BRAZIL

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DISTRIBUTION

PRE-CONDITIONS FOR DISTRIBUTION

1. WHAT ARE THE LEGAL PRE-CONDITIONS FOR A DRUG TO BE DISTRIBUTED WITHIN THE JURISDICTION?

Authorisation

The distribution of medicinal products is regulated by the National Sanitary Surveillance Agency (ANVISA).

Pharmaceutical products can be marketed and distributed if the following requirements are met:

- They are registered with ANVISA.
- They are manufactured or imported by establishments duly authorised by the federal government.
- They are manufactured or imported by establishments duly licensed by the state government.

To receive approval to launch and distribute drugs on the market, the applicants must submit to ANVISA regulatory data of the potential candidate, such as details of the manufacturing process, clinical trial results, safety and efficacy data. If all data is in accordance with the requirements established by ANVISA, marketing authorisation is eventually granted, therefore formally allowing the medicinal products to enter the market.

Exceptions

Exceptions to the requirement for a marketing authorisation exist, for example, if the new drug is intended to be exclusively used in a clinical trial or if it is required to meet the prescription for a specific patient. In these cases, it can be supplied and imported in Brazil without being previously approved, if the importation is formally authorised by ANVISA.

2. DO ANY TYPES OF NAMED PATIENT AND/OR COMPASSIONATE USE PROGRAMMES OPERATE? IF SO, WHAT ARE THE REQUIREMENTS FOR PRE-LAUNCH ACCESS?

The National Sanitary Surveillance Agency's (ANVISA) RDC No. 38 of 13 August 2013 sets out several pathways through which patient access to new drugs is provided before these drugs are officially approved and available for purchase.

In the compassionate use programme, ANVISA provides authorisation, under a public welfare programme, by promising access to a new drug without agency registration for the treatment of patients with serious or rare diseases. These specific pathways comprehend the possibility of importing new, unregistered drugs, if needed.

According to ANVISA, the authorisation approval for the compassionate use is evaluated, depending on the severity of the illness. The absence of satisfactory treatment alternatives available for the patient's condition is assessed before issuing an authorisation. The patient's doctor must submit a formal request to obtain the drug from the entity funding the assistance programme and the entity places a corresponding request with ANVISA.

The entity funding the treatment provides for the complete treatment and medication at no cost for the patient under the expanded access, compassionate use or post-study programmes (*chapter VIII, section 18, RDC No. 38/2013*).

LICENSING

3. WHAT IS THE PROCEDURAL STRUCTURE REGARDING LICENSING A DRUG FOR DISTRIBUTION?

Structure

Licensing of a drug is mandatory before its widespread use.

Licences are only granted if predefined standards of safety and quality are met, covering the whole development and manufacturing process of a drug.

To be granted a licence, the drug must be developed and tested.

Regulatory authority

The health surveillance over products and services is conducted by the National Sanitary Surveillance Agency (ANVISA), which covers the supervision of processes, used ingredients and applied technologies (*Law No. 9782, 26 January 1999*).

According to Law No. 9782/1999, ANVISA is the only authority responsible for granting licences for medicinal drugs and other health-related products.

4. IS THERE A SIMPLIFIED LICENCE PROCEEDING, OR RELAXED LICENSING CONDITIONS, FOR DRUGS WHICH HAVE ALREADY BEEN LICENSED FOR DISTRIBUTION IN ANOTHER JURISDICTION?

When dealing with a drug with a foreign licence, marketing authorisation from the National Sanitary Surveillance Agency (ANVISA) is still required.

With imported drugs and active pharmaceutical ingredients, in addition to the usual registration requirements, the applicant must also show evidence proving that the product is already registered in the country of origin (*Article 18, Law No. 6360, September 23, 1976*) and further complies with the good manufacturing practices (GMP) standards in that country.

Regarding parallel imports, a product manufactured in accordance with a process or a product patent that has not been placed on the internal market directly by the patentee or with his consent can represent a violation of the patent holder's exclusive rights, therefore

allowing the patent holder to enforce its exclusive rights (*section 43, item IV, Brazilian Industrial Property Law*). Whether implicit consent can avoid the parallel importer's liability for patent infringement is always a hot topic before the courts, so all situations must be examined on a case-by-case basis and bear in mind their own particularities.

5. IS VIRTUAL DRUG DISTRIBUTION POSSIBLE FROM YOUR JURISDICTION?

The sale of drugs through the internet can only be undertaken by accessing websites from pharmacies and drugstores with fixed commercial establishments, which are open to the public.

The services provider must also provide for a direct and immediate method of communication between the patient and a pharmacist.

Drugs subject to special control (*Ordinance No. 344, 12 May 1998*) cannot be sold on the internet.

Brazil-based pharmacies can attend online orders with some restrictions. According to the law, only licensed Brazilian pharmacies can sell prescription drugs online. An internet pharmacy must post its National Sanitary Surveillance Agency's (ANVISA) authorisation number on its website. Personal importation of medicine is legal where the patient has a valid prescription and where the frequency and quantities are clearly limited in the prescription signed by the medical doctor.

6. WHAT IS THE PROCEDURE TO APPEAL (LEGAL REMEDY) A LICENSING DECISION?

It is possible to proceed with an administrative appeal from rejections on the granting of the licensing for a drug within ten days starting from the day immediately after the publication of the rejecting decision.

The appeal is filed before National Sanitary Surveillance Agency (ANVISA) and this authority does not have to provide its decision within a prescribed term.

It is not possible to appeal from the final decision, issued by ANVISA after analysis of the technical appeal.

7. WHAT ARE THE COSTS OF OBTAINING LICENSING?

There are fees to be paid to the National Sanitary Surveillance Agency (ANVISA) to obtain the marketing authorisations. These fees vary depending on the type of product and on the size of the applicant (*Annex I, Resolution No. 222, 28 December 2006*).

For example, considering a large company as the applicant, the costs can vary from R$6,000 (generic drug) to R$80,000 (new drug).

DISTRIBUTION TO CONSUMERS

8. WHAT ARE THE DIFFERENT CATEGORIES OF DRUGS FOR DISTRIBUTION?

For distribution to consumers, medicinal drugs can be classified into the following categories:

- Drugs that can only be dispensed under a medical prescription (with retention).
- Drugs that can only be dispensed under a medical prescription (without retention).

- Drugs that can be sold without a prescription, known as "non-prescription products" or "over-the-counter drugs" (OTCs), which present a remote risk of causing side effects to patients.
- Drugs exclusively used in hospitals.
- Drugs subjected to special control, where the medical prescription must be notified to the health authority.

In considering whether a drug can be sold without the need for a prescription, the National Sanitary Surveillance Agency (ANVISA) takes into account, among other issues, whether the product is likely to, if incorrectly used:

- Present a substantial risk to the patient.
- Lead to addiction.
- Be used for illegal purposes.

9. WHO IS AUTHORISED TO DISTRIBUTE PRESCRIPTION DRUGS AND OVER-THE-COUNTER DRUGS TO CONSUMERS?

Prescription drugs

Prescription drugs are sold in licensed pharmacies, under medical prescription. This licence is obtained from the National Sanitary Surveillance Agency (ANVISA).

Pharmacist technicians can perform activities that are not exclusive to pharmacists, including dispensing or selling prescription medicines (*ANVISA's Resolution No. 44, 17 August 2009*). However, the pharmacist technicians must be under direct supervision of the registered pharmacist technically responsible (or a substitute, also a pharmacist), whose presence is required during working hours of the commercial establishment. The sale of prescription medicines can only be made on the presentation of a prescription, issued by a registered physician.

Over-the-counter drugs

Over-the-counter drugs are sold freely in licensed pharmacies, drugstores and some large supermarkets, without the need of a medical prescription.

10. WHAT DRUGS CAN AN ATTENDING PHYSICIAN DISTRIBUTE AND UNDER WHAT CIRCUMSTANCES?

Physicians can distribute free samples of marketed drugs to any patient, provided that it follows the medical prescription.

11. WHO IS AUTHORISED TO PRESCRIBE PRESCRIPTION DRUGS TO CONSUMERS?

Only physicians (medical doctors), dentists (for dental use only), veterinarians (for veterinary use only) and nurses (for medicines established by public health programmes and approved by the health institution) can prescribe drugs.

12. IS DIRECT MAILING/DISTANCE SELLING OF DRUGS PERMITTED IN YOUR JURISDICTION?

Resolution No. 96/2008, dealing with advertising and promotion of drugs, does not expressly mention the possibility of using e-mails as a way to buy or sell drugs.

There are also no particular rules referring to marketing medicinal products by mail order. However, provided all requirements for the acquisition of a particular drug on the internet are met, this may be a possibility (*see Question 5*).

13. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING DISTRIBUTION ACTIVITIES?

The regulation of the sector that distributes medicines is conducted on three levels:

- The federal government.
- The state governments.
- Municipalities.

The federal government enacts laws and regulations of general applicability, which are enforced and complemented by actions of the state governments and municipalities. At the federal level, the health and pharmaceuticals sectors are regulated and supervised by the Ministry of Health, through the National Sanitary Surveillance Agency (ANVISA).

14. WHAT IS THE PROCEDURE TO APPEAL (LEGAL REMEDY) A DISTRIBUTION DECISION?

The National Sanitary Surveillance Agency (ANVISA) can suspend the distribution, sale and use of a drug if the proprietor entity does not meet the requirements of the agency. In this case, eventually, a final decision is published in the *Official Gazette* and all the remaining lots have to be collected. The company can appeal from the initial ban (notification from ANVISA) within ten or 15 days, depending on the case. If the sentence is maintained, it can be appealed at the government level within 20 days counted from the date the decision was acknowledged or from the publication. All legal deadlines are set out in Law No. 6437/1977.

15. WHAT ARE THE LEGAL CONSEQUENCES OF NON-COMPLIANCE WITH CONSUMER DISTRIBUTION LAWS?

The consequences of non-compliance with consumer distribution laws include:

- Suspension of the authorisation to distribute.
- Suspension of the product registration licence.
- Fines.
- Imprisonment.

WHOLESALE DISTRIBUTION

16. WHAT IS THE LEGAL REGIME REGARDING WHOLESALE DISTRIBUTION OF DRUGS?

Distributors of pharmaceuticals must comply with the regulations (Good Distribution Practices) and hold the appropriate licences. Such distributors must obtain a:

- Licence to operate.
- Authorisation to operate.
- Special authorisation for medicines under special control, if necessary.

It is necessary to pay to obtain these licences and to present a certificate of the technical responsibility of the responsible pharmacist. It is also necessary to undergo an inspection carried out by the local health authority. These distributors must obtain a document called "Certificate of Good Distribution Practices", which is issued by the National Sanitary Surveillance Agency (ANVISA) to operate legally. This certificate is a statement confirming that the distributor is in conformity with all the good practices established and allows the distributor to operate.

17. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING WHOLESALE DISTRIBUTION ACTIVITIES?

Regulatory authority

The distribution and promotion of medicinal products by the wholesale distributors are subject to the legal regulation of the National Sanitary Surveillance Agency (ANVISA).

Supervision

ANVISA can issue legal provisions on human health issues (*Article 24, section XII, Brazilian Constitution* and *Article 7, Law No. 9.782/1999*). These enable the ANVISA to:

- Proceed with the surveillance and regulation of medicines and medical goods.
- Supervise the corresponding entities that manufacture and distribute them.
- Provide the registration of medicinal products.

Companies that apply for permission to distribute drugs must comply with the requirements of Good Distribution Practice and Storage established by ANVISA. As per this regulation, the distributor must comply with certain procedures to control the quality and keep track of the medicinal products distributed.

Rights of appeal

The same procedure of appealing a distribution decision applies for wholesale distribution activities (*see Question 14*).

18. WHAT ARE THE LEGAL CONSEQUENCES OF NON-COMPLIANCE WITH WHOLESALE DISTRIBUTION LAWS?

The consequences of non-compliance with wholesale distribution laws include penalties such as:

- Fines.
- Suspension of the Good Distribution Practices.
- Suspension of the authorisation to operate.

MARKETING

PROMOTION

19. WHAT IS THE GENERAL LEGAL REGIME FOR THE MARKETING OF DRUGS?

Legal regime

The main applicable legal instruments for marketing, advertising and promotion of medicinal products are:

- Law No. 6360 of 23 September 1976 (amended by Law No. 13,097 of 2015) that regulates the Sanitary Surveillance and describes general rules for the advertisement of drugs, medical products and other health-related products.
- Decree No. 79074 of 5 January 1977 (amended by Decree No. 8,077 of 2013), which regulates Law No. 6360/1976 that provides further provisions concerning the advertisement of medicinal products.
- Law No. 9294 of 15 July 1996 that regulates the advertisement of drugs.
- Decree No. 2018 of 1 October 1996, which regulates Law No. 9294/1996.
- Law No. 6437 of 20 August 1977 that defines violations of the federal health law and imposes the respective sanctions.
- Resolution RDC No. 96 of 17 December 2008 (amended by RDC 023/2009) that regulates the advertising and promotional practices of prescription drugs and OTCs.
- Normative Ruling No. 5, of 20 May 2009 that provides further clarifications concerning Resolution RDC No. 96/2008.
- Resolution RDC No. 60 of 26 November 2009 that regulates free samples.
- Ordinance No. 344 of 12 May 1998 that imposes specific restrictions on the advertising or promotion of medicinal products containing substances under special control such as anorexigenic drugs, immunosuppressant drugs and others.
- Law No. 8078 of 11 September 1990 (Consumer Protection Code) (CDC) that contains general provisions for the advertisement of products in general.

Limits to marketing activities

To market medicines, the entities must have been granted the necessary authorisations by the sanitary authorities.

Besides the general prohibition on direct marketing of medical products under prescription, the legislation aims to keep the relationship between industry and healthcare professionals or medical institutions, transparent and fully documented.

Another principle regarding the promotion of medicinal products is that the advertisement of drugs cannot differ or exceed the information provided in the dossier of register submitted to the National Sanitary Surveillance Agency (ANVISA).

20. ARE THERE OTHER CODES OF CONDUCT FOR THE MARKETING OF DRUGS (FOR EXAMPLE, BY PROFESSIONAL OR INDUSTRIAL ORGANISATIONS)?

The Advertising Self-Regulation Code, enforced by the Advertising Self-Regulation Council (CONAR) and adopted in 1978 regulates ethical rules related to advertisements as well as defining rules to over-the-counter drugs (OTCs). CONAR's objective is to eliminate misleading advertisements and campaigns that may be offensive or abusive in content, or could, among other things, distort competition.

There is also the Codes of Conduct of Class Associations such as the Association of Research Based Pharmaceutical Industries (INTERFARMA).

Finally there are the Resolutions of the Federal Council of Medicine:

- 1931/2009 that is the Medical Profession Code of Ethics.
- 1939/2010 that prohibits participation of doctors in medicinal products campaigns.
- 1974/2011 that sets out the criteria for the participation of members of the medical profession in promotion and advertising.

The National Sanitary Surveillance Agency's (ANVISA) regulation on advertising drugs is not related to any self-regulatory bodies like CONAR or INTERFARMA, whose decisions are not made public. ANVISA investigates only matters that cannot be compliant with the law and its regulations but can use the decisions of any such self-regulatory body to support their decision.

MARKETING TO CONSUMERS

21. WHAT IS THE LEGAL REGIME FOR MARKETING TO CONSUMERS?

Legal regime

Generally, advertising is a non-regulated area, subject to the self-regulatory body, the Advertising Self-Regulation Council (CONAR). The limitations on advertisement to consumers are regulated by RDC No. 96/2008. Law No. 6360/1976 establishes that marketing of medicinal products is subject to authorisation by the Ministry of Health.

Products

Only over-the-counter drugs (OTCs) can be directly advertised to end consumers in all types of media (*Law No. 9294/1996*). This law limits advertising prescription drugs to healthcare professionals.

22. WHAT KINDS OF MARKETING ACTIVITIES ARE PERMITTED IN RELATION TO CONSUMERS AND THE PRODUCTS WHICH MAY BE ADVERTISED TO THEM?

Law No. 6360/1976 limits the advertising and marketing of prescribed medicines to medical professionals and prohibits such activities in relation to consumers.

To avoid self-medication and the indiscriminate use of drugs, there are several provisions regulating the advertisement of over-the-counter drugs (OTCs).

Although it is not possible to advertise prescription drugs to the public, disease awareness campaigns are allowed. However, it is prohibited to mention any medicinal product.

It is possible to issue press releases concerning prescription products in non-scientific journals. In this case, the release cannot be "advertising" in its nature.

It is also possible to describe products and research initiatives in corporate brochures or annual reports.

23. IS IT PERMITTED TO PROVIDE CONSUMERS WITH FREE SAMPLES? ARE THERE PARTICULAR RESTRICTIONS ON SPECIAL OFFERS (FOR EXAMPLE, "BUY-ONE-GET-ONE-FREE")?

Free samples can only be distributed by entities to prescribing professionals (doctors and dentists), exclusively in ambulatories, hospitals, clinics and medical offices.

The concession of discounts is not prohibited according to RDC No. 96/2008, however, the promotional material offering such discounts must abide by the regulation.

24. ARE THERE PARTICULAR RULES OF PRACTICE ON THE USE OF THE INTERNET/ SOCIAL MEDIA REGARDING DRUGS AND THEIR ADVERTISING?

RDC No. 96/2008 has some specific regulations on internet advertising.

Entities are free to convey whichever information they wish to place on their websites, the exception being advertising or promotional materials related to prescription products, which are not permitted.

Online promotion of these medicines can only be accessible to professionals qualified to prescribe or distribute medicines. This is possible by means of an electronic registration system, and a liability statement setting out the legal restrictions on access must be provided.

The National Sanitary Surveillance Agency (ANVISA) often monitors sites of pharmaceutical companies, pharmacies, distributors, clinics and so on.

25. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING MARKETING ACTIVITIES TO CONSUMERS?

Regulatory authority

The National Sanitary Surveillance Agency (ANVISA) is the authority responsible for supervising advertising or promotional violations of marketing activities related to drugs.

Supervision

The supervision of these activities is done by the ANVISA's department called the General Management of Inspection, Quality Monitoring, Control and Supervision of Raw Materials, Medicines and Products, Advertising and Publicity (GGIMP).

According to Resolution RDC No. 96/2008, ANVISA can also demand the issuance of a corrective statement.

Rights of appeal

Violators can appeal a decision of ANVISA that considered an advertisement or promotion as contravening the regulation or a decision to request the issuance of a corrective statement.

This appeal is decided by the ANVISA's board of directors and any final administrative decision can be subjected to a judicial procedure.

26. WHAT ARE THE LEGAL CONSEQUENCES OF NON-COMPLIANCE WITH CONSUMER MARKETING LAWS?

Law No. 6347/1977 establishes penalties for failing to comply with the rules governing the advertising of medicines. It is the National Sanitary Surveillance Agency's (ANVISA) responsibility to enforce these rules.

These penalties can vary from warnings to suspensions of sales, prohibition of advertising and corrective statements. They can be also accompanied by a fine, the value of which depends on whether the failure was considered by the authority as "light", "serious" or "very serious".

MARKETING TO PROFESSIONALS

27. WHAT KINDS OF MARKETING ACTIVITIES ARE PERMITTED IN RELATION TO PROFESSIONALS?

Advertisements, visits by representatives, distribution of free drug samples or other gifts and sponsoring of meetings and seminars are all permitted provided that this interaction does not influence a physician's prescription decisions inappropriately.

28. ARE THERE ANY RESTRICTIONS ON MARKETING TO PROFESSIONALS?

Marketing activities

There are some restrictions related to marketing to professionals. For example, pharmaceutical companies cannot provide professionals with off-label information using the trademark of the product.

Additionally, advertising medicinal products that are not registered by the National Sanitary Surveillance Agency (ANVISA) is not permitted. A common practice used to overcome this prohibition is to promote campaigning with medical societies on the awareness and prevention of diseases, without specifically mentioning products.

Frequency

The frequency of sales representatives' visits to medical doctors is not regulated by RDC No. 96/2008. However, health institutions can elaborate specific regulations establishing criteria for receiving sales representatives, provided that other conditions set out in RDC No. 96/2008 are respected.

Provision of hospitality

There is not a direct mention of hospitality in RDC No. 96/2008.

Any contribution, including travel expenses, meals and hospitality to support healthcare professionals' attendance at medical conferences and scientific events (national or international) is allowed. However, it is important that the relationship is clearly declared by the physician and the company, in the prospectus, brochure or leaflets of the seminar and in the application form.

The Association of Research Based Pharmaceutical Industries' (INTERFARMA) Code depicts some restrictive rules related to payments made to a professional whenever attending a scientific meeting.

29. WHAT INFORMATION IS IT LEGALLY REQUIRED TO INCLUDE IN ADVERTISING TO PROFESSIONALS?

The required information in advertising to healthcare professionals is regulated in RDC No. 96/2008. According to this resolution, the promotional material must contain the:

- Brand name of the medicine.
- Name of the active ingredient.
- Number of the register granted by the National Sanitary Surveillance Agency (ANVISA).
- Therapeutic indications, including the dosage.
- Side effects.
- Interactions and contraindications.
- Warnings and precautions.
- Proof of safety and efficacy by scientific sources.
- The date of printing.

30. ARE THERE RULES ON COMPARISONS WITH OTHER PRODUCTS THAT ARE PARTICULARLY APPLICABLE TO DRUGS?

RDC No. 096/2008 sets out the rules for comparative advertising of medicinal products. Generally, comparative advertising is regulated by different legislations, including the Code of Ethics and the Advertising Profession and the Advertising Self-Regulation Code.

Products that are not authorised by the National Sanitary Surveillance Agency (ANVISA) cannot be mentioned in advertising.

Price comparison is only allowed between interchangeable products. If the products are not interchangeable, the price comparison can only be made to professionals, under specific conditions.

31. WHAT OTHER ITEMS, FUNDING OR SERVICES ARE PERMITTED TO BE PROVIDED TO PROFESSIONALS?

Discounts

No incentives to prescribing professionals can be (or be understood as) an exchange for assuring the prescriptions of a particular product.

Free samples

The restrictions for free samples are regulated in RDC No. 60/2009.

It is possible to provide professionals with sample of products, except for:

- Non-prescription products.
- Biological products.
- Products prepared in compounding pharmacies.

They can be distributed only in ambulatories, hospitals, medical and dentist's offices. The prescribing professional must sign a document indicating the receipt of the samples.

Generally, the amount offered in a free sample package must be 50% of the original and must clearly include the term "free sample".

Sponsorship of professionals

The scientist or physician must report to the conference organisation if they received financial support.

If a pharmaceutical company sponsors scientific events, this support must be made clear in all materials of communication.

RDC No. 096/2008 prohibits linking sponsorship of events (medical or health congresses, symposia, conferences and meetings) within assurance in prescribing or dispensing a medicine.

Other items, funding or services

The advertisement and indirect sale or the granting, offer, promise or distribution of promotional gifts, benefits and advantages to professionals are prohibited.

Only institutional gifts that are not related to any specific product can be given to professionals.

32. WHAT REGULATORY AUTHORITY IS RESPONSIBLE FOR SUPERVISING MARKETING ACTIVITIES REGARDING PROFESSIONALS?

Regulatory authority

The National Sanitary Surveillance Agency (ANVISA) is the authority responsible for supervising advertising and deciding on possible violations conducted on marketing activities related to drugs.

Supervision

The supervision of these activities is done by ANVISA, as it is in marketing to consumers (*see Question 25*).

Rights of appeal

The rights of appeal are the same ones related to marketing to consumers (*see Question 25*).

33. WHAT ARE THE LEGAL CONSEQUENCES IN CASE OF NON-COMPLIANCE WITH PROFESSIONAL MARKETING LAWS?

The consequences are the same of non-compliance with consumers marketing laws (*see Question 26*).

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. WHAT KINDS OF ACTIVITIES ARE PERMITTED IN RELATION TO ENGAGEMENT WITH PATIENT ORGANISATIONS? WHAT ARE THE RESTRICTIONS THAT ARE IMPOSED ON RELATIONSHIP WITH PATIENT ORGANISATIONS?

Generally, meetings with, and funding of, patient organisations are permitted and no specific requirements must be observed. Health authorities have been looking very closely at this issue.

RDC No. 096/2008 determines that the organisers of scientific events in which advertising and promotion of medicinal products are allowed must report to the National Sanitary Surveillance Agency (ANVISA) three months in advance of any such event indicating the date and place of the event and the professional categories that will participate in the event.

REFORM

35. ARE THERE ANY PLANS TO REFORM THE LAW ON THE DISTRIBUTION AND PROMOTION OF DRUGS IN YOUR JURISDICTION?

With regard to advertisement and distribution of drugs in Brazil, no changes in the regulation are expected for 2015, however, a review of RDC No. 096/2008 is scheduled to occur.