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Regulering van reclame voor receptgeneesmiddelen

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Abstract

The research study

European legislation on pharmaceutical advertising has been in place since 1992. This legislation permits advertising of prescription-only medicines to prescribers and pharmacists, but imposes strict requirements for the protection of public health. It is based on the principle that when prescribing medicines doctors must be able to carry out their duties completely objectively, without being influenced by direct or indirect financial incentives. The European legislature gave Member States the option to create a role for self-regulation as part of achieving these objectives. The Dutch legislature chose to exercise this option and created a dual system, in which legislation and self-regulation operate side by side.

This study investigates how the European requirements for the advertisement of medicinal products to healthcare professionals are implemented. It focuses on three legal sources: Directive 2001/83, the Dutch Medicines Act and the Code of Conduct for Pharmaceutical Advertising drafted by the Foundation for the Code of Conduct for Pharmaceutical Advertising (the CGR). Self-regulation by the CGR is binding on members of a large number of sector and professional organisations involved in the supply of medicinal products in the Netherlands, including the organisations for the pharmaceutical industry as well as for doctors and pharmacists.

The study covers both the substantive standard-setting aspects of the legislation and self-regulation for pharmaceutical advertising and the way in which compliance supervision is organised.

The analysis of the substantive standard-setting aspects was carried out by reference to a fixed framework. For each sub-topic a comparison was made between the provisions on pharmaceutical advertising in Directive 2001/83, the Medicines Act and the CGR Code and - where relevant - previous legislation and self-regulation. The interpretation given to the regulations by the competent judicial authorities and regulatory bodies was also considered. This primarily involved case law of the European Court of Justice and Dutch courts and regulators and decisions of the CGR's Code Committee and Appeals Committee. For this purpose the Dutch Health Care Inspectorate (the IGZ) provided previously undisclosed information about administrative fines imposed by the IGZ on behalf of the Dutch Ministry of Health since 2007 for breaches of the statutory requirements for pharmaceutical advertising.

The research into supervision focuses on the way the system in the Netherlands is structured to stimulate and monitor compliance with the requirements for pharmaceutical advertising and to impose sanctions for breaches. In this context, a comparison is made between the powers and methods of the IGZ as the regulator supervising compliance with the Medicines Act on the one hand and the Code Committee as the regulator supervising compliance with the CGR Code on the other hand. The relationship and cooperation between these regulators is also studied and an analysis of supervision in practice is conducted.

To understand the legislation and self-regulation for pharmaceutical advertising, some context and background information is needed. Chapter 2 therefore considers the framework of standards that forms the backdrop to the regulations for pharmaceutical advertising. It also deals with the playing field that the legal source documents are intended to regulate. It describes the relationships

between the various parties involved in the pharmaceutical field in the Netherlands and their various interests in and opportunities for influencing the process of prescribing and supplying medicines. This issue is approached from a legal perspective, on the basis of the Medicines Act and the system for the reimbursement and funding of medicines. The legislation and self-regulation for pharmaceutical advertising have a long history and are closely intertwined. Knowledge of this history contributes to a good understanding of the current situation. For this reason, Chapter 3 describes the medicines legislation in general and the advertising rules in particular from a historical perspective.

The dual system and the relationship between the different legal source documents

The choice of a dual system of legislation and self-regulation means that the requirements for pharmaceutical advertising aimed at healthcare professionals are in fact made up of a number of layers. The foundation for the regulations is set out in European legislation, which has been converted into legislation at national level and elaborated in further detail in the self-regulation rules.

Chapter 4 examines this layered structure of the regulations in the context of a number of issues of a more general nature. The legal status of and interrelationship between the three legal sources are examined. The sphere of operation and scope of the legislation and self-regulation for pharmaceutical advertising are also studied. In the subsequent chapters the substantive requirements for pharmaceutical advertising imposed in the different legal sources are compared. Chapter 5 deals with the key provisions that apply to all types of pharmaceutical advertising. Chapter 6 then considers the specific requirements for advertising for prescription-only medicines aimed at healthcare professionals. Chapter 7 deals with inducements.

With respect to the interrelationship between the legal sources and the way this has been implemented over the years the following should be noted.

Under EU law the Dutch legislature is obliged to implement Directive 2001/83 correctly in Dutch legislation. The aim of Directive 2001/83 is to achieve full harmonisation. This means that the Dutch legislature may only subject pharmaceutical advertising to the requirements set out in Directive 2001/83, except where it is explicitly provided that Member States are permitted to adopt different rules. The Dutch legislature made a deliberate decision to promote self-regulation alongside government regulation. The CGR, as a self-regulating body, was given a role in further elaborating the general, open standards in the legislation for pharmaceutical advertising. Since 2007, it has been agreed between the CGR and the IGZ as part of their working practices that the CGR has primary responsibility for developing standards for pharmaceutical advertising aimed at healthcare professionals. This is subject to the proviso that this conditional self-regulation must not conflict with the applicable legislative framework.

From the point of view of substantive standards, each of the three legal sources has, given their individual design and application, a clear added value as distinct from the others. Directive 2001/83 is abstractly formulated and very general in nature. Relatively little explanation of the requirements in the European legislation is available. Certain aspects need to be further applied to produce national legislation. The implementation of the European legislation in the Medicines Act carried out some of this application process. However, the requirements for pharmaceutical advertising in the Medicines Act are also characterised by very general descriptions and open standards. Only in the area of inducement have these general, open standards been further expanded by means of policy rules

issued by the Minister of Health. The self-regulation by the CGR differs from the legislation described above in the sense that the general provisions and open standards in the legislation are elaborated in much more specific detail in the CGR Code. The Code constitutes a highly detailed system of rules and requirements, which provides greater certainty and clarity than the legislation, increasing its applicability in practice.

The self-regulation is also much more dynamic than the legislation. At European level, the legislative framework for advertising has remained largely unchanged since 1992. In the Dutch legislation the introduction of the Medicines Act resulted in a number of more fundamental – intentional or otherwise – changes to the situation under the Advertising Decree that applied previously. However, as far as the advertising rules are concerned, the later changes to the Medicines Act are primarily of a technical nature and the revisions to the Policy Rules on Inducement referred to earlier cannot be regarded as genuine new policy or development of standards either. Clearly self-regulation has a closer relationship to the relevant parties in the field than the legislature, with the result that issues and needs arising in practice are more quickly identified. Self-regulation is also able to translate these issues and needs into standards relatively quickly, with involvement and input from the stakeholders. The legislation and self-regulation complement one another well in this regard.

However, the layered, multiple source-based system of legislation and self-regulation for pharmaceutical advertising is vulnerable when it comes to ensuring mutual consistency. This vulnerability is particularly apparent when revisions of a fundamental nature, such as changes to definitions or substantive provisions affecting the structure and design of the rules, are made to one of the legal source documents.

One of the occasions when this has occurred was on the introduction of the Medicines Act in 2007, when the Dutch legislature introduced – without any obvious cause – a new, broader definition of the term pharmaceutical advertising. A definition of the term inducement, which had not applied before and does not appear in Directive 2001/83, was also incorporated in the Medicines Act, linked to a general prohibition with a restrictive list of exceptions. This prohibition, and in particular the way in which the exceptions are formulated, makes the Medicines Act stricter in this area than Directive 2001/83.

A number of discrepancies that are more matters of principle have also arisen in the relationship between the Medicines Act and the CGR Code as a consequence of interim revisions. For example, in 2014 the CGR introduced a change to the definition of advertising corresponding to a change to the Dutch Advertising Code. This revised definition does not match the definition in the Medicines Act and is also inconsistent with the scope of the CGR Code itself. Another problem has arisen precisely due to an attempt by the CGR to bring its Code into line with the Medicines Act. The introduction already mentioned of a definition of inducement and a general prohibition on this in the Medicines Act led the CGR to decide in 2014 to add an identical definition and a general prohibition on inducement (which had not previously existed) to the CGR Code. However, the way in which this prohibition and the exceptions to it are described differs in text and scope from the Medicines Act and is inconsistent with the rest of the design and structure of the CGR Code.

The above shows that fundamental revisions to the Dutch legislation and self-regulation, such as changes to definitions or substantive provisions affecting the structure and design of the rules, should only be carried out when there is actual cause or necessity to do so and when consistency is

ensured during the revision process. A prior analysis of the potential consequences and consultation with all parties concerned are crucial aspects of this.

Satisfactory operation of conditional self-regulation and legislation also requires elimination of any uncertainty as to whether the regulator responsible for compliance with the Medicines Act endorses the CGR's further elaboration of the general and open standards in that legislation. In this study, two examples have come to light showing that the agreed working practices are not being properly adhered to and as a result the interests of the various parties in the field are not adequately safeguarded. The first example relates to the situation concerning sponsorship. The second example concerns fees for services.

The current working practice agreements, which acknowledge the CGR's primary responsibility for developing standards, already in principle offer an adequate safeguard to prevent divergence. However, parties in the field need to be informed much more clearly than is currently the case about whether the IGZ has decided to endorse the standards developed by the CGR or to distance itself from them and pursue its own course instead. This is not only the responsibility of the IGZ but that of the CGR as well. The parties to whom self-regulation applies need to be able to rely on its status. Timely consultation and clear, unambiguous communication with parties in the field about the status of standards and the outcomes of discussions between the IGZ and the CGR on this are of great importance.

The substance and application of the requirements for pharmaceutical advertising aimed at healthcare professionals

In determining whether the advertising rules apply, the deciding factor is whether a communication or action can be classed as advertising for a medicine. Although the definitions differ, it is the case that the term 'pharmaceutical advertising' is very broadly described in all the legal sources. Case law shows that all actions that are intended to promote the sale of medicines – regardless of the manner in which this takes place and the medium used – are regarded as advertising. Advertising is not restricted here to information communicated about medicines; the promotion of prescription or supply of medicines by holding out the prospect of or offering advantages in money or in kind also falls within the definition of pharmaceutical advertising. For the application of the advertising rules the nature of the party from whom the advertising originates is not relevant. Case law shows that parties who do not have any direct interest in the sale of medicines are also required to comply with the rules for pharmaceutical advertising.

As a result of this it is very quickly held that the advertising rules apply and this is confirmed in the case law. The three legal source documents contain a number of key provisions that apply to all types of pharmaceutical advertising, including advertising to healthcare professionals. A comparison of these key provisions and the way they are interpreted in case law as described in Chapter 5 results in the following observations.

All the legal sources contain a clear and unambiguous prohibition on advertising medicines for which no marketing authorisation has yet been granted. Case law shows that both the IGZ and the Code Committee take a strict and consistent approach to any breaches of this prohibition identified. In this context the IGZ and the CGR seem to divide up the duties more or less automatically on the basis of the type of breach. The IGZ primarily takes action against advertising on the internet for medicines for which no marketing authorisation has been granted. This is generally advertising for products that

are classified as medicines on the basis of the presentation criterion or lifestyle-type medicines for which no marketing authorisation has been granted. The cases that the Code Committee has dealt relate more to pre-marketing activities by pharmaceutical companies, who wish to bring their product to the attention of prescribers even before the marketing authorisation has actually been granted.

The requirement that advertising must be consistent with the SmPC is set out in the same way in terms of substance and in accordance with Directive 2001/83 in both the Medicines Act and the CGR Code. It is noteworthy that the IGZ has scarcely assessed any cases in which a conflict with the SmPC played a role, whereas this ground is often raised in the CGR's cases. As a result, the case law of the Code Committee is more developed on this point than the decisions of the regulator responsible for enforcing the legislation. The Code Committee's case law follows the lines set out by the European Court, but goes into much more detail (in terms of substantive medical and scientific issues) with respect to the issue of whether a conflict with the SmPC exists.

The requirement that advertising must encourage the rational use of medicines appears in all the legal sources, although the wording differs. The difference between the legal sources in the context in which the term 'rational use' is applied is particularly liable to give rise to questions and potential differences in interpretation. However, as yet there is no case law focusing on the fundamental principles in relation to this issue.

The prohibition on misleading advertising is set out in a similar way and worded very briefly in all the legal sources. In view of the fundamental importance of this provision, it is noteworthy that this prohibition has not played any role at all in the Minister's decisions imposing fines and in the inspection reports. Apparently the IGZ has not identified any breaches in this area or they have not given cause for action. The Code Committee on the other hand has issued a significant number of decisions on misleading advertising (and alleged misleading advertising). The consistent theme in those decisions is that the average professional - the average, observant doctor/medical specialist - must not be misled. Where breaches have been identified a combination of factors generally apply: incorrect, incomplete, unsubstantiated, misleading aspects in a communication, which give a doctor an incorrect impression of any characteristic or property of a medicine. The Code Committee's case law on this issue is strict and consistent and can be said to be of a high quality, in the sense that as well as a legal analysis the appropriate substantive medical and scientific aspects relevant to practice in the professional field are taken into consideration and discussed in detail in the decisions.

Advertising prescription-only medicines to the public is prohibited. This prohibition has extremely far-reaching consequences. Given this, it would be more appropriate for the prohibition to be included in the CGR Code itself, rather than by cross-referring to the Code for Advertising to the General Public. For the application of this prohibition it is crucial to know who the 'general public' is intended to include. The Medicines Act and the CGR Code take the same approach to this. Both contain a definition of the term 'professional', which includes those persons legally authorised to prescribe and supply medicines. Advertising for prescription-only medicines is only permitted when directed to professionals, all other persons are classed as the general public. The decisions of the Minister of Health imposing fines and the case law of the Code Committee show that compliance with the prohibition on advertising prescription-only medicines to the general public is strictly enforced. Scarcely any case law is available on the other prohibition on advertising medicines containing Opium Act substances to the general public.

In addition to the key provisions described above, the legal sources contain a number of specific requirements for advertisements to healthcare professionals. Chapter 6 shows that the specific requirements in Directive 2001/83 and the Medicines Act are limited in scope and only formulated to cover the main principles, whereas the standards in the CGR Code have been fleshed out in much more detail and at greater length. This is particularly apparent in the requirements imposed in the CGR Code for supporting evidence for claims and for comparative advertising, a subject that is not mentioned at all in the legislation on pharmaceutical advertising. In this respect the CGR Code supplements both the specific requirements in the pharmaceutical legislation concerning advertisement to professionals and the general legislation on comparative advertising and in a practical sense offers much useful guidance for the parties in the field.

The study shows that the specific requirements imposed by the CGR Code for advertising communications aimed at healthcare professionals have been continually subject to change over the years, partly as a result of the significant volume of case law from the Code Committee. The general trend here is for the standards to become stricter rather than being relaxed. To keep up with the current position of self-regulation it is necessary to follow the Code Committee's decisions and advice closely. This can raise barriers impeding the accessibility of self-regulation. Self-regulation also needs to be aware of the risk of over-regulation.

In Chapter 7 the requirements for inducement are studied. The rationale behind these requirements is that in choosing medicines prescribers and suppliers of medicines must not be improperly influenced by financial incentives intended to promote sales. The idea that offering such financial incentives will have the effect of influencing behaviour is an assumption that implicitly forms the basis for all the legal sources. The restrictions on inducement apply to both parties. Although this is not recorded in all legal sources in a complete and correct manner, the case law shows that both 'offering or giving' parties and 'requesting or receiving' parties are obliged to comply with the requirements on this issue. Prescribers of medicines and pharmacists bear their own responsibility in this regard.

The Dutch legislature diverged from the system used in Directive 2001/83 by incorporating in the Medicines Act a definition of the term 'inducement' linked to a general prohibition on inducement, with only four exceptions being permitted. These exceptions are formulated restrictively and relate to gifts, remuneration for services, hospitality at meetings and gatherings and bonuses/discounts. These forms of inducement are permitted to the extent that the conditions set out in the Policy Rules on Inducement are satisfied. One of the consequences of embedding the requirements for financial incentives that promote sales in this way is that any discussion about the possibility of offering any form of advantage whether monetary or in kind other than the four exceptions listed in fact becomes impossible, partly because the case law shows that it will quickly be held that a pharmaceutical company has the manifest objective of promoting the prescription, supply, sale or use of medicines. The rigid approach taken by the Medicines Act is inconsistent with the situation in practice. Evidence of this can be found in the advice statements issued by the Code Committee. These cover projects and initiatives that on the one hand do not fit within the tightly enclosed framework of the legal exceptions to inducement but on the other hand cannot be assumed to involve undesirable influencing of prescription behaviour.

When one specifically examines the restrictions on inducement in the legislation and self-regulation, then on the basis of this study one can draw the following conclusions. The statutory requirements

concerning inducement are explicitly characterised by being open in nature. So it is no coincidence that standard development by the CGR has progressed rapidly in this area in particular. In this one observes a clear and reasonably constant interaction between self-regulation and legislation – in particular the successive versions of the Policy Rules on Inducement – and between the regulations and the case law. This has resulted in the restrictions on the various forms of inducement being extensively developed and tightened up over the years.

For example, the restrictions in the legislation and self-regulation on giving and receiving gifts have been objectively defined, in the sense that maximum amounts have been stipulated for the value of the gift. The main restrictions with respect to services being permissible, consisting of further elaboration of the requirements for the content of the service provision agreement and the permitted maximum fee and expenses allowance, have also been sufficiently detailed, are consistent with standards broadly accepted within society and now produce the desired degree of clarity in practice.

The provision of hospitality to healthcare professionals by pharmaceutical companies is only permitted if requirements with respect to the programme and location of the relevant meeting or gathering are satisfied. The costs that companies are permitted to bear are also subject to limits. These requirements have been further developed and tightened up over the years. The compulsory preventive assessment of meetings abroad shows that the Code Committee assesses the applications concerned in their entirety in detail and generally consistently and that the excesses that would previously have occurred are now a thing of the past. Further tightening up of the standards on hospitality will not lead to significant improvements from the perspective of preventing undesired influence. On the contrary, we have reached the point where it is actually necessary to guard against over-regulation.

A solution does need to be found for the discrepancy between the legislation and self-regulation on the issue of sponsorship. The CGR Code has contained requirements for general types of sponsorship since 2008. The Medicines Act does not contain any provisions on sponsorship. However, the 2007 and 2012 versions of the Policy Rules on Inducement explicitly provided that sponsorship was permissible on certain conditions. In the Policy Rules on Inducement 2014 this provision was deleted without any further explanation. The consequence of this is that sponsorship has been prohibited under the general prohibition in Article 94 of the Medicines Act from that time onwards. After all, sponsorship is not mentioned in the restrictive list of exceptions to this prohibition and the Policy Rules on Inducement no longer contain any provisions on this. The CGR Code and the Medicines Act are therefore inconsistent with one another on this issue; parties who act in accordance with the requirements of the CGR Code run the risk of an administrative fine for a breach of the Medicines Act.

Supervision of compliance with the Medicines Act and the CGR Code

Chapter 8 investigates how supervision of compliance with the legislation and self-regulation for pharmaceutical advertising in the Netherlands takes place and how cooperation between the IGZ and the CGR is structured.

This topic cannot be understood without some historical context. In the period prior to the entry into force of the Medicines Act (1994-2007) enforcement of the advertising legislation was a matter for the criminal courts. Other than during a relatively short period (1999-2002), no active compliance

supervision was carried out by government during this phase. Under the Medicines Act supervision is an administrative law matter: breaches identified by the IGZ can be punished by a fine imposed by the Minister of Health without involving the courts.

The role of self-regulation in supervising compliance was originally the subject of some debate, among politicians and in society in general. Since 2002 a dual system has applied: the CGR and the IGZ both supervise compliance with the advertising rules based on their own responsibilities, with the intensity of supervision by the IGZ being determined by the effectiveness of supervision by the CGR. The IGZ remains formally responsible for secondary regulation of the CGR. Since 2007 the IGZ and the CGR have agreed working arrangements, which include specifying an allocation of tasks within supervision. This task allocation has not changed over the years. Incidentally, the parties do not provide any public accountability regarding the implementation of these working arrangements.

Each regulator adopts its own policy. The IGZ's Advertising Compliance department is partly dependent in this area on the general approach to compliance in healthcare and the way this is implemented for example in the IGZ's long-term policy plans. Key activities mentioned in the annual plans in the period 2007-2016 are enforcement of compliance with advertising legislation (including by imposing administrative fines), research into and reporting on the level of compliance with the Medicines Act with respect to specific topic areas and supervising the self-regulation of pharmaceutical advertising.

The CGR's policy on compliance is primarily established by the board of the CGR foundation, which has a reasonably large degree of discretion in this area within the limits of the foundation's constitutional documents and the applicable law. The CGR does not disclose annual plans and only occasionally produces a structured annual report. These reports and other public CGR sources show that its main activities in the field of supervising compliance with self-regulation can be described as providing information to and promoting knowledge among parties in the field, prevention (including voluntary and mandatory requests for advice to the Code Committee) and dealing with complaints about breaches of the CGR Code.

The IGZ's powers as the regulator responsible for compliance with the Medicines Act and the Code Committee's powers in dealing with complaints and advice regarding compliance with the CGR Code differ in a number of respects. As does the range of sanctions and intervention measures available to each of the regulators.

The IGZ has investigative powers. The primary measure that can be imposed when breaches of the advertising rules are identified is the punitive sanction of an administrative fine. The standard fine amounts established in the Policy Rules on Administrative Fines are, almost without exception, in the highest category (€ 150,000) and are significantly higher than the standard fine amounts that apply for many other breaches of the Medicines Act.

In the period from 2007 to 2016, 52 decisions were issued imposing an administrative fine for breach of one or more legal requirements relating to pharmaceutical advertising (on average 5 a year). In total 73 breaches of the advertising rules were identified in these decisions. Of these, fines were ultimately imposed for 59. It is striking that a relatively small proportion of these fines related to pharmaceutical companies: only 38% of all decisions imposing fines were addressed to the

authorisation holder or manufacturer of a medicine. The majority of decisions (46%) were addressed to commercial suppliers of medicines who were neither the manufacturer nor the authorisation holder. Of the 73 breaches identified, 61 related to advertising communications (84%). 75% of these cases involved breaches of Article 84(1) of the Medicines Act (the prohibition on advertising medicines for which no marketing authorisation has been granted) and Article 85(a) of the Medicines Act (the prohibition on advertising prescription-only medicines to the general public). It is noteworthy that only 12 of the breaches identified related to the prohibition on inducements. Fines were ultimately imposed for 9 of these breaches.

As well as administrative law measures, the IGZ is authorised to impose incentive measures and corrective measures. It is difficult to establish the extent to which these measures were deployed in the period from 2007 to 2016. During this period the IGZ issued a number of reports on specific topics within pharmaceutical advertising (5). The recommendations in these reports addressed to the Minister of Health and to parties in the field were only implemented by the latter. In addition to these reports, between 2012 and 2016 inspection reports were published on the level of compliance with the legislation relating to large-scale congresses (28), advisory boards (11) and market launches of medicines (2). It can be assumed that this approach has a preventive effect; the fact that the IGZ expresses its views on specific topics in the field of pharmaceutical advertising contributes to raising awareness among parties in the field regarding the legislation, its interpretation and the importance of compliance with it.

The Code Committee does not have investigative powers and acts only in response to issues raised by other parties. It only deals with complaints due to breaches (or alleged breaches) of the CGR Code and requests for advice presented to it by parties in the field. The range of sanctions available to the Code Committee is limited, but it is effective in the sense that it includes the power to order immediate cessation of breaches and reversal of breaches (rectification) and to impose measures to prevent further breaches.

In the period from 1999 to 2016 the Code Committee dealt with 192 complaints in total (on average 10 a year). By far the majority of these were submitted by pharmaceutical companies (84%). However, other parties also found their way to the Code Committee occasionally. An overwhelming majority of the complaints dealt with by the Code Committee related to advertising communications (90%). The remaining complaints concerned inducement and inducement-related matters. So for both regulators we see that the emphasis in the cases they deal with is much more on the requirements regarding what may be communicated about medicines than on the requirements intended to prevent undesired influence on prescription and supply behaviour through financial incentives. The fact that the IGZ has investigation powers and the Code Committee does not is not reflected in the relative numbers of different types of cases they deal with.

In the period between 2003 and 2016 the Code Committee issued at least 1150 advice notes. Almost 70% involved mandatory preventive assessment of hospitality at meetings abroad. A significant majority of the other 30% also involved requests (voluntary or otherwise) for advice concerning inducement. From the perspective of compliance, gaining insight into developments and trends in practice and development of standards, the relevance of these advice notes should not be underplayed.

In a general sense, one can conclude that the IGZ and the CGR complement one another in their regulatory role. In relation to information provision and prevention, self-regulation fulfils a significant and consistent role. In supervising compliance primary responsibility lies with the Code Committee, which has demonstrated its ability to assess the requirements for advertising aimed at healthcare professionals in their entirety and in a thorough, expert and well-executed manner. The fact that the Code Committee includes members who have substantive medical expertise and are skilled in the field of medicines contributes to this. On the other hand, just as the IGZ could not do without the CGR, the CGR needs the IGZ too. The real added value of the IGZ's role lies particularly in the fact that the IGZ has investigative powers and as a result is able to gain access to information and data on its own initiative. Moreover, the IGZ's ability to impose an administrative fine on anyone guilty of a breach is an important weapon. Although in many cases the amount of the initial fine is ultimately reduced in objection and appeal proceedings, the punitive character of the administrative fine is a valuable addition to the range of sanctions available to the CGR.

Final observations

Aside from a few structural flaws, the legislation and self-regulation that has developed over the past 25 years with respect to advertising aimed at healthcare professionals can, at the end of 2016, be regarded as solid and functional. Despite the dissatisfaction often expressed in society regarding self-regulation, it must be said that the legislature's decision to give the parties in the field a role in developing standards and supervising compliance for pharmaceutical advertising has added significant value.

Looking to the future, there are two observations to be made.

The foundations and basic rules underlying the present legislative framework and the self-regulation based on it date from the early 1990s and have remained unchanged in the interim. To the extent that this legislation and self-regulation is aimed at preventing undesired influencing of prescription of medicines by financial incentives, the focus is almost entirely on the direct relationship between pharmaceutical companies as authorisation holders for medicines on the one hand and healthcare providers authorised by law to prescribe and supply medicines on the other. In view of the changes to the playing field, a strategic vision also needs to be developed concerning the desirability and permissibility of prescribing behaviour being influenced by means of incentives offered by other parties with an interest in controlling costs, such as hospitals and health insurers.

A second observation relates to the key provisions of the legislation and self-regulation: the prohibition on advertising of prescription-only medicines to the general public. This study shows that the boundary between the parties classed as general public and those classed as professionals is strictly defined and linked to legal authorisation to prescribe and supply medicinal products. In the context of supervising compliance this boundary is strictly enforced. Under the definitions of the term advertising in the legislation and self-regulation, the objective of promoting (or apparently promoting) sales determines whether advertising applies and this objective will very quickly be assumed to exist where the party making the communication is a pharmaceutical company.

A number of developments may in future make it even more difficult to sustain the very stringent interpretation of the prohibition on advertising prescription-only medicines to the general public by pharmaceutical companies. It would therefore be advisable to develop a strategic vision with regard to the requirements generally applicable for communication about prescription-only medicines and if possible to implement this vision in policy and/or rules. This strategic vision should, in addition to a prohibition on communications to the public that are actually aimed at promoting sales, lay down clear parameters for information about medicines in a general sense (regardless of the party from whom the information originates).