



The Association of Research-Based Medical Technologies Manufacturers

GUIDE TO COMPLIANCE WITH COMPETITION LAW

This Guide has been prepared in accordance with applicable legislation, particularly Law No. 4054 on the Protection of Competition, to define the rules and responsibilities that ARTED members must observe, in line with competition law principles, in their activities under the auspices of ARTED and in their relations with one another. Particular care has therefore been taken to ensure that the ARTED Guide to Compliance with Competition Law is consistent with applicable legislation and the guidelines of other institutions and associations of which ARTED is a member. However, if any provision of this Guide conflicts, or subsequently comes into conflict, with applicable legislation, the relevant legislative provisions shall apply. Members may include more restrictive provisions in their internal procedures without contravening ARTED's principles, provided that those provisions do not conflict with this Guide.

GUIDE TO COMPLIANCE WITH COMPETITION LAW

ARTED – The Association of Research-Based Medical Technologies Manufacturers

I. INTRODUCTION

The Association of Research-Based Medical Technologies Manufacturers (ARTED) represents its member organisations (collectively, “members” and individually, a “member”) that develop, manufacture and market medical products, technologies, related services and therapies (“Medical Technology”) used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities, enabling patients to lead long and healthy lives.

ARTED is committed to devoting all its resources to advancing medical science, improving services for patients and, in particular, contributing to the development of high-quality, innovative medical technology to achieve these goals. To this end, ARTED maintains effective communication with institutions and civil society organisations and plays an active role in the sector through working groups comprising representatives of member companies. The effective application of competition law provisions in force, particularly Law No. 4054 on the Protection of Competition, is a fundamental requirement in ARTED’s internal and external communications and in activities carried out among its members.

II. PURPOSE OF THE ARTED GUIDE TO COMPLIANCE WITH COMPETITION LAW

ARTED pursues its objectives through its bodies and working groups, which are formed with the participation of its members and cover important areas of the healthcare sector. ARTED and its member companies, as legal entities, and member representatives, as individuals, are responsible for activities and meetings conducted within ARTED.

ARTED member companies may be considered competing undertakings in certain markets. Compliance with competition law provisions is therefore of great importance in their joint activities under the auspices of ARTED.

This Guide sets out the conduct that ARTED members must observe under competition legislation in relation to association meetings and activities conducted under the auspices of the association, particularly communications among members. Its purpose is to prevent conduct in ARTED-related activities that may have the object and/or effect of infringing competition law, as well as any situation that could create such an impression, even through misperception, and to ensure that members embrace competition rules and principles through ARTED’s responsible actions in the sector.

ARTED also recommends and expects, as a matter of principle, that its members conduct their activities in compliance with competition law provisions in force, particularly Law No. 4054 on the Protection of Competition.

ARTED's memberships in international associations and civil society organisations[1] also require compliance with relevant international standards. The provisions of this Guide have been prepared in light of applicable competition legislation and those international standards.

III. COMPETITION RULES AND FUNDAMENTAL PRINCIPLES

ARTED members are required to comply with all applicable competition legislation, particularly Law No. 4054 on the Protection of Competition. Members must retain their status as independent undertakings, make their economic decisions independently and be able to demonstrate that they have done so.

Competition legislation establishes two fundamental prohibitions applicable to all undertakings and associations of undertakings. Infringements may give rise to civil, criminal and/or administrative sanctions. Accordingly:

- 1) Agreements, decisions or concerted practices that prevent competition between two or more undertakings or within associations of undertakings are prohibited.
- 2) The abuse of a dominant position, held individually or jointly, is prohibited.

The following guiding rules and principles have been established for ARTED members to ensure full compliance with these fundamental principles and prohibitions.

III.1. General Rules on Agreements and Practices That Prevent Competition

The following are, as a general rule, considered examples of agreements, decisions and concerted practices between competing undertakings that prevent, distort or restrict competition and are prohibited. ARTED members must strictly refrain from such conduct:

- **Joint Determination of Prices and Other Commercial Terms:** The determination, through joint decisions between competing undertakings, of prices, terms of sale and any other commercial conditions, including, but not limited to, factors that determine prices, such as costs, discounts, price increases, accounting procedures or profit margins.
- **Market Sharing:** Any form of market sharing or control between competitors, including the allocation of customer groups or territories; the exchange of pricing information before or during tenders; or bid rigging through an agreement among competing undertakings to submit high bids in order to raise prices.
- **Production Restrictions:** Any restrictions on production, including agreements on investment rates or production quotas, and the control of quantities supplied or demanded.
- **Information Exchange:** The sharing of commercially sensitive information capable of eliminating uncertainty about the future and creating transparency, including information on pricing, production and sales plans, customer relations, and ongoing or planned tenders.

[1] ARTED is a member of MedTech Europe.

- Other: Collective boycotts; joint negotiations, joint purchasing or joint selling, except where confirmed as lawful following legal advice; any arrangement intended to avoid direct competition; resale price maintenance; and any agreement restricting competition, including pricing policies designed to exclude competitors or new entrants from the market.

An agreement or decision need not be in writing or binding to constitute an infringement of competition law. Oral exchanges or informal agreements, even “gentlemen’s agreements”, may constitute infringements. Furthermore, the matters agreed upon need not be implemented to constitute a competition law infringement; their potential to restrict competition is sufficient.

III.2. Competition Law Training

Employees designated by ARTED members as their representatives at association meetings are required to act in compliance with applicable competition legislation and the principles of this Guide in their activities within the association.

ARTED may organise competition law training, as needed, to provide information on applicable legislation and this Guide. The following requirements shall be observed in organising such training:

- Each January, the ARTED Ethics Working Group shall assess whether competition law training is needed. Following this assessment, specialist lawyers shall be engaged to support the relevant training. A training schedule shall be established and announced to members by the Chair of the ARTED Ethics Working Group. If additional competition law training is needed during the year, the Ethics Working Group shall assess that need and, where considered necessary and appropriate, add the training to the schedule and announce it.
- Member representatives’ attendance shall be documented during the training.
- At the end of the training, participating member representatives shall be assessed by the trainers.
- Following the training, attendance sheets, assessment forms, training materials and all similar documents shall be retained at the ARTED office. Training may be delivered in person, online or by other means.

- Working Group Chairs and Vice-Chairs elected each January must have received training on competition rules either through ARTED or within their own companies.
- A member representative who has not received competition law training may not attend association meetings or join email groups. Following publication of this Guide, member representatives who have not received such training shall complete the necessary competition law training within six months at the latest.

III.3. Rules on Communications Between ARTED Members

Under Law No. 4054 on the Protection of Competition, competing undertakings are prohibited from exchanging information that reduces or eliminates market uncertainty, may affect undertakings' independent decisions and, as a result, may produce or does produce non-competitive outcomes.

As ARTED is an association of undertakings, its activities may bring together representatives of undertakings that are competitors in certain markets. Member representatives and ARTED administrative staff must therefore ensure that communications during such activities comply with competition law provisions. Members must not, under any circumstances, exchange confidential or commercially sensitive information, whether in formal activities or meetings conducted under the auspices of the association or in informal discussions. ARTED must not be regarded or used as a forum for discussing commercially sensitive matters. All written or oral communications, including electronic communications, shall be assessed within the framework of these rules.

The exchange of information between members on the following matters, among others, is prohibited:

- Prices, discounts or contractual terms relating to prices. This prohibition covers planned or implemented price increases, whether or not a specific rate of increase is stated; dates of announcements of price increases; price rises; discounts; credit terms; promotions; and any other information that may affect prices, such as costs, production levels, capacity, inventories or sales volumes. Pricing and reimbursement policies implemented by public authorities, and communications aimed at improving such policies for the benefit of the sector as a whole, fall outside this prohibition. However, where the relevant working group sponsor, working group chair and/or Secretary General considers it necessary, such communications shall be conducted with legal support from lawyers.
- Customer relations and customer credit risks, including customers' identities or sales territories.
- Tenders, bids submitted or planned in ongoing tender procedures, and commercial procedures established for participation in such tenders.
- Business plans, commercial strategies and forecasts concerning market development, or plans for product authorisation.

- Competitive advantages and disadvantages in specific areas.
- Production plans or output levels, including inventory and backlog information.
- Individualised data on production volumes, sales or capacity. In particular, such data must not be shared with specific competitors, for example, the top three manufacturers in a particular sector segment in the previous quarter.
- Product development projects or investments within research programmes that have not yet been publicly disclosed.
- Individualised market share data.[2]

The following precautions shall be observed in communications between ARTED members:

- Due regard shall be given to the matters identified above that must not be discussed or communicated.
- Care shall be taken with the language and wording used when recording decisions made at ARTED meetings, or comments and explanations concerning those decisions. Language that goes beyond the intended purpose or is excessively emotional shall be avoided.
- Clear and unambiguous language shall be used. Statements that go beyond their intended purpose and may create unintended perceptions shall be avoided.
- The persons and/or organisations to whom information or documents are sent shall be considered when determining whether they may be shared.
- If any doubt or concern arises about the compliance of any ARTED correspondence or ARTED working group correspondence with competition rules, legal assistance shall be obtained where deemed necessary, in accordance with the decision of the ARTED Secretary General and Board of Directors.

III.4. Rules on Meetings Conducted Within ARTED

Although meetings conducted within ARTED are generally subject to the rules on communications between ARTED members, they have also been considered separately, and the following specific standards and procedures have been established.

III.4.1. Actions Required Before Meetings

- An agenda shall be prepared in advance for every meeting.
- The meeting agenda shall be shared with the member company representatives on the participant list, the working group chair, the working group sponsor and the ARTED Secretary General sufficiently in advance to allow adequate time for amendments proposed by members before the meeting. Where the working group chair or sponsor and the ARTED Secretary General consider it necessary, the agenda shall also be shared with ARTED's lawyers. If the agenda is amended, the revised agenda shall be recirculated in accordance with this provision no later than two (2) business days before the meeting. If no objection is received within two (2) business days after circulation, the meeting agenda shall be deemed final.
- Except in exceptional circumstances, each participant shall have an administrative or technical connection with the meeting agenda.

[2] For the rules on obtaining consolidated market share information, see Section III.4.

III.4.2. Actions Required During Meetings

- Every meeting shall have a person responsible for coordinating the meeting and guiding discussion of the agenda.
- If any objection or concern arises regarding the agenda, the ARTED Secretary General, the relevant Working Group Sponsor or the Board of Directors may, following the necessary assessment, decide to obtain appropriate legal assistance, including, but not limited to, arranging for ARTED's lawyers to attend the meeting.
- A reminder stating that participants representing ARTED members have read and accepted this Guide and will comply with its rules throughout the meeting shall be included at the top of all meeting minutes and attendance sheets.
- An attendance sheet shall be prepared for each meeting, recording participants' names, companies, times of arrival and departure, and signatures.
- The fundamental rule is to adhere to the predetermined agenda. During a meeting, a new agenda item may be proposed only where urgent and important circumstances require its inclusion.
- Any member or members who consider a matter being discussed, whether or not it is on the agenda, to be contrary to competition rules or this Guide shall raise their concern with the person responsible for the meeting. That person shall address the concern, and, if necessary, discussion of the matter shall be deferred for assessment by specialist lawyers. If the situation identified by members as contrary to competition rules is not remedied, members may leave the meeting after stating their reservation. This shall be recorded in the meeting minutes.
- Members who leave a meeting early for any reason may request that their reservations concerning a matter discussed after their departure be recorded in the minutes.^[3] In such cases, the minutes shall be updated to reflect the reservations submitted by members, and the final version shall be circulated to the relevant parties.

[3] For entering a reservation in meeting minutes circulated to members after the meeting, see Section III.3.4.

III.3.3. Actions Strictly Prohibited During Meetings

- Members must not exchange information on commercially sensitive matters in these activities or meetings. The matters specified in Section III.2 must not be included in the agenda or scope of, or discussed at, any meeting.
- The following are examples of matters on which members must not, under any circumstances, reach a joint decision:
 - Determining product prices.
 - Establishing any production quota or imposing any restriction on production.
 - Refraining from selling products to any supplier, distributor or other third party, or taking any other action that may affect trade with such persons.
- Any action that would prevent member companies, as independent commercial undertakings, from making their economic decisions freely shall be avoided.

III.4.4. Actions Required After Meetings

- A meeting attendance sheet recording participants' names, companies and positions, and meeting minutes containing the meeting notes, shall be prepared. The minutes shall be sent to the ARTED Secretary General, meeting participants and, where the ARTED Secretary General considers it necessary, ARTED's lawyers.
- Meeting participants are required to maintain the confidentiality of matters discussed at the meeting. Accordingly, care shall be taken to ensure that participants share matters discussed and information exchanged at meetings within their own companies only with authorised persons concerned with the subject. Unless otherwise specified by ARTED, matters discussed and information exchanged at meetings shall not be shared, directly or indirectly and in any manner, with third parties outside ARTED's membership.

III.5. Collection of Commercial Data by ARTED

Within the scope of its activities and objectives, ARTED may collect data, with the approval of its Board of Directors, to compile objective information about its sector. For data collection activities conducted within ARTED, an independent and impartial service provider may be engaged pursuant to a decision of the Board of Directors, and legal assistance may also be obtained before the activity begins. Data collection for any purpose may be carried out by the ARTED Secretary General, specialist lawyers or independent and impartial authorised persons or organisations (an "impartial person or organisation") only under the following conditions:

- The data to be shared must not include current price information, meaning price information from the preceding six months or a more recent period.
- Where considered necessary or required, an exemption notification shall be submitted to the Competition Authority before data collection. In such cases, the Competition Authority's exemption decision must be awaited before the data are collected, and action must be taken in accordance with that decision.
- The impartial person or organisation collecting the data must undertake to compile and share the collected data with members in consolidated form, preserving confidentiality and the anonymity of members.
- The impartial person or organisation collecting the data must undertake to destroy the individual data collected within a reasonable period. Before each data collection activity, the ARTED Board of Directors shall separately determine the reasonable retention period for the individual data collected in that activity.
- Only consolidated data shall be shared with members, public authorities and third parties. All commercial information shall be recorded only in anonymous form.
- The information of any individual member must not be identifiable from the compiled data. Unconsolidated data must not be shared with any member or third party.
- Data shall be collected on a voluntary basis. ARTED members may not be compelled to provide data.
- The final consolidated data shall identify the ARTED members that participated in the data collection activity. Consolidated data resulting from the activity shall not be shared with ARTED members that did not provide their data. Consolidated data publicly disclosed by ARTED in any manner pursuant to a unanimous decision of the ARTED Board of Directors shall be excluded from this restriction.
- With the unanimous agreement of the members participating in the data collection process, ARTED may also include other sector participants in the process on a voluntary basis and without restrictions on participation.
- The consolidated results of data collection may be considered or discussed within ARTED or among members only in accordance with the anonymity and confidentiality principles set out above. Where the ARTED Secretary General and Board of Directors consider it necessary, legal assistance shall be obtained at meetings or discussions in which these results are considered.

IV. On-Site Inspections

In performing its duties under the Law on the Protection of Competition, the Competition Board may conduct inspections at undertakings and associations of undertakings where it considers such inspections necessary. As part of an on-site inspection, experts working under the Competition Board may arrive at the ARTED office without prior notice and examine all files and data held there. Accordingly, in the event of an on-site inspection, the provisions of the attached On-Site Inspection Procedure shall be followed (Annex 1: On-Site Inspection Procedure).

V. Actions to Be Taken in the Event of a Breach of This Guide

In the event of non-compliance with the rules and procedures set out in this Guide:

- If any breach of the rules and procedures set out in this Guide is suspected, the Secretary General shall be informed first.
- The Secretary General shall report the matter to the Board of Directors.
- If there is uncertainty as to whether a breach has occurred, a legal opinion shall be obtained pursuant to a decision of the Secretary General and the Board of Directors.
- Following an investigation, if the Board of Directors determines by resolution that a breach has occurred, the Secretary General shall, on the Board's instructions, immediately initiate the measures necessary to bring it to an end. The Secretary General shall take all necessary steps pursuant to a decision of the Board of Directors and with the support of legal advice, including, but not limited to, notifying the Competition Authority where required under applicable legislation.