European Communities for many years. Her experience includes challenges, on behalf of industry clients, to decisions of EU institutions, and advising governments and public bodies on their national and international obligations arising from the EC Treaty and the European Economic Area (EEA) Agreement. Her practice includes advising on the challengeability of decisions of EU Institutions and the validity of EU legislation. She has successfully challenged decisions of EU institutions before the European Courts. Elisabethann also advises on issues of EU administrative and constitutional law and public international law. Prior to joining Hogan Lovells, Elisabethann served as Senior Legal Officer and Hearing Officer at the EFTA Surveillance Authority.

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France

"Hogan Lovells (Paris) LLP runs one of the market's most comprehensive practices. ... Practice head Cécile Derycke is a top choice."

Legal 500 EMEA 2017

How to challenge false advertising in the Life Sciences Sector

When a company wishes to challenge a competitor's advertising in France, the complainant company commonly sends a cease-and-desist letter to that company that must be answered generally within 3 to 15 days. The competitor may make a cease-and-desist declaration in which case the matter is re-solved, at least for a while. If the cease-and-desist declaration is not provided, the claimant can apply for mediation before a regulatory body or, alternatively, initiate legal proceedings.

Before initiating legal proceedings, and for the pur-pose of keeping evidence of violations of advertising regulations, companies may instruct a bailiff to record facts and draft a report.

When a false advertising dispute requires an urgent decision to be taken by a judge, even if only in the interim, summary proceedings can be initiated before the Presiding Judge of the relevant Commercial Court. These proceedings may be initiated in all ur-gent cases in order to obtain any measures that do not entail any serious challenges or that are justified due to the very existence and nature of the dispute. In these cases, the claimant has to prove that the situation is urgent and that either the claim is not seriously challengeable or that the dispute requires the Judge to take measures. Other legal grounds further allow the Presiding Judge to impose protec-tive measures to avoid an imminent damage or to put an end to a manifestly illegal nuisance. The claimant may submit an ex parte motion to the Presiding Judge for authorisation to summon the allegedly in-fringing party to summary proceedings on short no-tice (expedited proceedings known as "référé d'heure à heure"). Since summary proceedings are adversar-ial oral proceedings, both the claimant and the alleg-edly infringing party are heard in the proceedings. The Presiding Judge usually hands down an en-forceable summary order within 2 to 6 weeks of the hearing. Once served, the summary order is prelimi-narily enforceable and has to be complied with de-spite a (potential) appeal. The Presiding Judge may order daily penalties to be paid should the infringing party refuse to comply with the order.

A claimant may also file a claim on the merits in order to request damages for unfair competition. Such a claim must refer to the infringement of the legal pro-visions governing the advertising of health products and the claimant must prove that it has suffered a loss which was caused by the infringement. This is usually hard to prove. Proceedings on the merits can last from 18 months up to 2 years or more in the Court of first instance. The Court ruling on the case may order damages and that the losing party bear some costs. In consequence, the losing party may choose to appeal the judgment. Unless the first in-stance Court expressly states that the judgment is enforceable immediately, the appeal has a suspen-sive effect (meaning that the first instance judgment is not enforceable until the conclusion of the appeal).

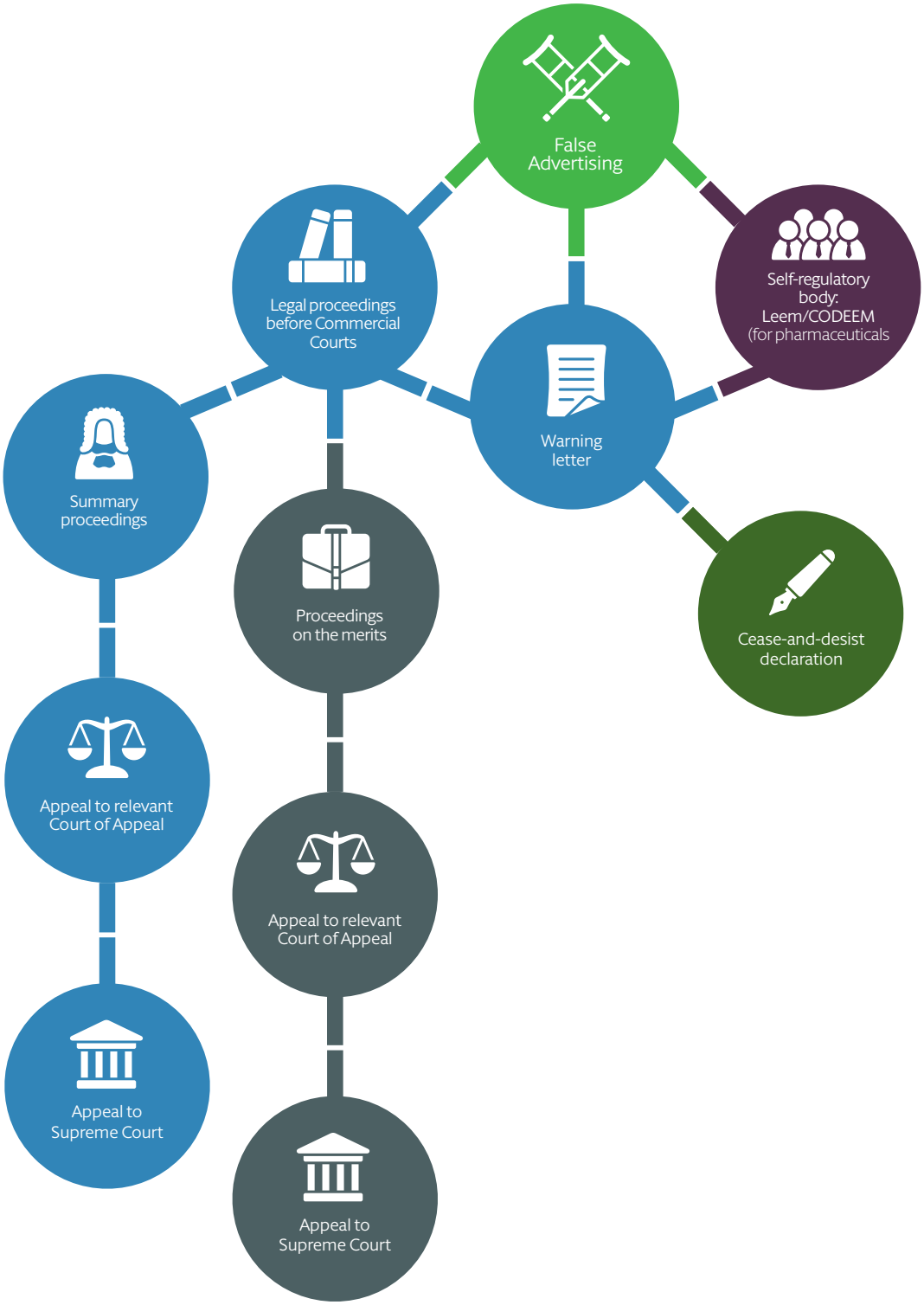
Should a pharmaceutical company wish to avoid court proceedings, it can choose to discuss the mat-ter with the allegedly infringing party before CODEEM, the pharmaceutical committee of ethics within the French pharmaceutical companies associ-ation Leem. CODEEM aims to enforce professional rules on ethics and, to achieve this, the litigation de-partment of CODEEM has both a sanction role and a mediation role. Similar avenues would be available for medical devices manufacturers before the French medical devices association.

Facts and figures

Definition of False Advertising	In France, the Public Health Code (PHC) and the Consumer Code both prohibit false and misleading advertising. **Advertising of medicines** must not be misleading or involve a risk to public health. It must objectively present the medicine and promote its proper use. Advertising of medicines is prohibited prior to obtaining a marketing authorisation. It must comply with the provisions of the said marketing authorisation and the therapeutic strategies recommended by the French High Health Authority (HAS). Comparative advertising of medicines to the general public is prohibited. More generally, advertising of medicines to the general public is strictly regulated and not all medicines can be the subject matter of an advertising campaign. **Advertising of medical devices** must objectively define the device and, where relevant, its performance and compliance with health and safety essential requirements. It must promote its proper use. Advertising can be neither misleading nor involve a risk to public health. Rules may apply differently depending on the nature of the medical device (reimbursed by social security or not, medical device or in vitro medical device) and of the advertising in question (for the information of the general public or healthcare professionals).
Self-Regulatory Bodies	For **medicines**, CODEEM acts as a mediation body and its litigation department can order sanctions. For **medical devices**, SNITEM, the French professional organisation of medical devices manufacturers, may also act as a mediation body.
Public Authorities	Depending on the product concerned (medicine or type of medical device), French Health Authority ANSM proceeds to a preliminary control resulting in an authorisation ("visa") or to an a posteriori control. Where ANSM finds that the advertising breaches applicable provisions, it may reject the application and ask for modifications, suspension or withdrawal of the advertising. It may also impose a fine. Such a fine is neither exclusive of the award of damages to a competitor in the scope of civil proceedings nor exclusive of criminal liability.
Possibility of Expedited Proceeding	Summary proceedings may be initiated before the Presiding Judge of the relevant Commercial Court: (i) where an urgent solution needs to be found; or (ii) to avoid an imminent damage or to put an end to a manifestly illegal nuisance. Expedited summary proceedings may be authorised by the Judge based on an ex parte motion filed by the claimant.
Initiation of Proceedings	The claimant usually starts by sending a 'cease-and-desist' letter. The defendant may respond favourably and give a cease-and-desist declaration. If not, the claimant may apply for summary proceedings and/or proceedings on the merits based upon the grounds of unfair competition.
Court's Decision	• Summary proceedings usually take 2 to 4 weeks after the writ of summons has been served (or a few days for an expedited summary proceeding). The Presiding Judge usually hands down an enforceable summary order within 2 to 6 weeks of the hearing (or possibly on the same day for expedited proceedings). • Proceedings on the merits last for approximately 18 months to 2 years. The Court has the power to order damages, unlike the Judge's ruling in summary proceedings.
Deadlines for Initiation	The 5-year statute of limitations applies to false advertising claims.

Enforcement	• Summary orders are preliminarily enforceable. In some cases, the Presiding Judge may order daily penalties to be paid should the defendant refuse to comply with the order. • Judgments on the merits are not enforceable until the end of any appeal. As an exception, first instance Courts may specify in their judgments that the latter are immediately enforceable once served, despite any appeal. This is quite common with Commercial Courts.
Appeal	Appeals against summary orders must be lodged within 15 days of the service of the order. First instance judgments on the merits may be appealed within 1 month of service of the judgment. Appellants domiciled abroad have an additional period of 2 months within which to lodge an appeal.
Costs	The costs of the proceedings vary from case to case. The losing party may have to pay the court costs as well as the legal costs (which are assessed at the discretion of the Judges and granted as a lump sum).
Representation by an Outside Counsel	Representation is not mandatory for some types of proceedings (e.g. summary proceedings and proceedings before the Commercial Courts). Yet, representation by outside Counsel is recommended in practice.
Criminal liability	Some violations of the rules governing advertising of **medicines** (e.g. advertising without any "visa" from ANSM, advertising of prescription-only medicines to the general public) are deemed criminal offences and may give rise to criminal liability pursuant to the PHC. Criminal sanctions relating to comparative advertising and laid down in the Consumer Code might also apply to both **medicines** and **medical devices**. ANSM may refer cases to the Public Prosecutor. In particular, the criminal liability of the Head Pharmacist ("Pharmacien responsable") of pharma companies may be sought. Pharma companies and medical devices manufacturers may be criminally liable themselves in cases of false advertising since there is corporate criminal liability in France.
Legality of Advertising a Medical Device before a CE Mark has been granted	As a general rule, advertising of medical devices before the CE Mark has been granted is prohibited.
Legality of Advertising Unpublished Study results ("data on file")	• The following unpublished studies may be used for the advertising of **medicines**: studies from the marketing authorisation dossier and which are in accordance with the wording of the marketing authorisation; studies used to prepare the opinion of the Transparency Commission and which are in accordance with the conclusions of the Transparency Commission.The use in promotional materials of an ongoing clinical trial or a clinical trial to come is not possible. • For the advertising of **medical devices**, all mentioned statements, results and claims must be verifiable and evidenced by data.
Hogan Lovells false advertising experience in France	We provide regulatory advice regarding the granting by ANSM of preliminary authorisations ("visas"). We also assist leading companies in connection with false advertising claims and with the review of promotion and marketing materials, advice ahead of public events, etc. We also help our clients deal with ANSM suspensions/withdrawals.

The legal system at a glance



Your contacts in France

Cécile Derycke

Partner, Paris

Cécile Derycke is co-head of our global Life Sciences Litigation Arbitration & Employment Team. Cécile specialises in litigation, focusing exclusively on pharmaceuticals, biotechnologies and medical devices. She pleads before the French civil, commercial and administrative courts.

According to clients, she is "a go-to expert in France" and a "very skilled lawyer who is an expert in pharmaceuticals" (*Who's Who Legal Product Liability Defence/Life Sciences 2017*). Cécile is lauded for her litigation expertise as an "excellent strategist and refined and persistent courtroom lawyer" (*Legal 500 Healthcare and Life Sciences 2016*). Clients also praise her "further expertise in regulatory matters" (*Chambers Europe Life Science 2017*).

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Charles-Henri Caron

Senior Associate, Paris

Charles-Henri is a Senior Associate in the Litigation practice of the Paris office. Charles-Henri works extensively with French and international pharmaceutical companies, biotech companies and medical devices manufacturers in supply chain litigation, product liability and group actions. He assists our clients on a regular basis with respect to inspections carried out by health authorities and related business disruptions and potential liabilities. He also provides strategic advice to clients with respect to false advertising claims and potential litigation in this regard.

Representative experience

- assisting a biotech company in relation to potential violations of regulations on promotion of pharmaceutical products by a competitor during a scientific congress;
- advising a biotechnology company in connection with the suspension of a promotion by the French authorities following an alleged reassessment of the risk/benefit balance;
- advising a pharmaceutical company in relation to the potential prohibition of promotion triggered by an advertising campaign;
- advising a global biotechnology company in relation to unlawful comparative advertising statements made by the sales representatives of a competitor; and
- assisting a medical device company in relation to allegedly unlawful promotion materials.

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Germany

"Superb, highly aggressive, sharp-tongued and successful lawyer for competition disputes."

JUVE 2016

How to challenge false advertising in the Life Sciences Sector

In Germany, the course of action against misleading or false advertising predominately starts at a level between competitors. After detecting misleading or false advertising material, a competitor (or a consumer protection agency) can issue a warning letter to the allegedly infringing company and demand the signing of a cease-and-desist declaration.

In complying with this demand, the infringing company must reimburse the competitor for any costs it has incurred. Furthermore, the infringing company will be obliged to pay a penalty for each further violation of the cease-and-desist declaration as a result of repetition of the misleading or false advertisement or use of similar advertising material. The specific misleading or false advertisement (or a so-called "core equivalent advertisement") dispute ends at this point.

If the infringing company is unwilling to sign a cease-and-desist declaration, the infringed company can apply to any Regional Court in Germany for a preliminary injunction. Germany has quick and effective proceedings for injunctive relief and in many cases the initiation of main proceedings becomes unnecessary. Generally, a preliminary injunction can be obtained in an ex parte proceeding within the course of a few days. In most cases, the court does not set a date for an oral hearing but decides on the basis of what has been submitted by the applicant, taking into consideration the allegedly infringing party's arguments in its response to the warning letter or in a caveat. The preliminary injunction is enforceable as soon as it is served on the infringing party which is, thereafter, obliged to refrain from using the marketing materials concerned. Most cases are brought before the Regional Court of Hamburg since its judges are thought to be the most rigorous.

These courts apply the so-called principle of strict interpretation when it comes to the advertising of medicinal products or medical devices. Hence, advertising in this sector is regarded in a much stricter way than any other advertising, and preliminary injunctions are frequently granted.

If the infringing company accepts the injunction as final and binding, main proceedings are not required. However, if the infringing company does not accept the injunction, it can file an appeal with the same chamber of the court which then seeks written arguments from both parties and conducts an oral hearing. These proceedings only take a few weeks or a few months at most.

Proceedings only become protracted if, after an affirmation or a repeal of the injunction, a further appeal is filed with the Higher Regional Court, in which case, the proceedings can take over a year.

Where the unsuccessful party does not acknowledge the court's preliminary decision as final and binding, main proceedings become necessary. However, due to the costs-, involved an acknowledgement usually makes sense.

Although self-regulatory bodies exist, hardly any false advertising claims are brought before them.

Hogan Lovells has high quality expertise in Germany in the field of combating or defending misleading or false advertising. In the last few years, we have conducted several hundred proceedings in this field and have accumulated extensive experience and, consequently, are able to assist you at each step. We have the necessary skillset to enable you to either achieve your advertising goals by protecting your own advertisements or to vigorously fight your competitor's advertising.

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Facts and figures

Definition of False Advertising	In Germany, false or misleading advertising occurs when an advertise-ment is capable of causing a misconception by an average person in the target market. Claims are based on the Pharmaceutical Advertising Act (Heilmittelwerbegesetz) in conjunction with the Act against Unfair Com-petition (Gesetz gegen den unlauteren Wettbewerb) since both prohibit misleading advertising. Promises of efficacy are likewise prohibited. In pharmaceutical advertising the so-called principle of strict interpretation applies (particularly strict requirements). For medicinal products, courts will always take into account the wording of the SmPC as advertising must not contradict the SmPC. Further, advertising for indications not listed in the marketing authorization is prohibited.
Self-Regulatory Bodies	The German self-regulatory body is the FSA (the Voluntary self-regulatory body for the Pharmaceutical Industry), but advertising dis-putes are not usually mediated there.
Public Authorities	The Federal Institute for Drugs and Medical Devices (BfArM) does not intervene; only in some – extremely rare – cases (advertising to con-sumers) have the local authorities initiated proceedings.
Possibility of Expedited Proceeding	Most legal disputes against false advertising are limited to preliminary legal proceedings. Once the opponent declares the acknowledgement of a preliminary injunction as final and binding, a main proceeding is not necessary.
Initiation of Proceedings	• In general, the applicant has to send a warning letter to the allegedly infringing party (the deadline for that party's response is 3 days to a week). The allegedly infringing party can give a 'cease-and-desist'-declaration containing a contractual penalty; in that case, the matter is resolved and the defendant has to cease using the advertising in question immediately. • If the 'cease-and-desist'-declaration is denied, the applicant can apply for a preliminary injunction and file it with any court in Germany.
Court's Decision	• The court reaches its decision within 3 days to a week. Once the injunction has been issued, it is valid only after it has been served on the defendant. • The court decides in an *ex parte* proceeding; the defendant is, in general, not heard. However, with some courts, a preceding warning letter is necessary to ensure that the response of the defendant to the warning letter is heard. As a pre-emptive measure to contest a potential request for an injunction in advance, the allegedly infringing party can file a caveat with the court. • The court's decision only pertains to injunctive relief. No rectification is available under German law. Compensation is theoretically possible. Usually, however, the applicant is not able to prove that damages have been suffered as a result of the advertisement. If damages are sought, they need to be sought in a main proceeding (accompanied with a demand for information as to where, when and towards whom the advertisement had been distributed).
Deadlines for Initiation	Application for an injunction must be made within approximately 4 weeks to 2 months (depending on the court) of the applicant becoming aware. Once this time period has elapsed, only a main proceeding is feasible (statute of limitation is 6 months).
Enforcement	The injunction, once it has been served, is immediately enforceable and has to be complied with. It can even be served during a congress, in which case, the defendant has to immediately remove brochures etc. containing the statements in question.
Appeal	An appeal can be launched after the injunction has been granted (no deadline applies). In this case, the same court will schedule an oral hearing and make a further decision. After the first appeal, a second appeal can be launched in the court of next instance.

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Costs	• The costs of a proceeding generally depend on the amount in question; the unsuccessful party bears the costs (court costs and costs for successful party's lawyers). • There is a limited compensation for legal costs of the prevailing party; for preliminary injunctions, costs are generally less than EUR 10,000 for the unsuccessful party. • The costs of the warning letter can be reclaimed from the infringer.
Representation by an Outside Counsel	Representation by outside counsel is required before the German Regional and higher courts.
Criminal liability	Although misleading advertising may be subject to a custodial sentence of one year, the provision is not usually enforced.
Legality of Advertising a Medical Device before a CE Mark has been granted	There is no provision prohibiting such advertising; it will be regarded as misleading though, however, if there is no clarification as to the fact that the CE mark has not yet been granted. This means that during a congress, a new medical device can be introduced even before the CE mark has been granted, provided that it is clarified stated that the CE mark still has to be obtained.
Legality of Advertising Unpublished Study results ("data on file")	In Germany, it is common practice that "data on file" is advertised. It is unclear if this practice will be regarded as lawful in the future. In one case, we were able to successfully attack the advertising of a nonpublished study; however this is not prevailing case law. In any case, it should also be made clear that the data has not been published. Furthermore, in Germany the term "study" should be avoided unless it is a published study.
Hogan Lovells false advertising experience in Germany	• We are a leading firm in the field of false advertising in Germany. • We handle about 100 contentious matters a year, approximately 50 of them ending up in court. • In several cases, in the past, our clients' competitors had no material for distribution other than their SmPC during a congress since we had secured the prohibition of all other material. • Our expertise comprises pharmaceuticals as well as medical devices in different indications (such as, inter alia, allergy, bionic eye, diabetes, dialysis, hemophilia, hepatitis C, iron deficiency, nail fungus, thrombotic disorders, vaccines, veterinary products).

The legal system at a glance

Your contact in Germany

Tanja Eisenblätter

Partner, Hamburg

Tanja Eisenblätter is one of Germany's most successful and renowned lawyers in the field of advertising. International pharmaceutical and medical devices companies rely on her knowledge and experience, especially when it comes to handling complex cross-border litigation. Tanja has been involved in multiple product launches, advising on world-wide advertising strategies, bringing together legal knowledge and in-depth scientific experience. Tanja is co-head of the firm's global litigation practice.

Her team is dedicated and successful; they handle our client's matters with passion and professionalism. Only recently we were able to successfully defend our client's Facebook posts for a prescription medicinal product which our client had published after a 'shit storm'. The Higher Regional Court of Cologne in this landmark decision was of the opinion that advertising of an Rx product was lawful in order to contradict false facts that had been disseminated on the internet.

Representative experience

- successfully challenging a competitor's advertising before a congress resulting in the competitor distributing the SmPC only;
- successfully defending the client's advertising of therapy costs which were determined by using the Defined Daily Dose;
- successfully defending all claims that were used in a product launch for a blockbuster medicinal product (such as "safer"); and
- Tanja and her team handled hundreds of false advertising proceedings in recent years.

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Hungary

"The lawyers 'have employed the resources of the firm locally and internationally,' adding that they 'are attuned to public policy and able to build consensus.'"

Chambers Europe 2018

How to challenge false advertising in the Life Sciences Sector

If a company wishes to challenge false advertising by a competitor in Hungary, it is first obliged to try to resolve the legal dispute out of court, for example, by sending a warning letter to the allegedly infringing competitor, or to, jointly with the competitor, record a protocol regarding the dispute. Thereafter, it may choose between dealing with the state courts or the applicable self-regulatory bodies.

The complainant company can file a court action against the allegedly infringing competitor and request the court to grant a preliminary injunction. Subject to certain exceptions, the request for preliminary injunction can only be filed either simultaneously with or subsequent to the filing of the court action. The Hungarian courts are usually fairly conservative in their assessment of preliminary injunctions and are reluctant to grant such requests. The court must make a decision on the preliminary injunction without delay but no later than within 8 days of the request and may order the personal hearing of both parties if such hearing is necessary for the decision-making. The preliminary injunction is enforceable on the day following the service of the first instance order on the competitor. An appeal against the first instance order on the preliminary injunction can be filed within 15 days of its service. It remains enforceable irrespective of any appeals. The preliminary injunction ceases to exist after the conclusion or termination of the relevant lawsuit.

A proceeding on the merits of a case is an inter partes proceeding. The court may, in its judgment, impose a number of obligations on the infringing company, such as the discontinuance of the breach of the law and cessation of the unlawful activity. The Court's decision is enforceable once judgment becomes final. The first instance judgment can be appealed within 15 days of it being delivered and results in the suspension of its enforceability. Second instance judgments can be submitted for judicial review to the Supreme Court on a limited number of legal grounds.

If an infringing competitor has breached the Code of Pharmaceutical Communications, and is a member of an association which is a signatory to the Code, or has agreed to be subject to the Communications and Ethics Committee of Pharmaceutical Associations (CECPA) procedures, the complainant company can also choose to file a claim against that competitor with CECPA, a Hungarian self-regulatory body. CECPA must adopt an order within 60 days (the deadline can be extended by 30 days). No legal representation is allowed in the proceeding. CECPA may, in its decision, by way of example, warn the competitor or oblige it to cease its unlawful activity. Whilst CECPA's decision is binding, there are no laws or regulations governing its enforcement.

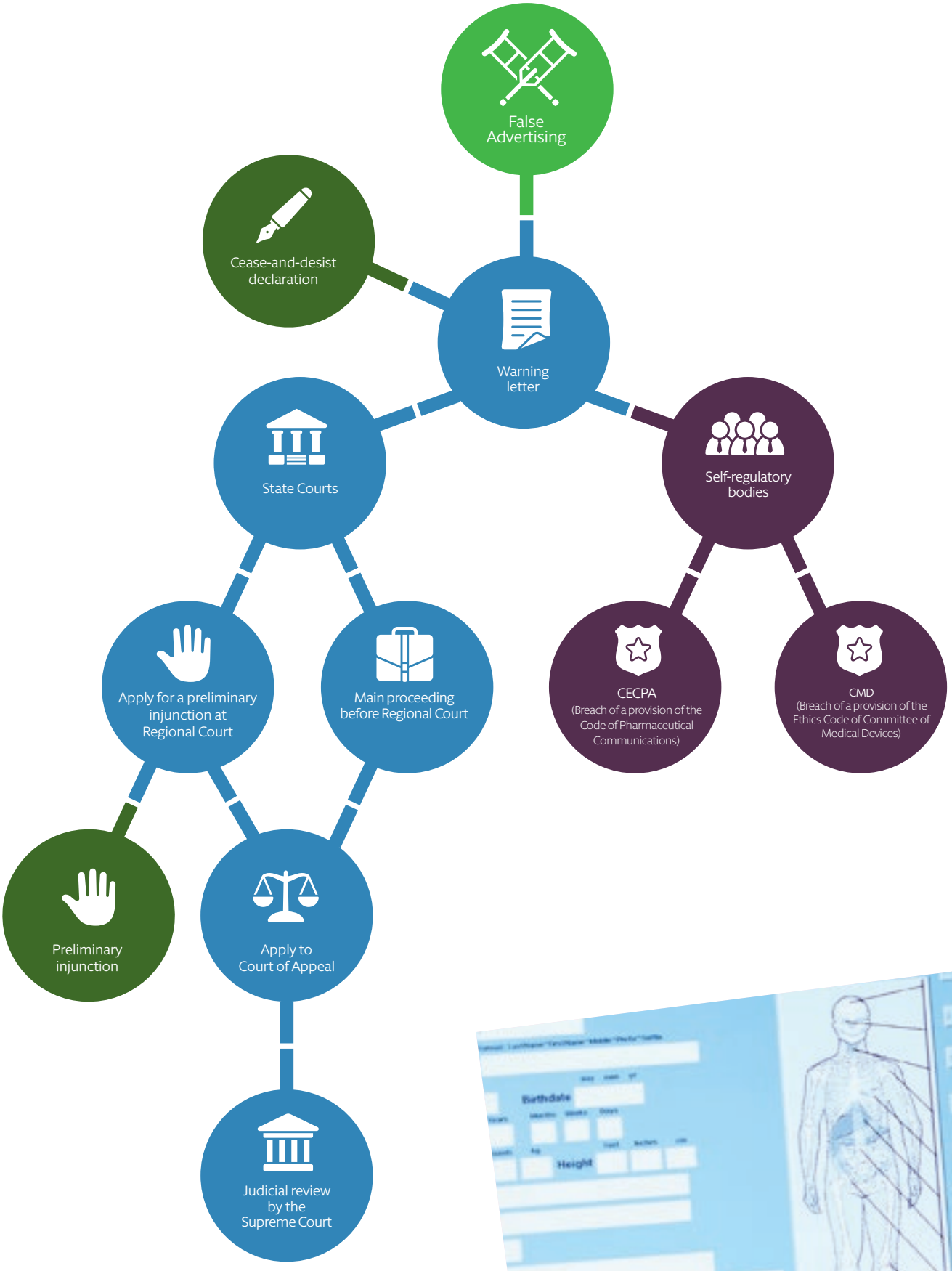
Where medical devices are concerned, a company may file a claim with the Committee of Medical Devices (CMD), another Hungarian self-regulatory body, against the competitor, if that competitor has breached the Code of Ethics of CMD and is a member of that body, but only after attempting to resolve the dispute amicably. CMD proceedings are also inter partes and must commence within 30 days of the filing of the claim. CMD may, for example, warn the competitor or propose that the general assembly of CMD terminate the infringing competitor's membership. The CMD's decision can be circulated amongst its members or alternatively can be published. An appeal against the decision of the CMD can be submitted within 15 days of its decision. If the competitor fails to act in accordance with the CMD's decision, the complainant company can file a court action against the infringing competitor. There are no regulations in Hungarian law governing the enforcement of CMD decisions.

Facts and figures

Definition of False Advertising	False advertising has no precise legal definition in Hungarian law. How-ever, by way of interpretation, advertising would qualify as false or mis-leading if it materially misrepresents or is likely to materially influence the decision of an average consumer regarding the purchase or other-wise of a product, or if it impairs a consumer's ability to make an in-formed decision and thereby causes the consumer to make a decision that it would not have otherwise made.
Self-Regulatory Bodies	• Self-regulatory bodies include CECPA and CMD. • CECPA and CMD are independent. Claims against competitors may be filed with any of the state courts or CECPA or CMD; how-ever, their procedural rules and the possible consequences and scope differ. • A company may file a claim with CECPA or CMD if the competitor has breached any provisions of the Code of Pharmaceutical Com-munications or the Ethics Code of CMD provided its infringing com-petitor is a member of one of these bodies.
Public Authorities	• The Hungarian Competition Authority (certain comparative advertis-ing activities, certain false advertising activities). • The consumer protection departments of the Ministry of National Development, the Government Office of Pest County, and 197 dis-trict offices (violation of the prohibition of unfair commercial practic-es provisions).
Possibility of Expedited Proceeding	Subject to certain exceptions, requesting the court to order a prelimi-nary injunction can only be initiated simultaneously with or subsequent to the filing of an action. The Courts rarely accept injunction requests. If an injunction is granted, the court may require the applicant to provide some form of security as a condition precedent.
Initiation of Proceedings	• As a first step, the parties are obliged to attempt to resolve their le-gal dispute out of court (e.g. by sending a warning letter to the competitor) or, alternatively, to jointly record a protocol regarding their dispute. • If the attempt to resolve a dispute out of court is unsuccessful, the complainant company may file a court action against its competitor on the grounds of a breach of applicable competition law. • If the attempt to resolve a dispute amicably is unsuccessful, the company may also file a claim with a self-regulatory body (i.e. CECPA or CMD) against the Competitor if the Competitor is a member.
Court's Decision	• The court must first deal with the request for preliminary injunction and must adopt an order without delay, but no later than within 8 days of the filing date and may order the personal hearing of both parties if necessary for making a decision. • The main proceeding is by way of an *inter partes* proceeding. • The court has a number of options to stop the competitor's false ad-vertising, including rectification.
Deadlines for Initiation	The deadline to file a lawsuit is 6 months, but a delay can be condoned. The final deadline is 3 years. The deadline for self-regulatory claims is 1 year from the breach of the law.

Enforcement	Compliance with the preliminary injunction is due on the day following the service on the infringing competitor of the first instance order re-garding the preliminary injunction. The final deadline for compliance is determined by the court. An appeal against the order on the preliminary injunction does not affect such due date and deadline for compliance. Compliance with the judgment adopted by the court in relation to the Plaintiff's claims is due once it becomes final and enforceable. The deadline for compliance is usually 15 days. An appeal suspends its en-forcement in terms of the law.
Appeal	• An appeal may be filed against the first instance order on prelimi-nary injunction within 15 days of its issue. • An appeal may be filed against the first instance judgment. A se-cond instance judgment may be submitted for a judicial review by the Supreme Court on limited legal grounds. • An appeal may be filed against self-regulatory decisions within 15 days of delivery of the decision.
Costs	• Litigation costs are usually borne by the losing party. The costs comprise statutory duty, legal fees, expert's fees, witness costs and other litigation costs. • The first instance statutory duty is calculated according to the amount of damages sought, if any, and should be between EUR 48 and EUR 4772. • CECPA and CMD proceedings bear no costs.
Representation by an Outside Counsel	Representation by outside counsel is not obligatory in proceedings con-cerning advertising litigation in Hungary. Representation by outside counsel is not permitted in a CECPA proceeding.
Criminal liability	False pharmaceutical advertising may result in misrepresentation and/or the misleading of consumers which is a criminal offence under the Hungarian Criminal Code.
Legality of Advertising a Medical Device before a CE Mark has been granted	Under Hungarian law, it is not permissible to advertise a medical device before the CE Mark has been granted. Accordingly, the entity ordering the advertising must declare to the advertising service provider that the conformity procedure has been carried out and the CE marked medical device can be distributed on that basis. In the absence of such declara-tion, it is prohibited from publishing any advertisement.
Legality of Advertising Unpublished Study results ("data on file")	The applicable Hungarian laws do not set out any explicit provisions on the legality of using unpublished study results for advertising purposes. Reference to such results involves a legal risk for evidential reasons. The potential risks are significantly higher if unpublished study results do not comply with the product characteristics of the medicinal product concerned.
Hogan Lovells false advertising experience in Hungary	Our practice advises on a wide range of issues in this area and has in-cluded: • advising a US multinational medical devices' manufacturing com-pany in relation to various regulatory issues and advertising mat-ters; and • advising a Hungarian pharmaceutical group on regulatory issues and advertising matters.

The legal system at a glance



Your contact in Hungary

Dr. András Multas

Senior Associate, Budapest

Dr. András Multas is a senior associate in Hogan Lovells Budapest office. His main areas of expertise are intellectual property, employment, and regulatory law, including information technology and data privacy issues. He also specialises in life sciences matters including, in particular, false advertising cases.

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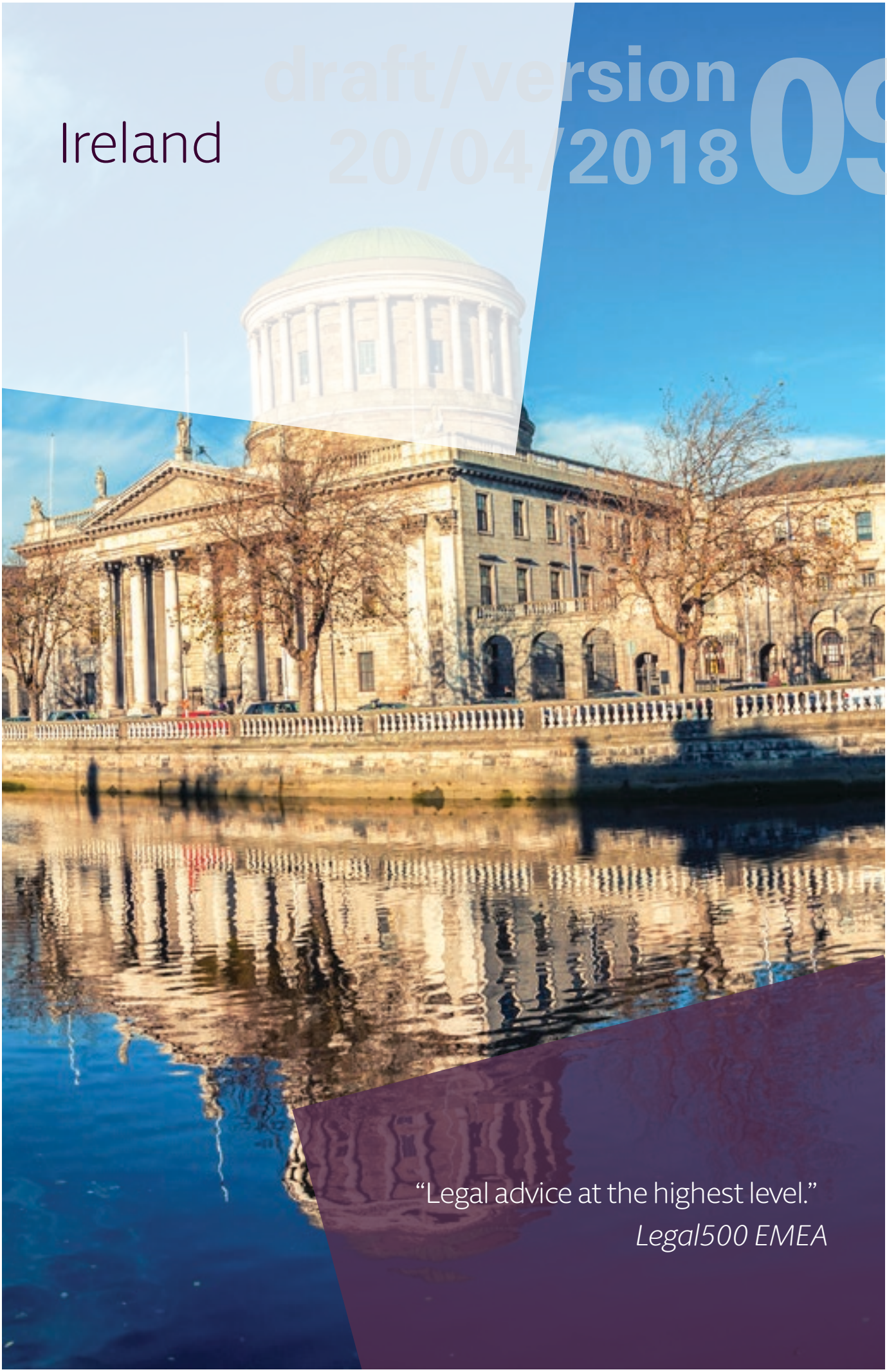
Representative experience

- advising a global manufacturer of medical devices on labelling and advertising requirements;
- advising a leading international pharmaceutical company on intellectual property matters;
- comprehensive compliance review of the Hungarian subsidiary of an international pharmaceutical company;
- advising an international pharmaceutical company on transparency requirements;
- advising a number of food producers and distributors on labelling and advertising requirements;
- advising a number of international clients on clinical trial agreements;
- advising a number of multinational pharmaceutical companies on data protection and employment law compliance matters;
- advising a medical device manufacturer on distribution related matters; and
- advising a US-based biotechnology company on intellectual property and employment law related matters.

Ireland



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Legal500 EMEA

How to challenge false advertising in the Life Sciences Sector

In Ireland, false advertising can be challenged through court action or by filing a complaint with the self-regulatory body. The competent authorities are also permitted to investigate infringements of the laws and regulations governing the advertising of medicinal products.

The Irish Pharmaceutical Healthcare Association (IPHA) is the self-regulatory body in Ireland. Member companies can submit a false advertising claim to the Code Council which will investigate the purported infringement. IPHA can impose a number of sanctions in accordance with the Code of Practice for the Pharmaceutical Industry. For instance, IPHA can request the withdrawal of the advertisement or require the infringing company to publish a corrective notice, the terms and content of which must be approved by the Code Council. IPHA could also require the infringing company to publish its final decision. If the infringements are serious, IPHA may refer the case to the Health Products Regulatory Authority (HPRA) or, alternatively, expel the infringing member company from the organization.

HPRA investigates activities relating to the advertising of medicinal products and, after completing its investigation, can request the withdrawal of the misleading advertisement or require the infringing company to issue a corrective statement.

Companies may also initiate actions on the basis of the Misleading and Comparative Marketing Regulations and the Consumer Protection Acts. Applicants can seek redress by submitting a complaint to the Competition and Consumer Protection Commission (CCPC). Such complaints may also be litigated in the Commercial Courts by either an applicant company or CCPC itself.

If CCPC considers that there are grounds for an injunction or a prohibition order against the infringing company, it may, as a first step, accept a written undertaking from the allegedly infringing party. If the infringer thereafter fails to comply with its undertaking, CCPC can request a prohibition order from the Commercial Court.

Applicants can also apply to the Circuit Court or the High Court for a prohibition order to prohibit an alleged infringer from engaging in or continuing to engage in the prohibited advertising. The court may order the withdrawal of the advertisement and the publication of a corrective statement.

The decision of the court is enforceable once the judgment is delivered. Applicants could also have a right of action for relief by way of damages before the Commercial Courts. Damages fall into the following categories: general damages, special damages, exemplary/punitive damages or nominal damages. However, the court will only award damages where it is reasonable in all the circumstances of the case.

The deadline for initiating summary proceedings before the courts is two years from the date of the infringement.

Decisions of the Circuit Court can be appealed to the High Court, whose decision can then be appealed to the High Court. Commercial Court decisions can be appealed to the Supreme Court.

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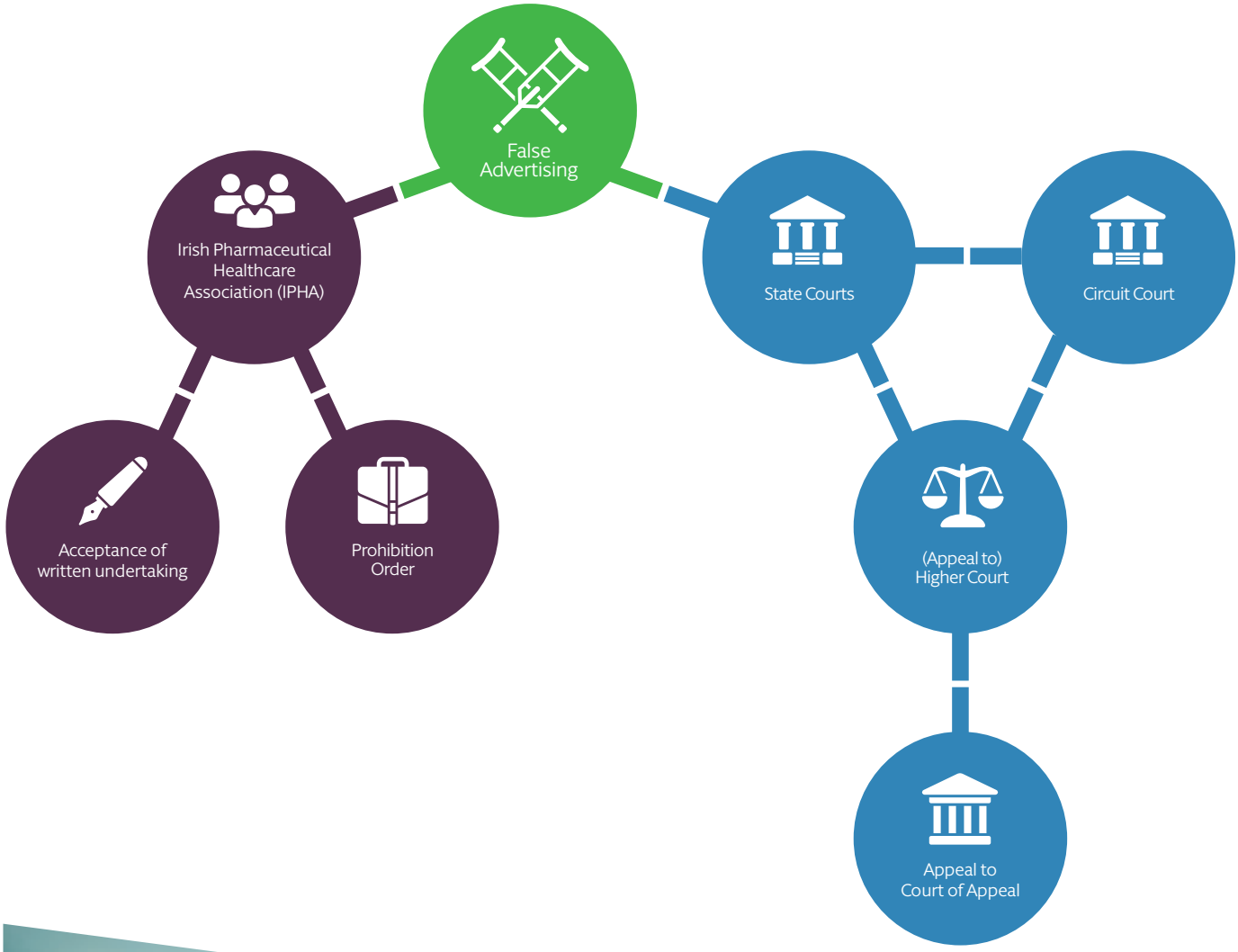
Facts and figures

Definition of False Advertising	In Ireland, misleading advertising is defined as any advertising which, in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for the same reasons, injures or is likely to injure a competitor.
Self-Regulatory Bodies	IPHA can investigate misleading advertising complaints by its member companies.
Public Authorities	HPRA is responsible for monitoring compliance with the applicable laws and regulations governing the advertising of medicinal products. CCPC may also issue a compliance notice to an infringing company who is engaging in an act which is prohibited in accordance with the applicable consumer protection legislation.
Possibility of Expedited Proceeding	An application for expedited proceedings may be brought before the Commercial Court for breaches of the Misleading and Comparative Marketing Regulations and the Consumer Protection Acts. It is not, however, possible to submit an application for expedited proceedings to the Courts to obtain a prohibition order.
Initiation of Proceedings	A company can submit an application to the Circuit Court or the High Court for an order prohibiting the act and/or an order obliging a company to take action to amend or withdraw the infringing act. For breaches of the Misleading and Comparative Marketing Regulations and the Consumer Protection Acts, an applicant must first inform the alleged perpetrator and CCPC. If CCPC considers that there is a case for seeking an injunction or a prohibition order against an allegedly infringing company, it may (as a first step) accept a written undertaking from that company. If that company then fails to comply with its undertaking, CCPC may then request a prohibition order from the Commercial Court.
Court's Decision	The court could order a withdrawal of the advertisement and the publication of a corrective statement.
Deadlines for Initiation	The deadline for initiating summary proceedings is 2 years from the date of the infringement.
Enforcement	The decision of the court is enforceable once the judgment is delivered. Applicants could have a right of action for relief by way of damages before the Commercial Courts. The court will only award damages where it is reasonable in all the circumstances of the case. Damages fall into the following categories: general damages, special damages, exemplary/punitive damages or nominal damages.
Appeal	• A decision of the Circuit Court can be appealed before the High Court. • The Court of Appeal has jurisdiction to hear an appeal from the High Court. • Decisions of the Commercial Court can be appealed to the Supreme Court.
Costs	An order for costs is at the discretion of the courts.
Representation by an Outside Counsel	Representation by outside counsel is not obligatory in proceedings concerning misleading and false advertising in Ireland. A lay litigant is able to bring a case before the courts. This, however, is not common.

The legal system at a glance



Your contact in Ireland

Elisabethann Wright

Partner, Brussels

Elisabethann Wright is a partner in Hogan Lovells Brussels office. Her experience in European Union law includes periods in private practice and periods working with international institutions. She focuses on European Union (EU) and Belgian law relating to life sciences, with a particular emphasis on pharmaceutical law, medical devices, food law, and environmental law. Her experience includes assisting clients in the promotion and marketing of their products and in the conduct of compliance and anti-bribery investigations. She also challenges national authority and EU Institution decisions concerning the marketing of medicinal products and medical devices.

Elisabethann's practice was ranked in Band 1 by *Chambers Belgium 2017 for Life Sciences* and Band 2 by *Chambers Europe 2017 for Life Sciences*.

She is a member of the Northern Ireland Bar and has extensive experience in litigation before the European Court of Justice (the European Court of First Instance) and the European Free Trade Agreement (EFTA) Court. Elisabethann was a Référendaire at the Court of Justice of the European Communities for many years. Her experience includes challenges, on behalf of industry clients, to decisions of EU institutions, and advising governments and public bodies on their national and international obligations arising from the EC Treaty and the European Economic Area (EEA) Agreement. Her practice includes advising on the challengeability of decisions of EU Institutions and the validity of EU legislation. She has successfully challenged decisions of EU institutions before the European Courts. Elisabethann also advises on issues of EU administrative and constitutional law and public international law. Prior to joining Hogan Lovells, Elisabethann served as Senior Legal Officer and Hearing Officer at the EFTA Surveillance Authority.

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Italy

"'Focused on the customer' with a 'proactive approach and commercial sensitivity.'"

Chambers 2018

How to challenge false advertising in the Life Sciences Sector

In Italy, false advertising can be challenged in the civil courts, before the Authority for Competition and Commerce (AGCM) and before the *Giurì* at the Institute of Advertising Self-regulation (IAP). A complainant can choose between preliminary injunction proceedings or ordinary civil proceedings. In either case, proceedings may be brought by a complainant company which claims that its rights have been violated due to the misleading/false advertisement of an allegedly infringing competitor.

A Preliminary injunction can provide a cost and time effective relief (2 to 3 months). Italian courts grant preliminary injunctions when the claims of the petitioner prima facie appear well grounded (the so-called *"fumus boni iuris"*) and the matter is urgent (usually the urgency requirement is met, if proceedings are brought within 6-12 months from the date of the infringement).

Unless the order is granted *ex parte* (and, in that case only for its confirmation at the time of enforcement), the court will schedule – within a relatively short time period – a hearing for the parties to discuss the case and a decision is issued shortly after that hearing (generally within 1-2 weeks). The decision can be appealed by both parties before a panel of different Judges of the same court.

Ordinary civil proceedings last up to 2-3 years for a first instance ruling. Decisions of the court of first instance can be appealed to the Court of Appeal. The measures usually ordered are a final injunction prohibiting the further distribution of the advertisement, the publication of the order and compensation for damages. These decisions can be further appealed to the Supreme Court.

Another avenue available to a competitor is to inform AGCM about the alleged violation by forwarding a petition via the Public Authority's website or via mail. AGCM can initiate proceedings on its own motion (it is at the discretion of the Authority whether to investigate upon a notice filed by a third party and usually priority is given to misleading advertising or unfair practices that may adversely affect consumers). In both cases, an officer for that particular proceeding is appointed. The proceeding lasts between 120-240 days. The Authority has the power to order the immediate termination of the advertising which is in breach of the law and/or order other measures in order to restore fair competition in the market.

A further alternative for a competitor is to initiate a proceeding at IAP, the private entity which regulates commercial communications aimed at providing consumers with proper information and fair competition between competitor companies. Companies which have committed to abide by the rules of the self-regulation advertising code *"Codice dell'autodisciplina della comunicazione"* can sue and be sued before such Authority. The majority of cases concerning OTC products are resolved before IAP since numerous advertising and broadcasting companies are signatories to the code. At the end of the hearing, the *Giurì* can, for example, decide that the case is sufficiently supported by the evidence to render a ruling. Decisions rendered by the *Giurì* are final and are not subject to appeal. The proceeding normally takes less than a month.

Notice of violations may also be submitted to the competent Authorities (the Italian Medicines Agency – AIFA – in the case of medicinal products; the Ministry of Health, in the case of medical devices). However, it is at the discretion of the Authority whether to investigate the case, and the third party would not have control over the further prosecution of the notice.

Facts and figures

Definition of False Advertising	In general, the definition of false advertising set out by Italian law is fully in line with EU law (see Directive 2006/114/EC concerning misleading and comparative advertising).
Self-Regulatory Bodies	The *Giurì* at IAP can issue an order (which is not subject to appeal) to cease misleading advertising.
Public Authorities	• Misleading advertising can be brought to the attention of the AGCM, which may also start proceedings on its own motion. • AGCM is an independent administrative authority responsible for, among other things, monitoring advertising and may initiate administrative proceedings against comparative or misleading advertising in order to ensure a level playing field in the market. • The Authority may at its discretion investigate the third party's notice on violations. When exercising its discretionary powers, the Authority usually attaches particular importance to false advertising and unfair practices that may adversely affect consumers.
Possibility of Expedited Proceeding	A preliminary injunction is a cost and time effective relief available to prevent misleading or comparative advertising. Italian courts will grant a preliminary injunction when clear evidence of the infringement is filed and it is proven that the applicant cannot wait for the outcome of an ordinary proceeding on the merits of the case (urgency). The length of a preliminary injunction proceeding is approximately 2 to 3 months.
Initiation of Proceedings	A person or company who claims that their rights have been violated due to misleading or comparative advertising can file an action with the civil courts.
Court's Decision	• Usual measures granted in ordinary proceedings are the final injunction prohibiting the further distribution of the advertisement, publication of the order and compensation for damages. • The length of the ordinary proceeding is approximately 2 to 3 months for a first instance ruling.
Deadlines for Initiation	There are no specific deadlines to initiate ordinary proceedings. Summary proceedings can be started on an urgent basis (i.e. within 6-10 months).
Enforcement	Courts may issue preliminary or final injunctions.
Appeal	Decisions of civil courts and of the AGCM may be appealed.
Costs	Costs depend on the venue and the type of proceedings. Normally, an IAP proceeding would be less expensive due to the shorter duration and the more informal procedure.
Representation by an Outside Counsel	Representation by outside counsel is necessary in proceedings concerning advertising litigation in Italy.
Criminal liability	As a rule, no criminal sanctions apply to misleading advertising.

Legality of Advertising a Medical Device before a CE Mark has been granted	• Medical devices that are not CE marked may be displayed at trade fairs, exhibitions, demonstrations, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been registered. • According to the Ministry of Health, medical devices that are not CE marked cannot be advertised to the public (which would be otherwise possible for non-prescription medical devices upon prior authorisation of that Authority). • No case law or guidelines from the Authority concerning advertising not CE marked available to HCPs is available.
Legality of Advertising Unpublished Study results ("data on file")	• Statements contained in promotional material of medicinal products addressed to HCPs must be precise, up to date, verifiable and sufficiently complete in order to allow the addressee to be adequately informed on the therapeutic effects and the characteristics of the medicinal product. • Articles, tables and illustrations excerpted from medical journals or scientific works that are used in promotional materials addressed to HCPs must be integrally and faithfully reproduced, with the exact indication of the source. • According to AIFA's guidelines, promotional materials for HCPs must not contain any reference to abstracts, posters and in-press articles. • Advertising of medicinal products by reference to unpublished results and "data on file", even though not expressly prohibited, does not seem to be consistent with AIFA's interpretation of Italian regulation. • Advertising to the public of OTC medicinal products by reference to studies or other complex data is prohibited. • Advertising of medical devices to HCPs is subject to the general rules on commercial advertising. Reference to unpublished data or "data on file" is not prohibited and could be accepted, as long as the data are sufficiently robust and reliable to support the advertising claims.
Hogan Lovells false advertising experience in Italy	We have gained significant experience in defending our clients in proceedings concerning misleading advertising. In particular, in the last few years we have: • Successfully brought appeal against the decision of the Ministry of Health to deny the authorisation of an advertisement to the public of a medical device where a sport celebrity was used as testimonial. • Successfully brought appeal proceedings before the main administrative court (TAR del Lazio) against a decision of a competent authority, which was issued against a major cosmetics company unjustly accused of publishing false advertising in relation to a cosmetic facial cream. • Successfully defended before IAP a globally reputed Food and Beverage Company accused by a competitor of misleadingly advertising and packaging a food product on its launch on the Italian market. • Successfully brought several proceedings before the Courts, IAP and AGCM in favor of one of the major bioplastics manufacturers and the Italian association of bioplastics against competitors publishing false information on biodegradable products.

The legal system at a glance

Your contact in Italy

Riccardo Fruscalzo

Counsel, Milan

Easy to reach and ready to come back to you, Riccardo is proud to have assisted start-up companies, from the first steps in the Italian market to established businesses, as well as to support the expansion and internationalisation of Italian clients of the firm. Starting as an IP litigator and with a PhD from the University of Parma in Intellectual Property Law, Riccardo Fruscalzo focuses on the Life Sciences Industry, providing his clients full assistance in this sector. In patent litigation and commercial transactions, Riccardo believes that an in-depth knowledge of regulation and technology is a true strong point.

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He wants to understand the client business and thinks that legal advice is a tool for the solution of problems: tell us your objective and we'll tell you the right way to achieve it. As an experienced patent litigator, he assists clients of the firm in highly complex litigations. Advising on regulatory issues, his knowledge ranges from clinical trials to authorisation procedures, from import/ export to advertising, pricing and commercialisation of products of the healthcare and life sciences sector.

Riccardo is a member of the Italian Life Sciences Group of the Milan American Chamber of Commerce and author of several publications in Intellectual Property Law and the Life Sciences sector.

Representative experience

- successfully brought appeal against the decision of the Ministry of Health to deny the authorisation of an advertisement to the public of a medical device where a sport celebrity was used as an endorser;
- advising a French medical devices manufacturer in the review, in the light of Italian law on medical devices, the law on comparative advertising to professionals, of advertising materials for the promotion of an intraluminal support device to health-care professionals;
- assisting the Italian subsidiary of a multinational company active in the field of dental medical devices on regulation, disclaimers and warnings to be inserted in the company's website for the online promotion of medical devices to HCPs;
- assisting a US leading internet service provider on regulatory aspects concerning the advertising through the use of AdWords of OTCs medicinal products and online pharmacies in Italy, including potential aspects of liability for the client in cases of the breach of Italian law on advertising of medicinal products and exercise of online pharmacies by the advertisers;
- assisting a multinational pharmaceutical company on the compliance with Italian law on the advertising to healthcare professionals of promotional materials where reference was made to efficacy and safety of a medicinal product in a subpopulation of patients, based on additional data obtained further to post authorisation clinical trials; and
- assisting an Italian pharmaceutical company providing a risk assessment on potential challenges from a competitor of a promotional brochure addressed to healthcare professionals for alleged lack of support in referenced clinical studies and arbitrary extrapolation of the advertising claims.

The Netherlands

"'European network and ability to work in multiple jurisdictions smoothly' as its key strengths, in addition to the 'very good quality the lawyers deliver.'"

Chambers Europe 2018

How to challenge false advertising in the Life Sciences Sector

In the Netherlands, if a pharmaceutical company wishes to challenge a competitor's false advertising, it will usually first send a warning letter with a deadline of three days to a week for a response. To avoid litigation, the alleged infringer may give a cease-and-desist declaration which could include a contractual penalty.

Often, the parties are able to negotiate an amicable solution, for example, the sending of a rectification letter or the removal of the infringing marketing materials from the market. Where a cease-and-desist declaration is not given, the claimant can opt to file a complaint before the self-regulatory body or, alternatively, initiate a court action.

Most disputes about pharmaceutical advertising claims are litigated before the self-regulatory body *Stichting CGR* (CGR), which has issued a Code of Conduct on Pharmaceutical Advertising *Gedragscode Genees-middelenreclame* (CGR Code of Conduct). The CGR Code of Conduct contains rules on matters such as advertising, hospitality, sponsoring, rendering of services and transparency.

CGR has a complaint procedure to assess alleged infringements of the CGR Code of Conduct. Complaints must be filed in writing and are dealt with by the Code Committee of CGR. The alleged infringer is given the option of filing a statement of defense. Thereafter, the Code Committee holds a hearing and can impose measures such as a cease-and-desist order or a recall order. Due to the self-regulatory character of CGR, the parties have committed themselves to voluntarily comply with the decisions of the Code Committee. CGR cannot impose any financial penalties. Any Appeals can be filed with the Appeals Committee of CGR.

Self-regulation has been successful in pharmaceutical advertising disputes in the Netherlands. In consequence, the Dutch Healthcare Inspectorate (IGZ) and CGR have entered into a formal agreement containing an arrangement that pharmaceutical advertising matters in normal circumstances be dealt with by CGR.

Alternatively, a complainant can initiate a civil court action. Legal representation is mandatory. In urgent cases, a preliminary injunction proceeding is usually the best option. *Ex parte* proceedings are not available in pharmaceutical advertising cases in the Netherlands. Claims for damages are not available in preliminary injunction proceedings.

A preliminary injunction proceeding is initiated by the issue of a writ of summons containing all of the claimant's arguments and claims. There is always a hearing and the decision normally takes 2 to 3 weeks. If the advertising is found unlawful, an injunction is issued and can include a financial penalty for non-compliance. A recall of the marketing materials may also be ordered.

Proceedings on the merits are also initiated by the issue of a writ of summons and, after a round of exchanging written arguments, the court usually orders a hearing. It normally takes a couple of months before a decision is rendered. Besides an injunction, recall and/or rectification, the court may also order the destruction of the marketing materials. Claims for damages are not normally successful because of the difficulties in proving damages suffered as a result of unlawful advertising.

An appeal can be filed with the Court of Appeal. The appeal deadline in preliminary injunction proceedings is four weeks and is three months in proceedings on the merits.

Facts and figures

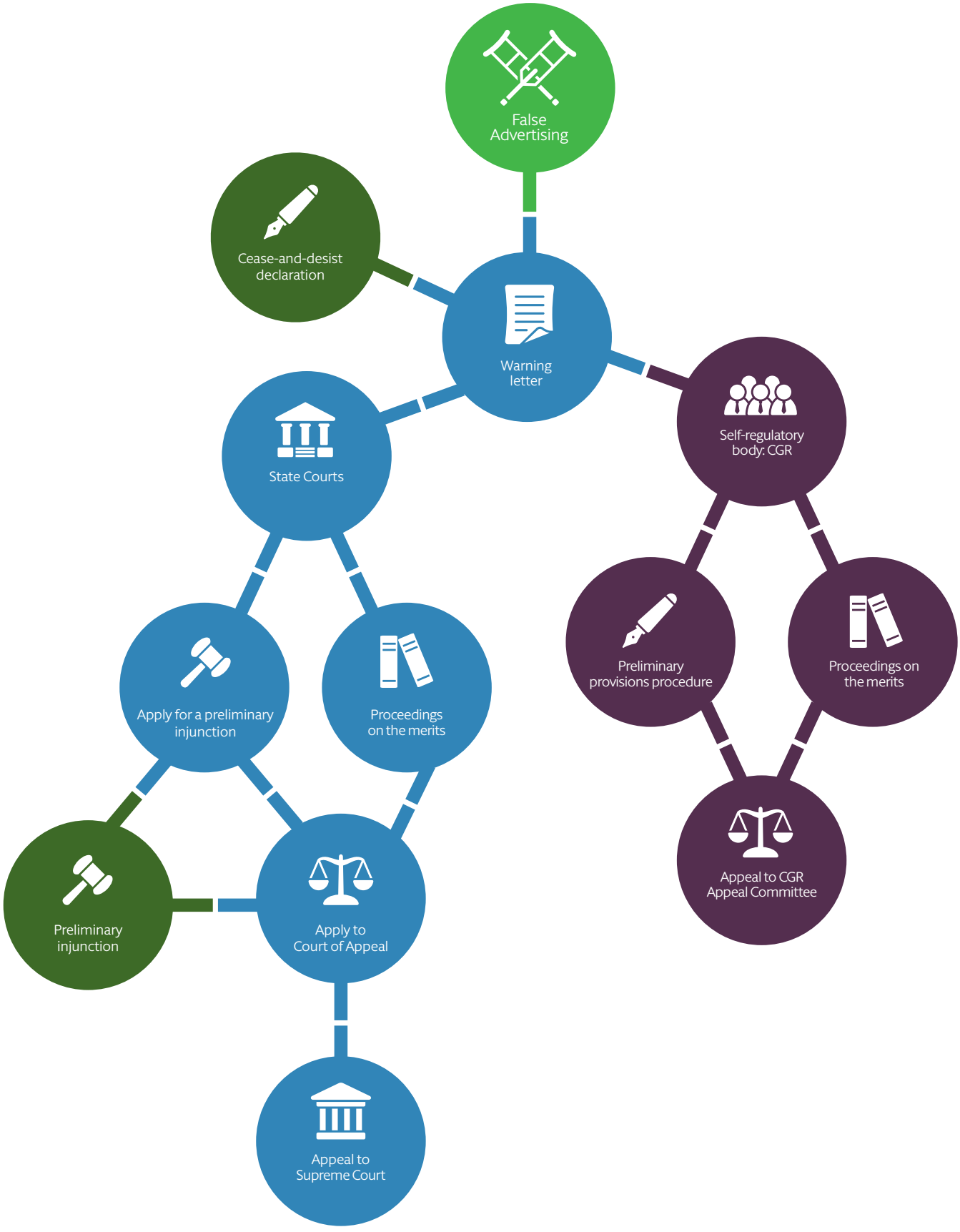
Definition of False Advertising	In the Netherlands, false or misleading advertising occurs when information provided in advertising material is incorrect or misleading, for example, as regards the nature, composition, quality, characteristics (e.g. efficacy and safety) or possibilities for use (e.g. registered indication).

Self-Regulatory Bodies	Most pharmaceutical advertising claims are litigated before the self-regulatory body (CGR):
	• 2 types of complaint proceedings:
	  • Preliminary proceedings; and
	  • Proceedings on the merits.
	• Preliminary proceedings are the most usual.
	• Initiated by a written complaint containing all arguments.
	• There will always be a hearing.
	• CGR can impose measures such as a cease-and-desist order, rectification, reprimand or recall.
	• No financial penalties.
	• A decision is rendered within 2 to 3 weeks.

Public Authorities	• The Dutch Healthcare Inspectorate (IGZ) is the relevant public authority. • The IGZ and the CGR have entered into a formal agreement that pharmaceutical advertising matters are, in principle, dealt with by CGR. • IGZ may still initiate enforcement actions, usually resulting in a substantial administrative penalty (> EUR 100,000).
Possibility of Expedited Proceeding	• In urgent cases, a preliminary injunction proceeding before a state court is possible. • There will always be a hearing. • A decision usually follows within 2 to 3 weeks.
Initiation of Proceedings	Proceedings before state courts are initiated by the issuing of a writ of summons containing all of the claimant's arguments and claims.
Court's Decision	• In preliminary injunction proceedings, an injunction may be issued and include a financial penalty for non-compliance. • The judge may also order a recall of the marketing materials and/or a rectification. • In proceedings on the merits, besides an injunction, recall and/or rectification, the most common court orders in pharmaceutical advertising cases are for the destruction of marketing materials.
Deadlines for Initiation	• There are no exact deadlines for taking action. • In preliminary proceedings before both CGR and the court, the claimant needs to have an urgent interest. • The claimant has an urgent interest as long as the advertising is still used and the claimant has not unnecessarily delayed taking action.

Enforcement	• CGR is the self-regulatory body and its members have committed to voluntarily comply with its decisions. • Court decisions are not enforceable until they have been served by a bailiff.
Appeal	• CGR decisions can be appealed to the CGR Appeal Committee. • First instance decisions of state courts can be appealed to a Court of Appeal. • Decisions of a Court of Appeal can be further appealed in cassation before the Supreme Court.
Costs	• CGR charges EUR 1,250 for the filing of a complaint. • The court fee for a procedure before a state court is EUR 618. • In CGR proceedings and in proceedings before state courts each party bears its own costs for legal representation. • There is no risk of being ordered to pay the other party's legal representation costs.
Representation by an Outside Counsel	• Representation by outside counsel is not strictly necessary in CGR proceedings, but is highly recommended. • In proceedings before a state court legal representation is mandatory.
Criminal liability	Most violations of statutory pharmaceutical advertising rules are not criminally enforceable.
Legality of Advertising a Medical Device before a CE Mark has been granted	• Advertising a medical device before a CE mark has been granted is not explicitly prohibited. We would, however, recommend that it is made clear in the advertising that the medical device does not yet have a CE mark and that the medical device may not yet be used
Legality of Advertising Unpublished Study results ("data on file")	• Use of or reference to data on file in advertising of medicinal products is, in principle, not permitted.
Hogan Lovells false advertising experience in The Netherlands	• The Amsterdam office of Hogan Lovells is one of the leading firms in the Netherlands in the field of pharmaceutical advertising. • We have extensive experience in representing and advising pharmaceutical companies on matters concerning pharmaceutical advertising, including proceedings before the self-regulatory body (CGR), administrative and civil proceedings. • We assist in reviewing marketing materials as well as in the setting-up of internal compliance programs and review procedures (SOPs). • We provide in-house training on pharmaceutical advertising issues. • Our expertise includes pharmaceutical products for human and veterinary use as well as medical devices. • Pharmaceutical advertising matters are often not limited by state borders. We work together with our offices in other jurisdictions to make sure arguments in proceedings in other countries are aligned

The legal system at a glance



Your contact in the Netherlands

Hein van den Bos

Partner, Amsterdam

Hein van den Bos assists pharmaceutical companies in marketing and advertising issues. He has successfully represented different pharmaceutical companies before the Dutch self-regulatory body (CGR). He also regularly assists companies with government enforcement actions against alleged violation of pharmaceutical advertising and healthcare compliance rules and he challenges financial penalties imposed by the Minister of Health. In addition to advertising, Hein advises on a variety of EU and Dutch Life Sciences Regulatory matters.

Hein is recognized as an "excellent lawyer" (*Chambers Europe Life Sciences 2018*), "praised by clients for his really helpful understanding approach to internal issues" (*Chambers Europe Life Sciences 2017*) and an "experienced lawyer in this field with superb expertise" (*Who's Who Legal Life Sciences 2018*).

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Ruth Franken

Senior Associate, Amsterdam

Ruth Franken has vast experience in representing and advising (veterinary) pharmaceutical and medical device companies in (veterinary) pharmaceutical and medical device marketing and advertising issues. Ruth represents clients during court proceedings and proceedings before self-regulatory authorities. Ruth further assists and advises on the review of marketing materials and the development of SOPs to ensure marketing materials are compliant. Ruth also assists companies on a number of compliance matters, such as financial relations with healthcare professionals, anti-corruption and sunshine rules.

Legal 500 EMEA listed Ruth as "next generation lawyer" (2017 and 2018). *Who's Who Legal Life Sciences* listed Ruth as a regulatory expert (2016-2018).

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Poland

"I consider Hogan Lovells an excellent firm. It is my first choice in Europe. It has very high-level professionals who have a very good understanding of the life sciences field. They understand the business background and the regulatory framework." (client)

Chambers Global 2016

How to challenge false advertising in the Life Sciences Sector

In Poland, false pharmaceutical advertising can be challenged by a civil action initiated by a complainant, (usually a competitor), or an action by the relevant administrative or government authorities, i.e. the Chief Pharmaceutical Inspector (CPI), or the President of the Office of Competition and Consumer Protection (OCCP). *Ex officio* proceedings are also possible.

Civil actions are usually based on unfair competition regulations and commence with a statement of claim being filed by a complainant (usually a competitor) with the court (this can be preceded or accompanied by a motion for an interim injunction). The courts of general jurisdiction are the competent courts in such cases. The most frequently requested demand (and the one most frequently accepted by the court) is the cessation of prohibited practices. The court can also order, among other measures, the removal of the effects of the prohibited practices, the release of single or repeated statements in the media, or the reimbursement of any damages suffered by the complainant.

If a civil action is chosen, the deadlines for the initiation of proceedings, in particular the 3-year limitation period, should be borne in mind. The petitioner bears the costs of the civil proceedings if it loses the case.

An appeal against the court's ruling must be filed with the higher court within 2 weeks of the date of the delivery of the first instance ruling.

CPI and OCCP usually commence their actions once they have been notified about the allegedly false advertising, but they can also commence proceedings based solely on information they have gathered themselves. The person/entity who notifies these bodies does not usually become a party to the proceedings before CPI or OCCP.

CPI can order that the advertisements violating the applicable regulations be ceased and/or order that its decision be published in the same media that the false or misleading advertisement was published thereby mitigating/removing the effects of the violations.

Within 14 days of the delivery of the decision, the alleged infringing party can request that the CPI reconsiders the case. If the CPI upholds its decision, an appeal can be filed within 30 days with the regional administrative court.

OCCP can order that the advertisements violating the collective interests of consumers be ceased. Additionally, OCCP can order that measures aimed at removing the negative effects of the violation are taken, such as making single or repeated statements (e.g. an apology) in the media. OCCP can also order the payment of a fine (up to 10% of annual income). Any appeal must be filed with the Regional Court in Warsaw – the Court of Competition and Consumer Protection – within 2 weeks of the date of the delivery of the decision. The case is then heard in the civil courts.

Certain provisions of the Pharmaceutical Law carry criminal liability for violations of such provisions.

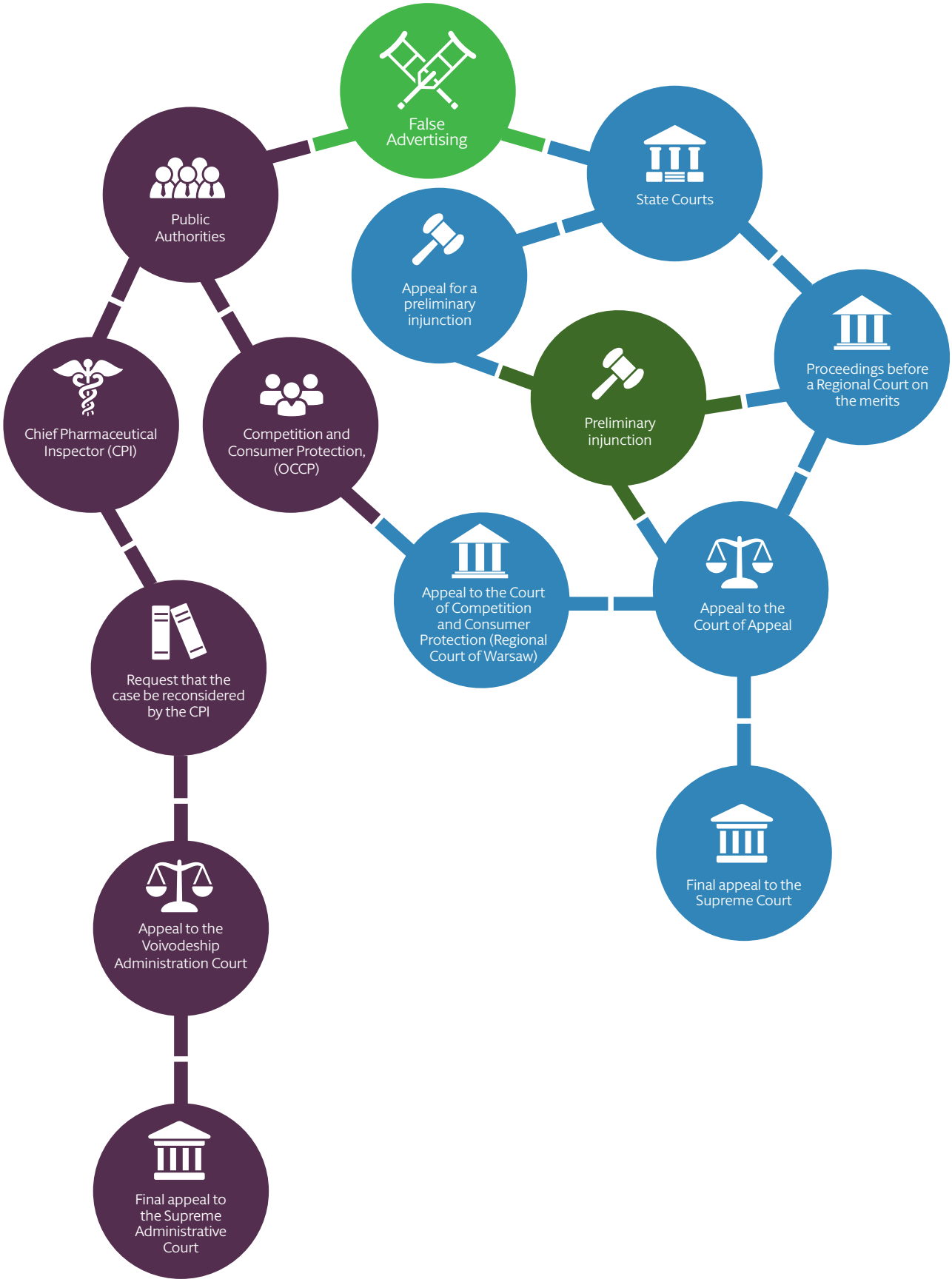
09

Facts and figures

Definition of False Advertising	In Poland, false or misleading advertising is any communication directed at consumers that can deceive an average consumer and have a significant influence on their decision as to whether or not to make use of or purchase a product or service. The notion of false or misleading advertising covers both messages that are objectively false and messages that are inaccurate, and which can mislead the consumer.
Self-Regulatory Bodies	There are self-regulatory bodies dealing with advertising in general (including pharmaceutical advertising) that issue non enforceable decisions and which are becoming increasingly important for regulating market practices.
Public Authorities	• False advertising is subject to the supervision of CPI and OCCP. • CPI can order that advertisements violating the applicable regulations be ceased. In addition, CPI can order that its decision be published in the same media in which the advertisement was originally published thereby mitigating the effects of the violations. • OCCP can order that the advertisements violating the collective interests of consumers be ceased. Additionally, OCCP can order that measures aimed at removing the lasting effects of the violation are taken, such as making single or repeated statements in the media. OCCP can also order the payment of a fine (up to 10% of annual income).
Possibility of Expedited Proceeding	A preliminary injunction can be issued within days or a few weeks after an *ex parte* proceeding. Injunctions are, as a rule, immediately enforceable. Thereafter, the petitioner must file a statement of claim (usually within 2 weeks of the date of the preliminary injunction). Otherwise, the preliminary injunction will expire.
Initiation of Proceedings	False pharmaceutical advertising claims are litigated before the state courts if the litigation is based on the civil action of a competitor. Civil actions are usually based on unfair competition regulations, so it is initiated by a statement of claim filed by another person/entity (usually a competitor) with the court (optionally preceded by a motion for an interim injunction). The courts of general jurisdiction are competent.
Court's Decision	The most frequently requested demand (and that most frequently accepted by the court) is the cessation of prohibited practises. The court can also order, among other things, the removal of the effects of such prohibited practices, making statements (e.g. an apology) in the media, or payment for the damages suffered by the infringed complainant.
Deadlines for Initiation	If a civil action is planned, the deadlines for an initiation of proceedings, in particular the 3-year limitation period, should be borne in mind.
Enforcement	If a cessation of the prohibited practise is ordered by the court, but the defendant does not comply, the court, at the petitioner's request, can impose additional fines to force the defendant to desist the malpractice. If the cessation of the prohibited practise was ordered by CPI, but the entity does not comply with the order, CPI can impose additional fines to force the defendant to desist their malpractice. Fines ordered by OCCP can be enforced by the competent authorities.

Appeal	• An appeal against a court's ruling in a civil action must be filed with the higher court within 2 weeks of the date of the delivery of the first instance ruling. • Within 14 days of the delivery of a decision by CPI, the party can request that CPI reconsiders the case. If CPI upholds its decision, an appeal can be filed, within 30 days, with the regional administrative court. • An appeal against a decision of OCCP must be filed with the Regional Court in Warsaw – the Court of Competition and Consumer Protection – within 2 weeks of the date of the delivery of the decision. The case is then heard in civil proceedings.
Costs	• The initial costs of the preliminary injunction are low (the court fee is approximately EUR 25). The court fee for the statement of claim is 5% of the total value of claims (however, no more than approximately EUR 25,000). The petitioner bears the costs of the proceedings in a civil proceeding if it loses the case. • A petitioner must bear in mind that the defendant may demand reimbursement of damages caused by the preliminary injunction if the petitioner's case is not successful.
Representation by an Outside Counsel	Representation by outside counsel is not obligatory in false advertising proceedings in Poland.
Criminal liability	False advertising may be subject to criminal liability in cases of non-compliance with the order of CPI to cease such prohibited practises.
Legality of Advertising a Medical Device before a CE Mark has been granted	A medical device, which has not, as yet, been granted a CE mark, can only be marketed at trade fairs, exhibitions, shows, presentations and conferences. Such presentation is conditional upon explicit indication that a medical device cannot be placed on the market or put into service until it is granted a CE mark. Also, the device cannot be used to test and obtain specimens from the participants of aforementioned events.
Legality of Advertising Unpublished Study results ("data on file")	There are no explicit provisions of binding law regarding the legality of advertising unpublished study results. However, according to the Pharmaceutical Industry Code of Good Practices approved by the association of pharmaceutical companies in Poland, the data on file cannot be advertised unless the data is included in the registration file available on request.
Hogan Lovells false advertising experience in Poland	• Advising a leading international pharmaceutical company based in the US and its affiliate on advertising issues, clinical trials, regulatory, commercial agreements, and tax. We have represented the client in disputes with their competitors regarding unfair advertising. • Advising German and Polish subsidiaries of a leading Italian pharmaceutical company on regulatory, advertising, and distribution issues. • Advising a leading Japanese pharmaceutical company and its affiliates on complex clinical trial matters. We have also advised them on advertising disputes with their competitors.

The legal system at a glance



Your contact in Poland

Ewa Kacperek

Counsel, Warsaw

As a counsel leading the Warsaw Intellectual Property, Media and Technology practice, Ewa Kacperek focuses on intellectual property, unfair competition, privacy and e-commerce matters. Ewa brings over 15 years' experience in drafting and opining on IP transfer and licensing agreements, IP and unfair competition litigation, as well as privacy and e-commerce matters. As a litigator, Ewa has appeared before the Polish Supreme Court on a number of occasions, enforcing the trademark rights of her clients. She has represented clients active in areas as diverse as domestic appliances, mobile telephony, and the food and beverage industry. Whether it is complex loyalty schemes, copyrights connected to commercial centres, domain name disputes, or trademark litigation, Ewa quickly gets to the heart of the problem and solves it efficiently.

Keen on techy stuff and with a deep understanding of how the internet and new media work, Ewa is on the same page as her tech-savvy clients. Unusually for a lawyer, she is not interested in the law purely for the sake of the law, but instead uses it to find pragmatic solutions to those issues which confront her clients. Ewa has authored many articles, for both specialist periodicals, and the daily press. In addition to her regular work, she often gives client seminars. Seeing the importance of an understanding of law in peoples' day-to-day lives, Ewa has co-founded a programme for teaching the basics of law to secondary school students.

Representative experience

- advising a neurovascular company on advertising its products in Poland;
- advising a large disinfectant manufacturer in connection with unfair advertising strategies employed by one of its competitors;
- assisting several clients in connection with parallel import of drugs;
- representing an OTC manufacturer in proceedings against a competitor using unfair advertising methods;
- advising an international producer of beverages in trademark cancellation proceedings before the Patent Office of the Republic of Poland; and
- advising and representing an international producer of beverages in trademark protection issues, including the legal measures of protection against infringements on the Polish market, parallel importers from outside of the EEA, and unfair domain users.

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Russia

"Everything is on time, very effective and we could speak till midnight before disputes."

Chambers Europe 2018

How to challenge false advertising in the Life Sciences Sector

The Federal Law "On Advertising" No. 38-FZ of 13 March 2006 (the "Advertising Law") is the main piece of Russian legislation regulating almost all issues related to advertising and marketing activities, both general and industry-specific.

The main regulatory body within the marketing/advertising field is the Federal Antimonopoly Service (FAS Russia) which conducts administrative proceedings with respect to infringements of Advertising Law.

In Russia, when a company wishes to prevent/stop the distribution of a competitor's advertising materials which it considers to be incompatible with Advertising Law, it has three main options. The claimant can file a claim with FAS Russia, the Russian state arbitrazh (commercial) court, or, alternatively, with the Association of International Pharmaceutical Manufacturers (AIPM) – the Russian self-regulatory body. Proceedings before AIPM do not prevent a complainant from initiating parallel proceedings in FAS Russia or the commercial court.

Sending a warning letter is not necessary, unless the complainant wishes to bring the dispute before AIPM. Demands made in warning letters are usually limited to ceasing the further distribution of the misleading advertising material. The alleged infringing competitor has no statutory obligation to respond nor is it obliged to pay any compensation for damages caused by the advertising as alleged in the warning letter. Although not required under Russian law, the sending of a warning letter to an infringer before initiating any other proceedings is recommended since it may support evidence in future proceedings of an infringer's bad faith and refusal to cooperate. This could have a positive influence on the result of the case brought before the court.

The choice of which option to follow largely depends on the objectives of an applicant. Where an applicant has not suffered any significant damages which can be confirmed or proven in a Russian court, filing a claim with FAS Russia is recommended.

Although initiating proceedings before AIPM are possible, it is not common practice in Russia. To date, most false advertising cases have been heard by FAS Russia or the Russian courts.

Preliminary injunctions are available in court proceedings, subject to the applicant providing collateral and launching its claim in the court within 15 days of the grant of the injunction. However, the Russian courts are reluctant to grant preliminary injunctions and an applicant needs to provide compelling evidence that the injunction is required at such an early stage of the proceedings.

The Hogan Lovells Russian team has successfully represented a number of clients in Life Sciences false advertising and unfair competition litigation before the Russian courts and the competition authorities (FAS Russia and its regional offices) and has accumulated extensive and deep experience in advising clients during both pre-trial negotiations and proceedings in the court/FAS Russia. The team currently acts for a significant number of clients in the pharmaceutical, biotechnology and medical device sectors.

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Facts and figures

Definition of False Advertising	In Russia false or misleading advertising occurs when it contains incorrect comparisons and/or untrue information on, *inter alia*, the advantages of the advertised goods, any characteristics of the goods, manufacturer /seller of the advertised goods, and/or when it discredits the honour, dignity or business reputation of third parties/ competitors.
Self-Regulatory Bodies	• AIPM considers false or misleading advertisement cases initiated by either members of AIPM or third parties. • Before filing a claim, an applicant is obliged to send a warning letter which requires a response within 5 business days of the receipt of the decision. • Neither preliminary injunction nor compensation for either damages or legal costs is available. The proceedings take up to 2-3 months. • If an amicable resolution is not reached, a Special Panel is appointed to confirm whether the advertisement is or is not compliant with the Code of Conduct. If the infringer is liable, it is obliged to report to AIPM on the measures it will undertake to achieve compliance. • The decision of the Special Panel of AIPM may be appealed in writing to the Executive Director within 10 business days of the delivery of the decision.
Public Authorities	• FAS Russia and its regional offices have the task of terminating the distribution of false or misleading advertisements and bringing infringers to administrative liability (usually a fine). • Proceedings can be initiated by FAS Russia on its own initiative or based on the application of a third party. No preliminary injunction or compensation for damages or legal costs is available. The proceedings usually take 5-6 months. • The ruling of FAS Russia can be appealed to the Russian state arbitrazh (commercial) court within 3 months of its issue and can be further appealed before the courts of higher instance. • Based on its ruling, FAS Russia is entitled to initiate administrative proceedings against the infringer.
Possibility of Expedited Proceeding	• A preliminary injunction is available in court subject to the applicant providing collateral to cover the opposing party's possible losses resulting from an injunction. The court grants/ refuses to grant a preliminary injunction within 1 business day. Once the injunction has been issued it becomes valid and enforceable. • The Court decides on a preliminary injunction in an ex parte proceeding; its ruling on preliminary injunction can be further appealed. • If the preliminary injunction is granted, the claim is required to be formally launched before the court within up to 15 days of the grant.
Initiation of Proceedings	• Applicants are entitled to file claims with the Russian state arbitrazh (commercial) court claiming for: (i) recovery of damages; and/or (ii) public retraction of the infringing advertisement. • The proceedings are adversarial and both parties will provide explanations and evidence during the court hearings.
Court's Decision	• Usually it takes 3-6 months before the decision is issued (if no more than 2-3 court hearings are held). • The applicant bears the burden of proof that the defendant's advertisement does not comply with Advertising Law. • It is possible to recover damages, including legal costs, if the applicant proves the amount and cause-and-effect link.

Deadlines for Initiation	The general limitation period will apply to all proceedings – 3 years from the date the applicant became aware or should have become aware that his rights were being infringed by the defendant and discovered who was the proper defendant.
Enforcement	The ruling of the court of 1st instance enters into legal force within 1 month of its issue unless it is appealed.
Appeal	The ruling of the Russian state arbitrazh (commercial) court made in main proceedings can be appealed within 1 month of its decision. It can be further appealed before the courts of higher instance.
Costs	• No fee is required to be paid to initiate the proceedings before the AIPM or before FAS Russia. • The state duty for filing an application for a preliminary injunction before the Russian arbitrazh (commercial) court is approximately EUR 45; the state duty for filing a claim before the Russian arbitrazh (commercial) court is up to approximately EUR 2,900.
Representation by an Outside Counsel	Representation by outside counsel is not obligatory but is highly recommended.
Criminal liability	False and misleading advertising is not subject to any criminal liability.
Legality of Advertising a Medical Device before a CE Mark has been granted	• The Regulation on CE Marks does not extend to the territory of Russia; local Russian law applies instead. Medical Devices are subject to mandatory registration. Medical Devices cannot be put into circulation in Russia unless the registration is successfully completed. Moreover certain Medicinal Devices are subject to a declaration of conformity, and some – subject to certification of conformity. The products which have passed the conformity confirmation are marked with the special mark of circulation on the market. • The Advertising Law prohibits advertising of any goods that are subject to mandatory certification or other confirmation of compliance with technical regulations if no such certification/ confirmation have been granted. Although registration of Medical Devices is not explicitly referred to in the Advertising Law, we conclude that it is not possible to advertise Medical Devices in Russia until their registration has been successfully completed/ until they have issued the conformity confirmation (required under Russian law).
Legality of Advertising Unpublished Study results (“data on file”)	• There are no clear legal indications concerning use of unpublished study results in advertisements. It is recommended to making a disclaimer in the advertisements stating that the advertisement relies on unpublished study results to avoid potential misleading. • In any case is possible to disclose “data on file” when/ if is necessary to prove the claims made in the advertisements
Hogan Lovells false advertising experience in Russia	• The Hogan Lovells Russian team has extensive experience in advising clients who conduct business in the pharmaceutical, biotechnology and medical device sectors in respect of the optimum legal strategies and tactics involved in stopping and preventing the distribution of false or misleading advertisements. • The team has successfully represented clients in Life Sciences litigation before the Russian courts and competition authorities.

The legal system at a glance

Your contact in Russia

Natalia Gulyaeva

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Partner and Head of the Russian Life Sciences and IP practices, Natalia Gulyaeva is recognised as a leading Russian lawyer and is named in international legal directories including *Chambers & Partners* as a highly recommended Russian practitioner who is "really on top of things." Her diverse practice encompasses portfolio development, litigation and transactional work.

According to *Chambers & Partners*, she is praised by her peers and clients for "her business sense and clear management style" and is defined as "creative, flexible and able to guide clients through the specifics of the Russian market" and as a "tough and focused attorney".

Her clients particularly compliment Ms Gulyaeva's ability to see the legal issues from the perspective of an in-house counsel. She joined Hogan Lovells in 2000 having spent several years as legal counsel for an international corporation.

Natalia is admitted to represent clients before the Russian PTO, Chamber for Patent and Trademark Disputes, the Russian IP Court and other Russian courts, the Federal Antimonopoly Service and other state authorities. In addition to her qualification as a Russian lawyer, she has also been admitted as an English solicitor. She is well-known for a chain of victories in litigious matters before the Russian courts. Natalia is equally creative and successful in handling complex disputes between international and domestic corporations in Russia and other CIS countries and in coordinating multi-jurisdictional dispute resolution (arbitration and litigation). Natalia is the winner of 2015 "Client Choice Award" as well as the winner of *Euromoney's* "European Women in Business Law" Awards 2015. She was selected by her peers for inclusion in *The Best Lawyers in Russia*.

Representative experience

- representing a major pharmaceutical company in an action relating to unfair advertising before the Russian competition authorities;
- representing an international chemical and pharmaceutical company before FAS Russia challenging the use and advertising of similar packaging for an 'identical to the client product' in the Russian market;
- advising one of the world's leading pharmaceutical companies on implementation of co-promotion and co-marketing projects in compliance with the pharmaceutical, commercial, regulatory, advertising and competition regulations in Russia; and
- representing a major pharmaceutical company, one of the leaders in the development of HIV therapies, in a number of patent infringement and unfair competition actions in disputes with generic manufacturers in Russia, Ukraine and Kazakhstan.

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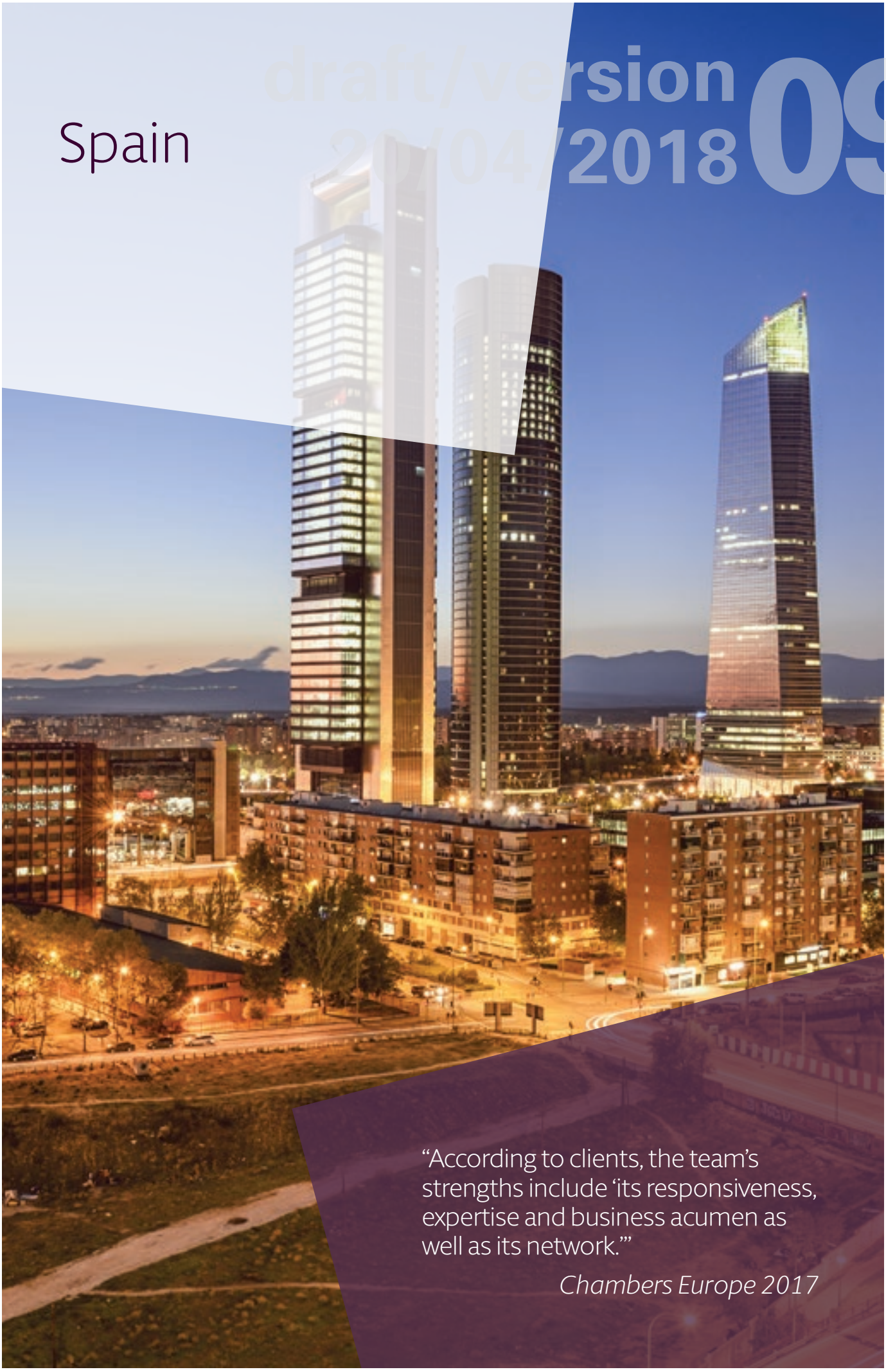
Spain



"According to clients, the team's strengths include 'its responsiveness, expertise and business acumen as well as its network.'"

Chambers Europe 2017

How to challenge false advertising in the Life Sciences Sector

In Spain, advertising of pharmaceutical products and medical devices is governed by specific life-science regulatory provisions, general unfair competition law, and self-regulatory codes.

Health authorities may order *ex officio* the suspension of any false advertising that poses an imminent and serious risk to public health.

At the competitor level, disputes on false advertising can be initiated by a cease-and-desist letter. Should the requested entity not comply with the terms of the request, the plaintiff would typically be required to submit the dispute before *Autocontrol* – the Spanish advertising self-regulatory body – if the involved parties are members thereto and/or belong to the main industry associations (Farmaindustria –pharmaceutical products – and Fenin – medical devices) which represent the vast majority of life sciences companies operating in Spain.

Proceedings before *Autocontrol* are characterised for being swift and cost-efficient. Its decisions are binding for its members and may be appealed before its board of appeals. *Autocontrol's* rulings are widely accepted (and well-regarded) by the industry so parties very rarely prosecute the case before the judiciary. *Autocontrol* reports that members decide to comply with its decisions in 95% of cases.

If one of the parties is not a member or being so the plaintiff is dissatisfied with the decision, it may file a complaint (and/or a preliminary injunction request) before the courts. Commercial Courts, specialised in unfair competition and advertising matters (in addition to IP matters), are competent to hear the case. The complaint is typically filed on the basis of Act 3/1991, of 10 January, on Unfair Competition (the "Act 3/1991"), and in particular:

- False advertising: Article 5 prohibiting any deceptive, false or misleading advertising that is causes altering change in the economic behaviour of the consumer in relation to, inter alia, the existence or nature of the product, its main characteristics, or its price as well as any false advertising that breaches a code of conduct and causes an alteration in the economic behaviour of consumers significantly;
- Wilful omissions: Article 7 preventing any (wilful) omission of relevant information in the consumers' decision making process.
- Violation of legal provisions: Article 15, prohibiting any act that breaches any laws or regulations governing competition in the market including regulatory provisions on advertising of pharmaceutical products and medical devices.

Under Act 3/1991, a competitor is entitled to request the Court to order, among others remedies: (a) an injunction and prohibition on resuming the advertising in the future; (b) the rectification of misleading information; (c) the recall and destruction of any infringing material; and (d) the publication of the judgment.

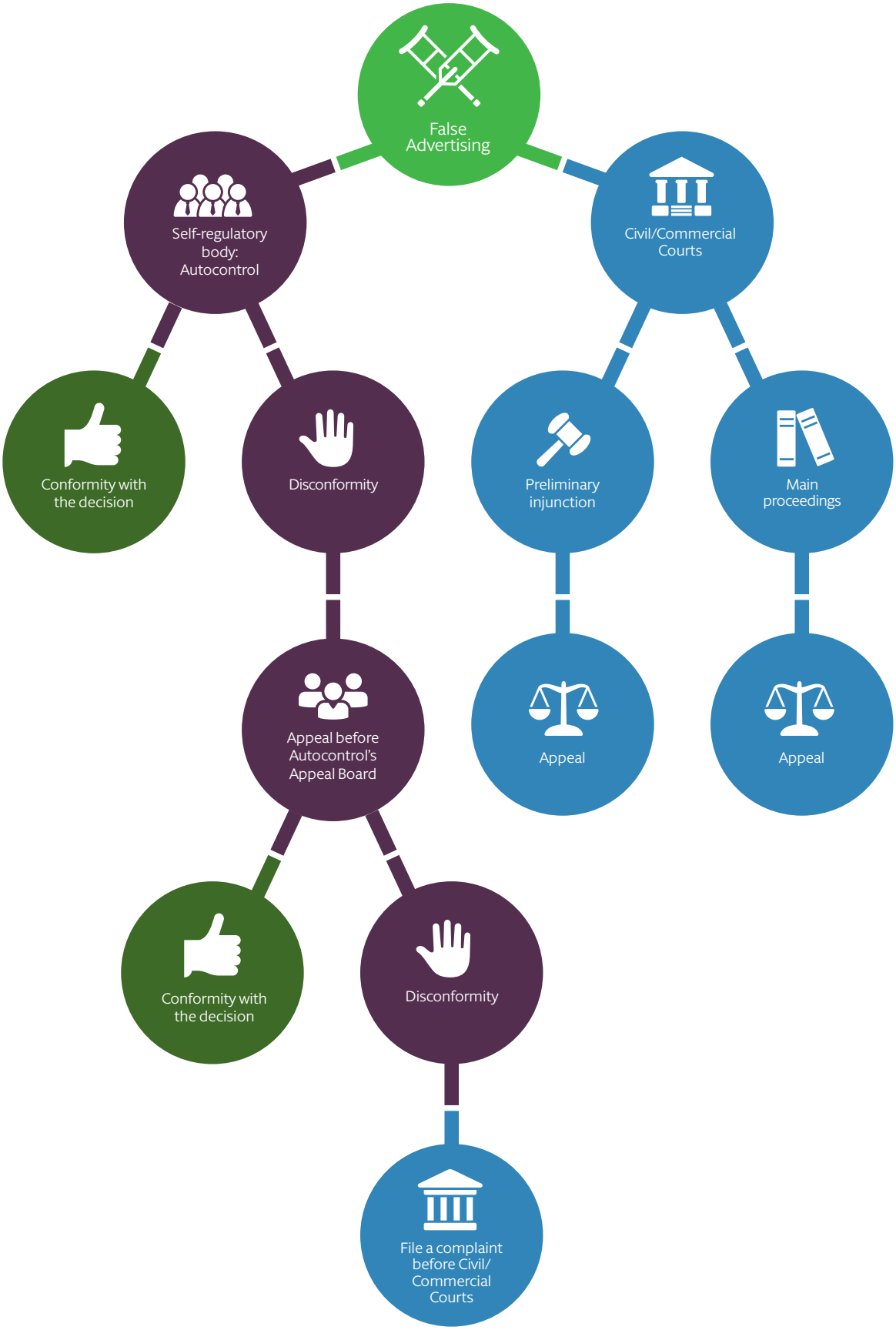
The plaintiffs are also entitled to apply for injunctive relief against any on-going advertising that breaches regulatory provisions on medicinal products and medical devices on the basis of Royal Legislative Decree 1/2015 of 24 July. If the advertising involves medicinal products, they complainant is required to send a cease-and-desist letter prior to initiating legal action. The law establishes a fifteen-day period for complying with the 'cease and desist' request.

Facts and figures

Definition of False Advertising	Any advertising or promotion containing information – or omitting it – that results in misleading consumers and altering their economic behavior. Such information may relate to the existence and nature of the product, its main characteristics, post-sale assistance services and price. Any advertising that breaches a code of conduct and results in significantly altering the economic behavior of consumers can also be deemed as false advertising. In the field of life sciences, false advertising would generally involve therapeutic indications and/or the composition or expected effects of the medicines or medical devices.
Self-Regulatory Bodies	*Autocontrol*, the advertising self-regulatory body, hears the vast majority of false advertising disputes within the life science industry. Claims must be brought before *Autocontrol* if defendant and claimant are members of *Autocontrol* and/or members of Farmaindustria – the association of the innovative pharmaceutical industry representing 99% of medicinal products sales in Spain – and/or to Fenin – the association of the medical devices industry representing 80% of medical devices sales in Spain. *Autocontrol* reports an overall compliance rate with its decisions of 95%. Therefore, less than 5% of cases end up in court.
Public Authorities	Health authorities can order *ex officio* the suspension of any false advertising that poses an imminent and serious risk to public health.
Possibility of Expedited Proceeding	• False advertising proceedings before *Autocontrol* can be expedited (average time for a decision to be issued is 15 days to 2 months). • Plaintiffs are entitled to apply for interim relief. In principle, preliminary injunctions are applied for with the claim based on the merits. • Interim relief may be also granted *ex parte*. Courts have granted ex parte preliminary injunctions when the claim is based on false advertising due to the short life of advertising campaigns. • Should the preliminary injunctions be ordered, they will be automatically lifted if the plaintiff does not file the main action within 20 working days of the service of the order.
Initiation of Proceedings	• Members of *Autocontrol* or belonging to Farmaindustria or Fenin must submit their disputes before *Autocontrol*. • Competitors, consumer's associations, or administrative authorities and, in general, any entity bearing a "legitimate interest" have legal standing to initiate false advertising proceedings.
Court's Decision	• A decision by *Autocontrol* can be issued between 15 days and 2 months from filing. • Although it will largely depend on the competent Court, an order on an *ex parte* preliminary injunction application may be rendered before the advertising campaign comes to an end. • Also depending on the Court handling the case, a judgment on the merits may be issued between 12-24 months from filing.
Deadlines for Initiation	• Applications for preliminary injunctions must be filed shortly after the plaintiff becomes aware of the false advertising. The law does not establish a time limit. In the case of advertising claims, the application must be lodge within weeks. • The statute of limitations of unfair competition actions dealing with false advertising is one year from when the plaintiff became aware of the false advertising or, in any event, 3 years from the date the false advertising came to an end. • False advertising complaints on the basis of Royal Legislative Decree 1/2015, of 24 July, must be brought before the advertising comes to an end unless there are reasons to believe that it would be resumed in the future.

Enforcement	• The decisions of *Autocontrol* are voluntarily complied with by 95% of the members of the self-regulatory body. • Court orders granting preliminary injunctions are enforceable. • First instance judgments are provisionally enforceable, including injunctions, in Spain.
Appeal	The rulings issued by *Autocontrol* may be appealed before the board of appeals. The appeal against the preliminary injunction order must be filed within 20 days of service.
Costs	The unsuccessful party will bear, in principle, the legal costs. Costs recovery and exposure is rather limited in Spain. Costs are calculated on the basis of the value of the proceedings. Unfair competition cases where the injunction is the main claim would formally involve legal costs of around EUR 3,000 – EUR 4,000.
Representation by an Outside Counsel	The parties must be represented in Court by a licensed attorney (in house or external) as well as by a court bailiff. Representation by outside counsel is not compulsory but is recommended before *Autocontrol*.
Criminal liability	False advertising is subject to the administrative penalties established in the Medicines and Medical Devices legal framework and, depending on the case, may be subject to criminal sanctions.
Legality of Advertising a Medical Device before a CE Mark has been granted	Advertising a medical device which has not been granted the CE mark and, which consequently, would not formally comply with the regulatory obligations under the applicable laws is not permitted in light of Article 38 of Royal Decree 1591/2009. An exception is set out in Article 41 of the Royal Decree, allowing the display of medical devices at trade fairs, exhibitions, and demonstrations provided that a sufficiently visible sign is displayed on or close by the products, clearly indicating that said products cannot be placed on the market.
Legality of Advertising Unpublished Study results ("data on file")	"Data on file" include published and unpublished studies and it may be used for the advertising of duly authorised medical devices provided that the data are accurate and reliable. Since there is no specific provision prohibiting such, unpublished studies could be used for advertising. In this sense, regulatory and supervisory bodies keep track of this advertising and therefore they could request copies of the data. This also applies for medicinal products although there is a general obligation to publish the results of a clinical trial, whether positive or not, and medical journals or scientific publications used in promotional materials must indicate their precise source.
Hogan Lovells false advertising experience in Spain	• We are experts in Life Sciences matters. • Our team regularly handles a variety of matters in the Civil and Administrative Courts. • Our accumulated legal skills and experience in advertising litigation enables us to handle different matters related to new technologies such as banners, call centers and online advertising.

The legal system at a glance



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Ana Castedo is a partner in the Intellectual Property practice of our Madrid office which she joined in 2006. She specialises in all contentious aspects of IP, including trademarks, designs, unfair competition, copyright and patents. Ana handles complex pieces of litigation mainly focused on the field of Life Sciences (pharmaceutical and medical devices) and on IT/Technology. Ana is well-known for her pleading skills, with peers rating her as a "consistently impressive adversary" (WTR 1000). Her clients also draw attention to her "quick response, deep technical knowledge and involvement in the matters that we entrust to her" (*Chambers & Partners*). She has been named an "IP star" for 2015 by *Managing Intellectual Property* and a Life Science Star in IP litigation by *LMG Life Sciences 2015 Edition*.

Carolina Revenga

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With extensive experience in product liability and tort claims, Carolina Revenga manages massive tort litigation related to medical devices and medicinal products and helps key industry sector clients to solve all types of critical challenges, these including frequent advice on regulatory and compliance matters. Carolina is an expert on civil litigation and witness interrogation techniques. She has been ranked in Expert Guides (2014, 2015, and 2016) in product liability litigation and she has been recognized as a "rising star" in the field of Product Liability (*Expert Guides, LMG Rising Stars 2017)*.

Representative experience

- representing a medical devices multinational against a competitor in unfair competition proceedings involving advertising claims;
- acting for a competitor in the medical devices sector in a number of false advertising cases before the Spanish self-regulatory body, *Autocontrol*;
- defending one of the world's leading life sciences companies following an international voluntary product recall and assisting the client in managing crisis communication;
- representing a worldwide leader in the snack sector in unfair competition proceedings filed by a competitor involving, inter alia, a false advertising claim related to energy efficiency; and
- acting for a leader in the IT industry in judicial proceedings filed by its main competitor involving a claim for misleading advertising previously brought to Spanish self-regulatory body, *Autocontrol*.

The UK

"The response times are excellent, the advice is well thought out and they are careful not to over-lawyer matters."

Chambers Europe 2018

How to challenge false advertising in the Life Sciences Sector

In the UK, the advertising of medicinal products and medical devices is regulated through a combination of legislation, regulatory authority guidance and self-regulation through industry codes of practice.

Usually, the first step is to raise any concerns about an advert directly with the advertiser. It may be helpful (and in some cases is mandatory for complaints made by another company) to include evidence of such communication in any formal complaint submitted to a regulator.

If the issue is not resolved, the complainant should then establish which is the appropriate body to submit the complaint to. The appropriate body to complain to about misleading advertising relating to medicines or medical devices depends on the type of product, the nature of the claim, the intended audience and whether the advertiser making the claim has agreed to comply with a particular industry code.

In the UK, advertising complaints are rarely dealt with by the courts.

For medicines, where the advertising falls within the remit of an industry body, the complaint is usually submitted to that industry body (if the advertiser has agreed to comply with that body's code). The main industry codes and bodies regulating the advertising of medicines are:

- The Prescription Medicines Code of Practice Authority (PMCPA), which enforces the Association of the British Pharmaceutical Industry Code of Practice (ABPI Code) covering the advertising of prescription-only medicines to healthcare professionals; and
- The Proprietary Association of Great Britain (PAGB), which enforces codes of practice (one for consumers and one for healthcare professionals) covering branded promotional materials for over-the-counter medicinal products.

If the advertiser is not a member of the ABPI or PAGB, the complaint should be submitted to the Medicines and Healthcare products Regulatory Agency (MHRA), which enforces the UK Human Medicines Regulations 2012 (HMRs).

For medical devices, complaints are usually made to the Advertising Standards Authority (ASA) on the basis of a breach of the UK Code of Non-Broadcast Advertising and Direct and Promotional Marketing (CAP Code) or UK Code of Broadcast Advertising (BCAP Code). The Association of British Healthcare Industries Code of Practice (ABHI Code) applies to advertisements addressed primarily to healthcare professionals.

The complaint process varies between the different bodies, but all involve the body investigating the issues raised in the complaint, giving the advertiser a chance to respond to the complaint in writing, and then ruling on whether the advertiser has breached the relevant code. The advertiser may appeal the decision in accordance with the particular body's appeal procedure. Most investigations are completed within a matter of months, but can take longer.

Rulings are usually published by the regulator and so can result in negative publicity for the advertiser.

The sanctions available vary depending on which body is investigating the complaint. Of the bodies mentioned above, only the MHRA has the power to prosecute the advertiser. Generally, if the complaint is upheld, the advertiser is required to amend or withdraw the statement in question. Other actions may be imposed, such as having to issue a corrective statement. Fines are unlikely, though some bodies impose an administrative fee.

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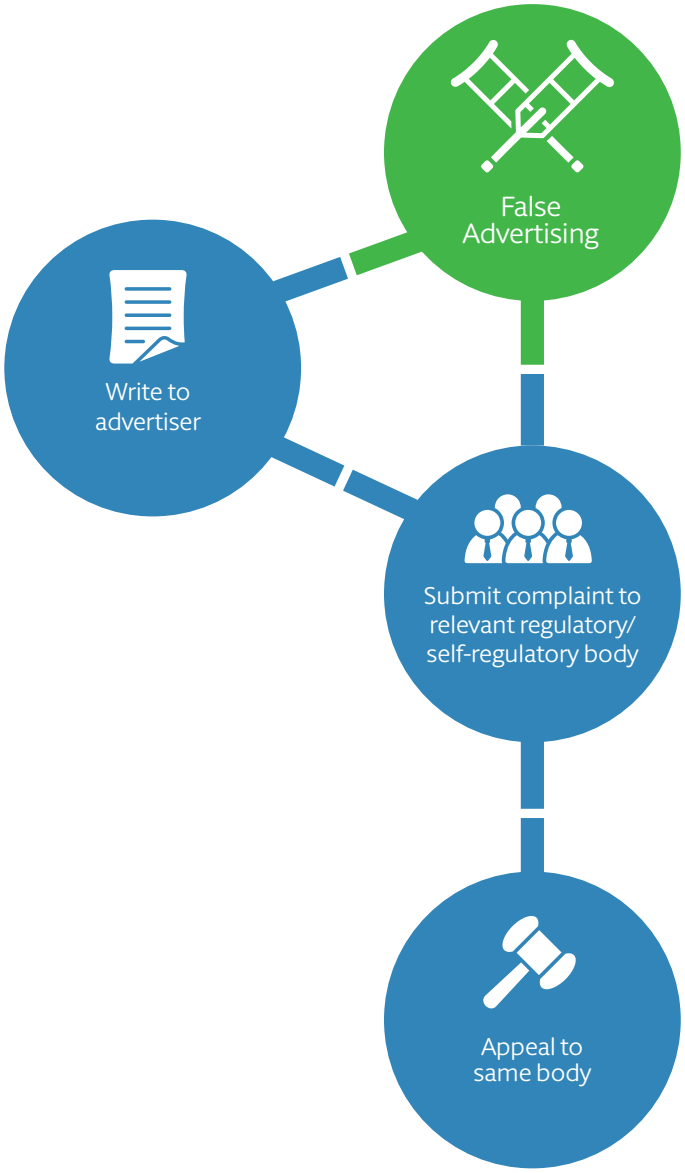
Facts and figures

Definition of False Advertising	Advertising is misleading if it does not comply with the general requirement that all claims must be true, not misleading (i.e. omit or exaggerate key information) and be capable of substantiation, or any of the detailed requirements set out in the relevant UK legislation or any applicable codes of practice.
Self-Regulatory Bodies	In the UK, advertising complaints are usually handled by the relevant self-regulatory body: • advertising of prescription-only medicines to healthcare professionals: the PMCPA, which enforces the ABPI Code; • advertising of branded over-the-counter medicines: the PAGB; and • advertising of medical devices: ASA or ABHI.
Public Authorities	The Medicines and Healthcare products Regulatory Agency (MHRA), which deals with the advertising of medicines where the advertiser is not an ABPI or PAGB member.
Possibility of Expedited Proceeding	No, though the complainant is free to flag to the regulator why they believe the issue should be dealt with urgently.
Initiation of Proceedings	Advertising challenges are initiated by submitting a complaint to the relevant self-regulatory body or public authority. Before submitting a complaint about a competitor, most regulatory bodies require a corporate complainant to have written to the competitor to try to resolve the issue.
Court's Decision	The body to which the complaint is submitted makes the decision. Advertising claims are rarely litigated in court.
Deadlines for Initiation	The deadlines vary between bodies (for example, complaints to the ASA must be submitted within 3 months of the advert appearing), but in general a complaint should be made as soon as the complainant becomes aware of the issue.
Enforcement	If the complaint is upheld, the body will set out the action the advertiser is required to take, such as amending or withdrawing the advertisement in question. If the advertiser does not comply, the body can refer the advertiser to the relevant governmental authority to take formal action (i.e. court proceedings), which is the MHRA for medicines advertising and Trading Standards or Ofcom for medical devices advertising. Rulings are usually published by the body and so can result in negative publicity for the advertiser.
Appeal	The advertiser may appeal the ruling in accordance with the relevant body's appeal procedure.
Costs	There may be no costs if the matter is handled by the advertiser internally, or there may be costs of outside counsel assistance if required. Fines are unlikely, though some bodies impose an administrative fee.
Representation by an Outside Counsel	Representation by outside counsel is not a requirement, but outside counsel may assist with drafting any written response submitted by the advertiser.
Criminal liability	Technically, formal proceedings with the possibility of criminal sanctions could be brought by the MHRA or Trading Standards/Ofcom, but this is rare where the advertiser agrees to amend or withdraw the advertising in question.

Legality of Advertising a Medical Device before a CE Mark has been granted	• Only medical devices that are validly CE marked can be advertised and then can only be promoted for their intended purpose(s) as set out in their labelling and instructions for use. • Prior to CE marking, medical devices can be shown at trade fairs, exhibitions and demonstrations so long as it is clearly indicated that the devices has not been CE marked and is not available.
Legality of Advertising Unpublished Study results ("data on file")	Data on file can be used to support promotional claims provided that the claims are: • accurate, not misleading and are adequately substantiated by the unpublished data; and • consistent with the labelling and instructions for use (for medical devices) or SmPC (for medicinal products). The data on file referenced in advertising must be provided on request, e.g. by a regulatory body or a healthcare professional, so should only be used if the advertiser is willing to provide a copy of the data if requested.
Hogan Lovells false advertising experience in the United Kingdom	We have advised a wide range of pharmaceutical and medical devices companies on ensuring that their advertising materials are compliant, challenging competitors' claims, and defending challenges from regulatory bodies and have advised: • a multinational medical device manufacturer on copy clearance of all print, online and TV advertisements for a range of medical device products; • the UK subsidiary of an international pharmaceutical company on compliance with the ABPI Code requirements and responding to a PMCPA complaint; • various international medical devices companies on copy clearance of internet content including online promotions, web-casts and product offer terms; • a U.S. pharmaceutical manufacturer on a global marketing compliance policy; and • various pharmaceutical and medical devices manufacturers on challenging competitors' advertising claims.

The legal system at a glance



Your contact in the United Kingdom

Richard Welfare

Partner, London

Richard is a Partner in the Commercial and Regulatory Practice with broad experience of advising on advertising and marketing issues, including in the life sciences industry sector. Richard assists clients with reviewing advertising campaigns and marketing activities and in responding to regulatory challenges from UK authorities and competitors, and works closely with clients in monitoring and, where appropriate, proactively challenging competitor advertising activity.

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Jane Summerfield

Counsel, London

Jane is a Counsel in the Commercial and Regulatory Practice. Jane advises pharmaceutical and medical device companies on regulatory issues including advertising and marketing activities, interactions with healthcare professionals, as well as clinical trial requirements, market access, marketing authorisations, manufacturing and distribution, quality and pharmacovigilance, CE marking, and pricing and reimbursement. Jane is experienced in dealing with challenges from competitors and from regulators including the PMCPA, MHRA and ASA. Jane combines her regulatory experience with commercial acumen and a scientific background.

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Quick guides

Denmark

How to challenge False Advertising in the Life Science Sector	Members of the Ethical Council for the Pharmaceutical Industry (ENLI) can challenge false advertising for medicines by means of a formal complaint to ENLI. Moreover, any false advertising for both medicines and medical products can also be brought before the Medicines Agency. Both proceedings are relatively time- and cost-efficient.
Definition of False Advertising	In Denmark, advertising of medicines and medical devices has to be comprehensive and objective and must not overstate the properties of the product or be misleading in any other way. Relevant public legal frameworks include the Law on Medicines (*Lægemiddelloven*), the Law on Medical Devices (*Lov om medicinsk udstyr*) and the regulations (*Bekendtgørelse*) by the Ministry of Health on advertising of medicines and medical devices respectively.
Self-regulatory bodies	There are several self-regulatory bodies monitoring marketing activities for medicines. Most pharmaceutical companies on the Danish market are members of the Ethical Council for the Pharmaceutical Industry (ENLI). ENLI oversees compliance with several industry codes, e.g. the advertising code (*Reklamekodeks*), which inter alia refers to the public regulations quoted above. In this capacity, it also rules on complaints inter alia by competitors regarding the advertising of medicines to medical professionals.
Public authorities	The Danish Medicines Agency (*Lægemiddelstyrelsen*) is competent to rule on any complaints regarding unlawful advertising of both medicines and medical products. The medicines agency cannot overrule the ruling of a self-regulatory body, but can decide on the same matter in parallel proceedings, where it will take the first ruling into due consideration.
Possibility of expedited proceedings	The rules of procedure of ENLI allow for expedited proceedings for an additional fee. The respondent will have four working days to react to the complaint, and a decision has to be made within eight working days of the receipt of the complaint by ENLI.
Appeal	• At ENLI, both parties can appeal against the rulings of the first-instance Examiners' Panel (*Granskningsmandspanelet*) to the Appeal Council (*Ankenævnet*) within 21 working days of the receipt of the first-instance ruling. • Decisions of the Medicines Agency can be appealed to the Ministry of Health; these decisions can be brought to state courts.
Costs	The unsuccessful party in first-instance proceedings at ENLI has to pay DKK 6,000 + VAT; expedited proceedings require an initial payment of DKK 25,000 + VAT. The costs of an appeal at ENLI vary: A party who was ordered to pay a fine in the first instance will have to pay half the amount of the ultimate fine as a fee if it is again defeated in the appeal proceedings. Otherwise, the defeated party will have to pay a fee of up to DKK 10,000 + VAT.

Austria

How to challenge False Advertising in the Life Science Sector	Competitors can apply for interim injunctions before the civil courts. Proceedings are not very fast, but provide an effective remedy against false advertising.
Definition of false advertising	According to the Medicines Act (*Arzneimittelgesetz*), the Federal Act on Medical Devices (*Medizinproduktegesetz*) and the Federal Act against Unfair Competition (*Bundesgesetz gegen den unlauteren Wettbewerb – UWG*), advertising of medicines has to be objective and consistent with expert information. It must not overstate the properties of the product or be misleading in any other way. Advertising addressed to the general public (*Laienwerbung*) is subject to even stricter limitations.
Self-regulatory bodies	Most pharmaceutical companies on the Austrian market are members of the Association of the Pharmaceutical Industry (Pharmig). Pharmig oversees compliance with its code of conduct (*Verhaltenscodex*), which also includes elaborate provisions on the advertising of medicines. Competitors can file complaints to Pharmig's Committee of Experts, which can order the party in breach to pay fines of up to EUR 200,000. Orders can be appealed to an arbitral tribunal.
Public authorities	The Federal Office for Safety in Health Care oversees the market for both medicines and medical products. It is entitled to order companies to cease the distribution of and recall advertising materials ex officio, but does not serve as a quasi-judicial forum for claims by competitors.
Possibility of expedited proceedings	The UWG explicitly entitles competitors to obtain an interim injunction before the civil courts to enforce their claims to cease and desist. The court will make its decision within four to eight weeks. The claimant must only certify that the abovementioned provisions on false advertising were violated. There is no oral hearing, but the court can hear the defendant if deemed necessary.
Enforcement	The court will order the enforcement of its decision ex officio. If deemed necessary, it can demand a security from the claimant.
Appeal	Both parties can appeal against the court decision within two weeks by invoking any circumstance that the court failed to consider in its initial decision (*Rekurs*). If the unsuccessful defendant was not heard by the court in the first instance, it can also (either alternatively or in parallel to the *Rekurs*) file an objection on any grounds within the same time limit (*Widerspruch*).
Costs	The costs of a proceeding generally depend on the amount in question; the unsuccessful party bears the costs (court costs and costs for successful party's lawyers).


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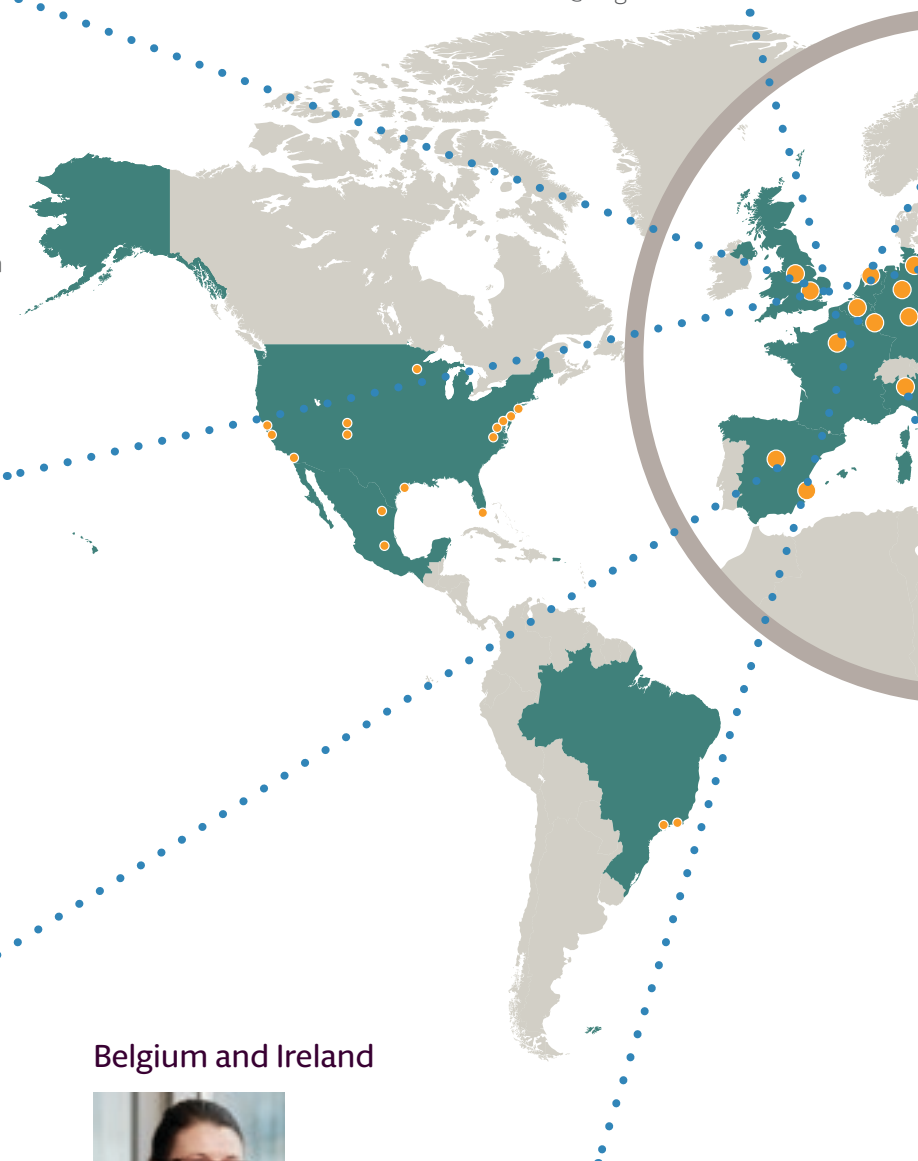

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Helping you make the world healthier

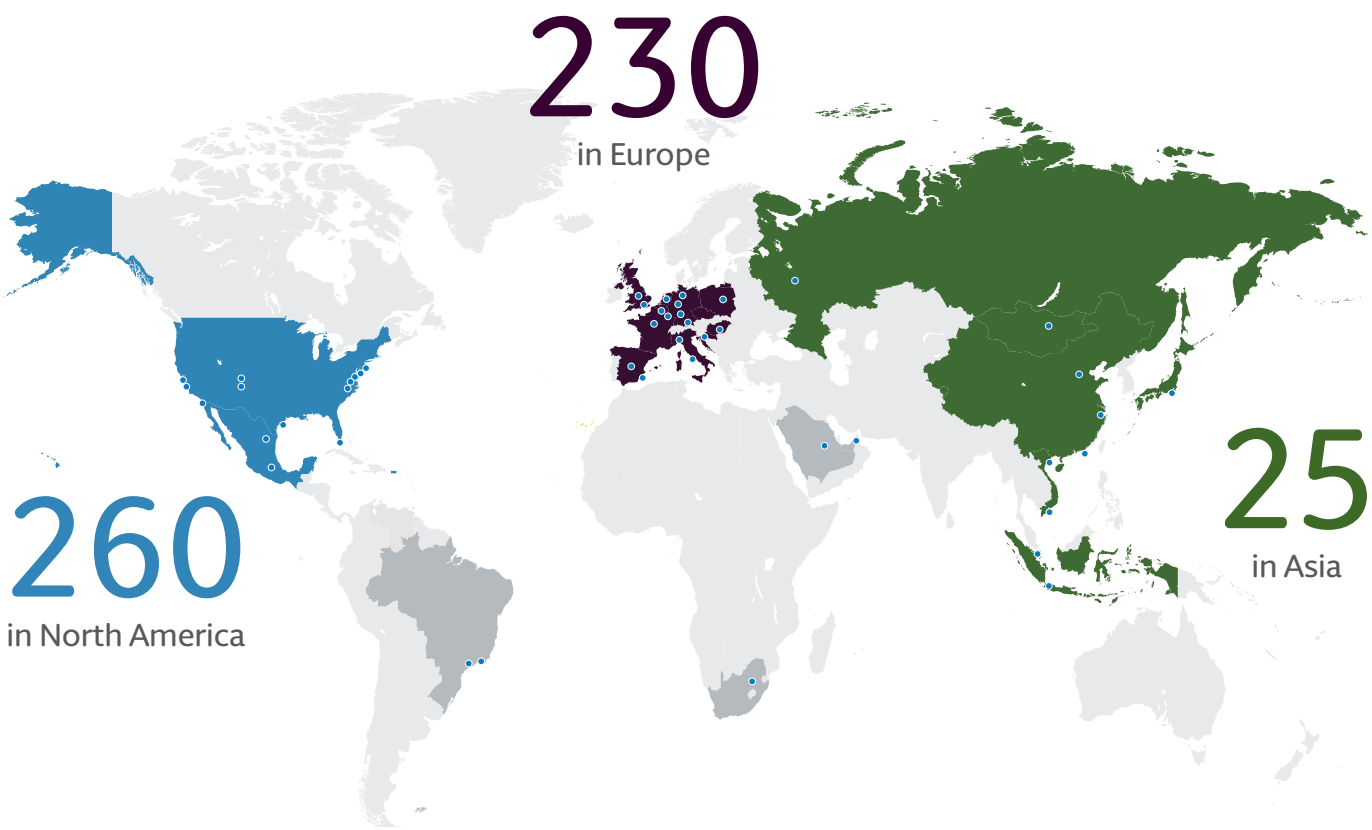
Navigating complexities in the life sciences and health care industries is no easy task. Successfully competing in the space requires a partner with a holistic, collaborative approach and a global perspective. It calls for a strategy informed by asking the right questions and rooted in identifying creative solutions to your unique challenges. For life sciences innovators of all sizes, anywhere in the world, Hogan Lovells is that partner — from cutting-edge start-ups and boutique venture funds to world-renowned research institutions and health systems to global biopharmaceutical conglomerates.

Your business and your challenges don't stop for oceans or disappear at national borders. Neither does Hogan Lovells. Our team of more than 500 Life Sciences and Health Care lawyers are located around the world but operate as if everyone is working from the same office — providing a seamless experience everywhere you do business.

And no matter the challenge — from creation to commercialization of a life-saving therapy, regulatory compliance to an international patent dispute, the formation of a strategic alliance to a complex, global merger — we've been there before and we understand how to prepare you for what happens next, helping you to anticipate risks and address future issues before they arise.

Whatever your challenge, wherever the issue, Hogan Lovells has you covered. It's that easy.

Over 500 Life Sciences and Health Care practitioners worldwide



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For additional information, visit:

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