Membership Kit

European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

COCIR
Advancing Healthcare

Contents

Who we are

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007.

COCIR represents corporate members and more than 10 national trade associations, together constituting more than 2000 companies.

VISION

Personalised and sustainable care that benefits patients, health professionals and healthcare systems.

MISSION

Our industry delivers innovative, data-driven, safe and efficient diagnostic imaging, radiotherapy and digital health solutions.

Our objectives are as follows:

- To support the transformation of European health systems, enabling better health outcomes and better experiences for patients and professionals.
- To promote the critical role of our industry as providers of essential or life-saving products and solutions for patients.
- To strive for the best innovation climate for our industry in Europe.

What our Members do

MEDICAL IMAGING

X-RAY

X-rays are the oldest and most widely used medical imaging technique. X-rays were discovered in 1895 and first used to visualise human tissue in 1896. They rely on ionising radiation to send beams through the body; depending on the density of the tissue, the x-rays are absorbed at different rates thus producing images of a person's internal structure.

X-ray radiation can generate three types of medical image; conventional X-ray imaging, angiography and fluoroscopy.

Conventional X-ray imaging generates an image of a localised part of the body, allowing it to be analysed for anatomical abnormalities. This kind of imaging usually evaluates:

- The skeletal system
- The oral cavity (bone and teeth)
- Any ingested objects
- The lungs
- The breasts (mammography)
- The digestive system.

Angiography uses x-rays in combination with a contrast agent (chemical compounds used to enhance specific structures in images) to visualise blood vessels, particularly the coronary arteries.

Fluoroscopy uses x-rays to visualise the internal structure in real-time, providing moving images of the interior of parts of the body, such as hearts when beating or throats when swallowing.

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1

MEDICAL IMAGING

COMPUTED TOMOGRAPHY (CT)

The first Computed Tomography (CT) scanner for medical use dates from 1972. Since its introduction, CT has revolutionised medicine, improved patient outcomes for millions of people, and is recognised as an invaluable asset in diagnostics and clinical decision-making. In recent years, Artificial Intelligence (AI) has enhanced even further the diagnostic accuracy and efficiency of CT and other imaging modalities.

The value of CT lies in its ability to provide detailed cross-sectional images of the body, capturing high-resolution, three-dimensional images of internal structures. From identifying subtle abnormalities in organs to detecting fractures or evaluating blood flow, CT scans serve as a powerful tool across various medical disciplines, allowing for unparalleled diagnostic accuracy.

Beyond diagnostics, CT plays a pivotal role in guiding medical interventions. The real-time imaging provided by CT scans assists surgeons and interventional radiologists in navigating complex anatomical structures during procedures. Whether it's guiding a minimally invasive surgery, facilitating a biopsy, or aiding in the placement of medical devices, CT ensures precision, minimises invasiveness, and enhances the safety of medical interventions.

MAGNETIC RESONANCE IMAGING (MRI)

Magnetic Resonance Imaging (MRI) is a technology that uses radio waves and a magnetic field to provide detailed images of organs and tissues. The first magnetic resonance image was taken in 1973, and the first MRI scanner for medical imaging was developed in 1977.

The type of radiation in this kind of imaging technique generates images of soft tissues rather than the skeleton. This ability has proven highly effective in helping diagnose a number of conditions, by showing the difference between normal and diseased tissues. MRI is often used to evaluate:

- Blood vessels
- Breasts
- Major organs.

1 MEDICAL IMAGING

ULTRASOUND

Diagnostic ultrasound, also known as medical sonography or ultrasonography, uses high-frequency sound waves to create images of the inside of the body. The ultrasound machine sends sound waves into the body and is able to convert the waves that echo back into a picture. The first image created with this technique was published in 1952.

MOLECULAR IMAGING-PET (MI-PET)

Molecular imaging is a diagnostic tool that allows metabolic processes to be visualised by administering small amounts of radioactive pharmaceuticals to patients. These accumulate in a specific part of the body in a controlled fashion.

Unlike other ionising radiation techniques, which can only generate anatomical images, this technique generates functional images. Some conditions initially have a physiological effect rather than an anatomical change in the body. Molecular imaging allows for an earlier diagnosis.

Combining molecular imaging with CT or MRI images can provide clinicians with superior images. Nuclear Medicine Europe (ex AIPES) has developed a comprehensive tool on nuclear medicine.

DIGITAL HEALTH

Digital Health Solutions refer to a wide range of technologies and applications aimed at supporting the delivery of healthcare - both stand-alone and integrated into medical devices and diagnostics. Examples of DHS include telemedicine, mobile health applications, health data analytics and digital therapeutics, or even electronic health records. DHS can support web-based consultations with health professionals, remote patient monitoring, real-time updating of algorithms based on patient data, or even the delivery of health interventions.

2

- Electronic health (eHealth)
- Big data
- Genomics
- Artificial intelligence
- Telehealth
- Telemedicine
- Mobile health (mHealth)

IMAGE GUIDED THERAPY

RADIATION THERAPY (RT)

A combination of four major treatment modalities – surgery, radiotherapy, immunotherapy and chemotherapy – may be used to create a comprehensive, customised treatment plan for a cancer patient, of which radiotherapy is an integral component. The International Atomic Energy Agency (IAEA) estimates that radiotherapy should be used to treat more than 55% of all patients diagnosed with cancer. This percentage may in fact be much higher in low-income countries – as many as 70-80% of all cancer patients in LMICs may require radiotherapy as part of their treatment.

From a clinical perspective, advances in radiotherapy have dramatically changed the delivery of cancer care. In an era of personalised medicine, radiotherapy beams may be shaped and modulated to conform to the shape of tumors.

Radiotherapy thereby offers the means to optimise the delivery of a prescribed dose to the tumor, potentially sparing more normal tissues. This advanced treatment tool may thus enable clinicians to treat in a curative manner when treating early stage primary tumors, cure localised disease and to palliate and minimise symptoms of incurable cancers.

From an economic perspective, radiotherapy can be highly cost-effective for both curative and palliative cancer therapy. One radiotherapy machine can treat tens of thousands of patients over an average ten-year life span. A recent Lancet Oncology Commission study demonstrates that building radiotherapy capacity in low- and middle-income countries could lead to the saving of 26.9 million life years and produce the benefit of US$278.1 billion over the next 20 years.

Radiation Therapy has evolved to be one of the essential therapies for cancer treatment. It uses photons from X-rays to impact the tumour and destroy its genetic material thus preventing its further growth.

- **External beam therapy**
- **Particle therapy**
- **Brachytherapy**

3

ROBOTIC SURGERY

“

We have, in COCIR, some of the best software minds in the European market in terms of medical devices. So it has been amazing to hear their view and also to be able to advocate.”

Quote from Members Survey 2022

Membership benefits

Being represented by a single and global voice for your industry sector.

Participating in committees and working groups with in-depth expertise on a broad range of relevant topics.

Engaging with high-level decision makers on policy matters.

“

I think they are reactive to what is going on and they are trying to push the position of the industry.”

Quote from Members Survey 2022

COMMITTEES & WORKING GROUPS (WGs)

INNOVATION & DIGITALISATION

- Research, Innovation & Funding Committee
- Innovative Health Initiative WG
- Digital Health Committee
- Data & Artificial Intelligence WG
- Security & Interoperability WG

ADVOCACY & OUTREACH

- Strategic Advisory Group

MARKET TRANSPARENCY

- Imaging Committee
- Imaging IT WG

REGULATORY & SUSTAINABILITY

- Technical Regulatory Affairs Committee
- European Affairs WG
- Trade Affairs WG
- Radiation Protection WG
- Expert groups on demand
- Sustainability Committee
- Environmental WG
- EcoDesign WG
- Expert groups on demand

INTERNATIONAL AFFAIRS

- Standardisation Policy WG
- AI Standardisation WG
- Crisis Preparedness WG
- 11 DITTA WGs

LEGAL AFFAIRS

- Code of Conduct Committee

Photo from Kevin Charit / Unsplash

“

I can rely on COCIR. I know if there is something important they will inform us.”

Quote from Members Survey 2022

KEY TOPICS

INNOVATION & DIGITALISATION

INNOVATION

- Innovative Health Initiative
- EU funding development, including Multiannual Financial Framework, ReactEU, NextGenEU, EU4Health,
- Cohesion and Structural funds, Digital Europe, Horizon Europe, Cancer Mission and IPCEI

DIGITAL HEALTH

- Artificial Intelligence (AI) ACT, AI Liability, European Health Data Space (EHDS), Data Act, General Data Protection Regulation (GDPR), Data Governance Act
- Cyber resilience, Interoperability in EHDS and in AI Act
- IHE Europe representation

MARKET INTELLIGENCE

- Quarterly reporting of Orders/ Bookings and Sales/ Billings for Imaging and Imaging IT product modalities

INTERNATIONAL AFFAIRS

STANDARDISATION

- CEN/CENELEC JTC 21, ISO/IEC JTC 1 /SC 42
- IEC TC 62, CENELEC TC 62, ISO TC 215, ISO TC 210

CRISIS PREPAREDNESS WG

- EMA and HERA activities

DITTA

- DITTA is the global diagnostic imaging, healthcare ICT, and radiation therapy trade association. www.globalditta.org

REGULATORY & SUSTAINABILITY

TECHNICAL AND REGULATORY

- Medical Devices Regulation (MDR)
- Trade barriers in third countries
- New European Economic Security Strategy/ Industrial Policy
- EU legislation on radiation protection
- Basic safety standards (BSS) Directive
- SAMIRA Action Plan and related studies and implementation
- Quality control and Quality Assessment protocols

SUSTAINABILITY

- EU Green Deal
- Circular Economy (Ecodesign, WEEE, Waste) and refurbishment
- EU Chemical Policy and Strategy on the use of substances of concern (REACH, RoHS, POP, Batteries, Packaging etc.)
- Green Public Procurement and Green Preferable Purchasing Policies
- Product environmental related International Legislation and transboundary movements of used MDs and waste (Basel Convention).

LEGAL AFFAIRS

- COCIR Code of Conduct
- EU, national legislation, and case law impacting interactions between the medical device industry, the Healthcare IT industry and healthcare professionals.
- Legislation impacting compliance aspects (e. g. whistleblower directive and national legislation transposing it).

MEMBERSHIP REQUIREMENTS

Active members and associate members may be national trade associations of manufacturers which develop and produce in

- the radiological, radiotherapy, electromedical and healthcare information technology industries and related sectors established in the European Union, the EFTA, the United Kingdom of Great Britain and Northern Ireland and Turkey; or
- companies which develop and produce in the radiological, radiotherapy, electromedical and healthcare information technology industries and related sectors

    a. whose registered office is established in the European Union, the EFTA, the United Kingdom of Great Britain and Northern Ireland, Turkey; and

    b. which are members of the national trade associations involved in the radiological, radiotherapy, electromedical or healthcare information technology and related sectors of at least one country of any of the following areas which are the European Union, the EFTA, the United Kingdom of Great-Britain and Northern Ireland, Turkey.

HOW TO JOIN

Contact info@cocir.org with a brief description of your Company and stating your turnover.

Our Membership Fees are based on:

- **Companies**. Turnover in products within the scope of COCIR in Europe for the preceding year
- **National Trade Associations** - based on the size of national market for products in the scope of COCIR for the preceding year
- **Associate Membership**
  - **a.** A fixed amount per Committee, or
  - **b.** For SMEs interested in joining the IHI working group only, and participating in an IHI project

All Membership applications are submitted to the COCIR Board for review and approval.

MEMBERSHIP CATEGORIES

COMPANIES	
Category	**European Turnover / year (€)**
1	< 2,5 million
2	< 5 million
3	< 10 million
3,5	< 40 million
4	< 70 million
4,1	< 90 million
4,5	< 160 million
5	< 250 million
6	> 250 million

NATIONAL TRADE ASSOCIATIONS	
Category	**National Market (€)**
A	< 37,5 million
B	< 75 million
C	< 150 million
D	> 150 million

“

What sets COCIR apart is the extensive expertise coming from members. I always felt that COCIR had a bit more credibility.”

Quote from Members Survey 2022

Priority actions on healthcare 24-29

Here we offer five core recommendations to European policy- and decision-makers to make these common objectives a reality.

1

KEEP THE EUROPEAN UNION (EU) ATTRACTIVE TO INNOVATION

Medical technology companies operate in a very dynamic sector. They contribute significantly to the EU's GDP and create highly skilled jobs, know-how and attractive innovation eco-systems across the EU. Our products underpin the functioning of healthcare systems and enable broad access to diagnosis and care.

EU R&D financing through the Horizon programmes and the **Innovative Health Initiative** (IHI) is critical and needs to be expanded. The EU Multiannual Financial Framework (MFF) should include a dedicated and integrated roadmap for funding the resilience, sustainability, and health innovation of healthcare systems. Healthcare infrastructure investments via the EU Recovery and Resilience Facility (RRF) and the EU Structural and Cohesion Funds should be enhanced. The RRF and the Cohesion Policy are essential mechanisms for steadily reducing health inequalities across the EU.

SUPPORT A FIT-FOR-PURPOSE LEGAL AND POLICY ENVIRONMENT

We ask the European institutions to critically assess the shortcomings of the **Medical Device Regulation (MDR)**, with a particular focus on the digital transformation and the green transition. Collaboration with the industry to ensure proper implementation is key. Our shared goal is a harmonised and effective framework that ensures patient safety and access to medical devices, prevents shortages, fosters innovation, and maintains a robust medical device industry in Europe. A strong internal market should ensure a sufficient level of harmonisation across EU Member States and avoid any market fragmentation.

To achieve a successful **digital transformation**, the **AI Act** should be implemented in coordination with the MDR, avoiding duplication of administrative procedures and removing unnecessary administrative burden and red tape.

European healthcare systems should effectively implement national data spaces and embrace the opportunities provided by the European Health Data Space, whose implementation should be supported by an **EU roadmap for digitalisation of healthcare**, while encouraging the effective and secure use of cloud services. The review of the General Data Protection Regulation (GDPR) should achieve a better harmonisation of data protection and privacy.

The European Union must ensure a legal framework that promotes growth and competitiveness and fosters research and development of new medical technologies that can enable the **green transition** of health systems while at the same time improving access to better healthcare for patients. Such a transition must support the ecosystem in which medical devices are developed. It should not be limited solely to Europe but should aim to be global, fostering sustainable trade by systematically including provisions in each of the sustainability chapters of trade agreements to incentivise green innovation.

2

RECOGNISE THE MEDICAL TECHNOLOGY SECTOR AS CRITICAL FOR HEALTHY POPULATIONS

Our industry needs continuity of supply chains and priority access to raw materials and components. In times of crisis, supply should be prioritised to produce medical devices as an essential sector. We also need to establish innovation procurement to address the broad disparities in equipment density amongst European countries. Strategic stockpiling of medical equipment at EU level should be established so that it can be quickly activated in response to health emergencies and other crisis situations.

3

SUPPORT THE COMPETITIVENESS OF THE MEDICAL TECHNOLOGY SECTOR

Our industry develops high-tech medical devices and healthcare services for a global market and needs support in achieving global regulatory convergence and in removing trade barriers. The European institutions should abolish tariffs for medical products on a permanent basis, ensure open supply chains, and address market barriers in third countries.

4

Harmonised international standards are an essential tool for global convergence and global market access for European companies. Mutual Recognition Agreements with relevant jurisdictions help improve patients' access to safe and effective medical devices, while reducing the burden on companies to demonstrate compliance with legislation.

5

LEAD ACTION AGAINST NONCOMMUNICABLE DISEASES

Europe needs to strive to achieve the target of Sustainable Development Goal 3.4 on noncommunicable diseases, to reduce premature mortality by one third through prevention and treatment.

Cardiovascular diseases are the leading cause of death globally. An estimated 17.9 million people died from CVDs in 2019, representing 32% of all global deaths. Of these deaths, 85% were due to heart attack and stroke. Access to prevention and treatment of cardiovascular diseases is uneven across the EU Member States.

While continuing to build on the achievements and maintaining momentum on the ongoing implementation of the Beating Cancer Plan, the EU should target cardiovascular diseases as a health priority for the next mandate, and propose an **EU cardiovascular health plan** embracing prevention, early detection, treatment and after-care. COCIR is ready to provide its input to the plan and to work with stakeholders to achieve its objectives.

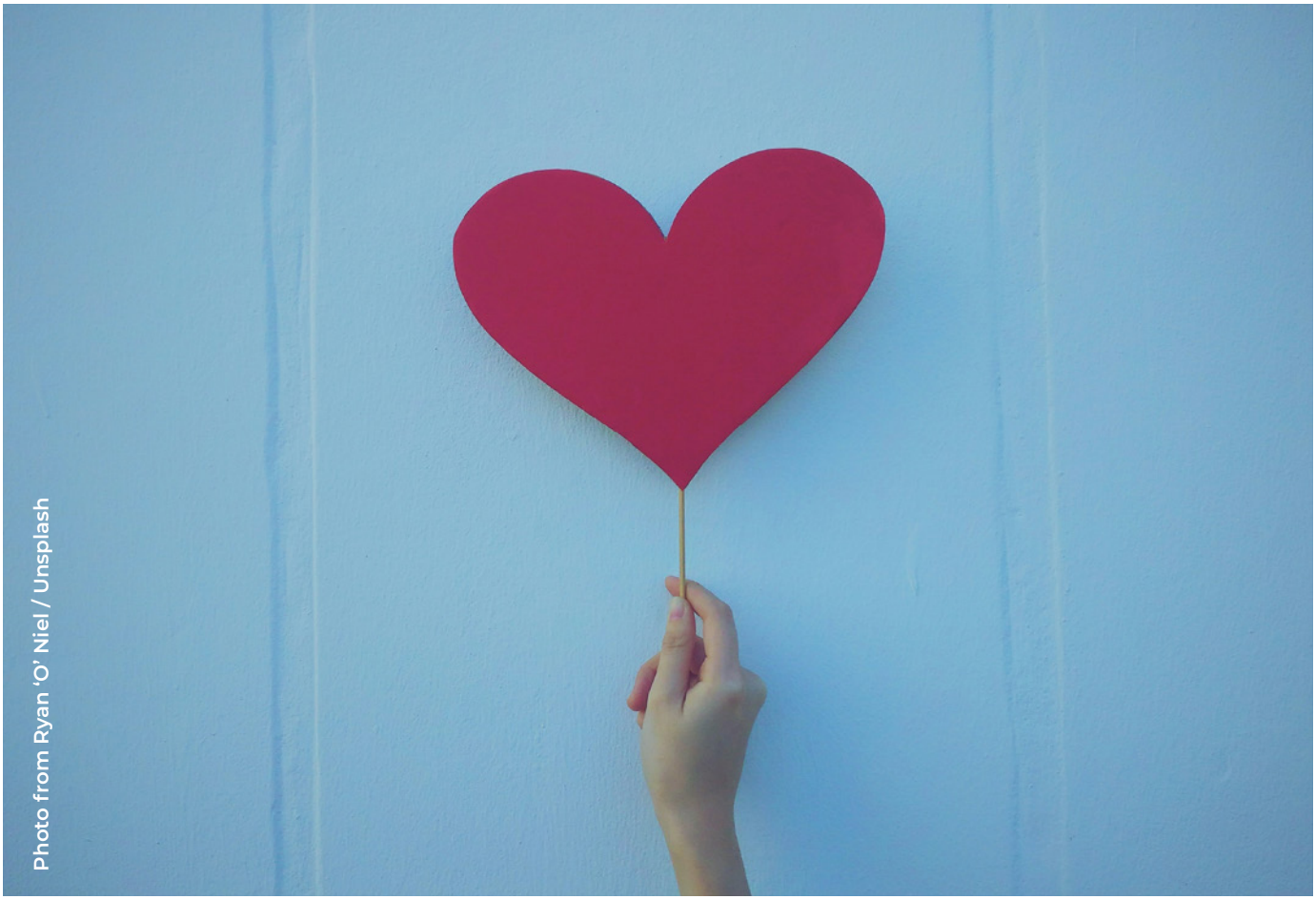

Photo from Ryan 'O' Niel / Unsplash

“

It is very important to have the chance to give our input when the new regulations are still not there yet”

Quote from Members Survey 2022

Statutes of COCIR AISBL

As revised by COCIR General Assembly on 20 March 2024

Crossroads Bank of Enterprises number 478.589.387

The official language of COCIR Statutes is French. In the event of any divergence in meaning between the English and the French versions, the terms of the French version will prevail.

I. FORM, NAME, REGISTERED OFFICE, PURPOSE, DURATION

Article 1. Form - Name

1.1. The international non-profit association (AISBL) is named: "COMITÉ EUROPÉEN DE COORDINATION DES INDUSTRIES RADIOLOGIQUES, ÉLECTROMÉDICALES ET D'INFORMATIQUE DE SANTE" in French, "EUROPEAN COORDINATION COMMITTEE OF THE RADIOLOGICAL, ELECTROMEDICAL AND HEALTHCARE INFORMATION TECHNOLOGY (IT) INDUSTRY" in English, shortened to "COCIR" (hereinafter the "Association").

The complete and abbreviated names may be used together or separately.

The name must always be preceded or followed by the words "association internationale sans but lucratif" (international non-profit association) or the abbreviation "AISBL".

1.2 The Association is governed by the Belgian Companies and Associations Code of 23 March 2019, as amended from time to time.

Article 2. Registered office

The registered office of the Association is located in the Brussels Capital Region. Upon decision of the Board of Directors, the registered office may be transferred to any other place in the Brussels Capital Region, insofar as the transfer of the registered office does not require changing the language of the Statutes of the Association.

Article 3. Purpose

3.1 The Association has a non-profit aim of international utility:

- to carry out studies on the development of the radiological, electromedical and health informatics industries and to support their progress;
- to develop scientific knowledge concerning the industrial, legal and technical environment of the radiological, electromedical and health informatics industries
- to promote, support and co-ordinate the economic interests and activities of its members belonging to the radiological, electromedical and health informatics industries at European level.

and in particular

- to promote the effective development of international, and if possible identical international and European, standards compatible with the maintenance of quality, safety, efficiency and the promotion of the worldwide liberalised trade in medical devices;
- promote the harmonisation of global regulatory control of medical devices, consistent with the maintenance of patient and user safety
- to encourage the use of technologies capable of providing medical care at efficient prices;
- promote the use of progressive design and production techniques by the European medical device industry, in order to maintain and strengthen its position in international markets
- improve technology transfer and promote knowledge and use of available research and development funds;
- to ensure that European authorities are notified of trade discrimination and other market distortions
- to act as a communication platform between the European authorities, the European Commission and the members of COCIR

- to find common solutions with other associations;

In addition, the Association may represent and promote the various interests of its members.

3.2 In order to achieve its aim, the Association may use all appropriate means, including

- the constitution of working committees
- the organisation of meetings;
- support for the activities of national committees
- publications;
- exchange of information.

3.3 The organs of the Association are: the General Assembly, the Board, the President, the General Secretariat and the Committee of Secretaries.

Article 4. Duration

The Association is established for an indefinite period.

Article 5. Financial means

5.1 The financial means available to the Association are:

- membership fees from active members and associate members;
- subsidies from public and private institutions;
- payments receivable for general services and the sale of publications;
- donations and legacies; and
- any other financial or in-kind contributions from active members or associate members.

5.2 The scale of membership fees and the methods of payment may be determined annually by the General Assembly upon the proposal of the Board of Directors. In the absence of an express decision of the General Assembly, membership fees are to be paid within thirty (30) calendar days after the receipt of the invoice.

5.3 Active members shall pay a full membership fee for access to any committees mentioned in article 26 and associate members shall pay a limited membership fee for access to a limited number of committees mentioned in the same article.

5.4. Based on a proposal of the Board of Directors, the General Assembly reserves the right to approve any additional amount to cover exceptional expenditures or specific projects.

5.5 Any payment default may lead to the suspension or restriction of the rights of the member concerned.

If the payment of membership fees or contributions mentioned above is three months in arrears despite a written reminder, the Secretary General is entitled to issue a debit note at the current legal interest rate.

II. MEMBERS

Article 6. Classes of membership – Register of members

6.1 The Association is composed of minimum two (2) members which can be either Belgian or foreign legal persons only.

The Association is composed of two categories of members, i.e. active members or associate members.

6.2 Active members and associate members may be:

- national trade associations of manufacturers which develop and produce in
- the radiological, radiotherapy, electromedical and healthcare information technology industries and related sectors established in the European Union, the EFTA, the United Kingdom of Great Britain and Northern Ireland and Turkey; or
- companies which develop and produce in the radiological, radiotherapy, electromedical and healthcare information technology industries and related sectors
  - **a.** whose registered office is established in the European Union, the EFTA, the United Kingdom of Great Britain and Northern Ireland, Turkey; and
  - **b.** which are members of the national trade associations involved in the radiological, radiotherapy, electromedical or healthcare information technology and related sectors of at least one country of any of the following areas which are the European Union, the EFTA, the United Kingdom of Great-Britain and Northern Ireland, Turkey.

6.3 A register of members is kept at the registered office of the Association. This register includes the denomination, the legal form and the registered office of each member. The Board of Directors records all decisions regarding admission, resignation and dismissal of members in the said register within eight

(8) calendar days after being informed of the relevant decision.

Article 7. Admission of members

Provided that the candidate member complies with the requirements for active or associate members set out under article 6.2, applications for membership must be submitted in writing to the Secretary General who shall then submit applications to the Board of Directors once applicants have signed a statement of acceptance of the statutes of the Association, and any other applicable internal rules, if any, as well the code of conduct of the Association as applicable and have undertaken to pay the membership fees or any other financial contributions mentioned in 5, as applicable. The Board of Directors may conditionally admit new members before the next General Assembly.

Nevertheless, such new members shall be finally approved by at least two-thirds of the members present or represented at the General Assembly. The decision of the General Assembly is final, discretionary, does not have to state reasons and is not capable of appeal.

Article 8. End of membership

8.1 Resignation

A member, whether active member or associate member, may decide to resign from the Association at any time by informing the Secretary General with a prior written notice by mail, fax or electronic mail received at least nine months before the end of the Association's financial year (i.e. no later than 31 March).

The resignation shall become effective the 1st of January of the year following the year where the letter of resignation was received by the Association.

For the avoidance of doubt, any membership fees or financial contributions or payment of whatsoever nature, due to the Association by a resigning member will remain payable to the Association by this member, even in case of its resignation for whatever reason.

8.2 Change of membership class

An active member wishing to become an associate member shall notify its decision to the Secretary General with prior written notice by mail, fax or electronic mail received at least nine months before the end of the Association's financial year (i. e. no later than 31 March). The change of membership class shall become effective on the 1st of January of the year following the year when the notification of change was received by the Association.

8.3 Dissolution and reorganization

The membership of a member comes automatically to an end by the voluntary or forced dissolution of this member, no notice period being required. It is the responsibility of a member to inform the Board of Directors, without delay about any major organisational changes such as a merger, that may have an impact on the future participation of the member in the Association.

8.4 Exclusion

If an active member or an associate member:

(i) contravenes the statutes or any internal rules issued by the Association, if any;

(ii) is no longer fulfilling conditions laid down in article 6.1 and 6.2 of the statutes;

(iii) is declared bankrupt or is the subject of insolvency or reorganisation proceedings linked to insolvency; or

(iv) is carrying out acts that are contrary to the aims and/or values of the Association,

the Board of Directors, deciding at the simple majority of the votes, or one-fifth (1/5th) of the active paid-up members may request the exclusion of an active member or an associate member of the Association. If the member who is the subject of the proposal to expel is also a member of the Board of Directors, the member may not participate in the vote.

The proposal to exclude a member will be communicated to the member concerned in writing and will be submitted to the General Assembly within two months following the date of the proposal to exclude. In case of urgency, the Board of Directors may decide to suspend the rights of the member suspected of a breach as mentioned under (i) from (iv) above, until the next General Assembly. The member shall comply with its obligations as a member of the Association during the period of suspension.

After having given such active or associate member an opportunity to present a defence, the General Assembly shall decide on the exclusion of this member by a two-thirds majority of the members present or represented, it being understood that the member who is subject to the proposal to expel may not participate in the vote. The vote shall be secret.

Notwithstanding the above, if a member fails to pay the membership fee within thirty (30) calendar days after a written reminder has been sent, the General Assembly may decide to terminate the membership with a simple majority of members present or represented, provided that the Board of Directors has passed a resolution to this effect. The member involved shall be notified of the exclusion by registered mail.

For the avoidance of doubt, any membership fees or financial contributions or payment of whatsoever nature, due to the Association by an excluded member will remain payable to the Association by this member, even in case of its exclusion for whatever reason.

8.5 Right to financial assets

Members which have resigned, been dissolved or been excluded shall have no right to the financial assets of the Association and cannot claim any reimbursement of membership fees or any financial contributions, of whatsoever nature, paid to the Association.

Article 9. Duties and rights of the members

9.1 Active members and associate members shall pay a membership fee and financial contributions, as set forth in article 5.

In addition, each member undertakes to:

- contribute to the development of the policies of the Association and implement the decisions taken by the General Assembly;
- contribute to the budget of the Association as agreed by the General Assembly; and
- abide by the terms of the statutes or any other internal rules, if any and by the code of conduct regarding ethics, as applicable.

9.2 Active members and associate members shall also have the right to take part in the general assemblies and committees of the Association under the conditions laid down in these statutes.

III. THE GENERAL ASSEMBLY

Article 10. Composition

The General Assembly is composed of all active and associate members.

Article 11. Powers

The General Assembly shall exercise all the powers attributed to it by the law and by the statutes.

The General Assembly determines the common policy to be pursued to achieve the objectives of the Association as well as the means to implement the policy.

In particular, the General Assembly has the following exclusive powers:

a. approve the annual accounts and provide discharge to the members of the Board of Directors and to the statutory auditor, if any;

b. determine the income and expenditure budget for the period until the next ordinary General Assembly meeting and determine the amount of the annual membership fees;

c. determine the general rules for financial contributions

d. appoint the President and Vice-President of the Board from the active members of the Association and revoke them;

e. appoint the members of the Board of Directors from the active members of the Association and revoke them;

f. approve or exclude members;

g. appoint and revoke the statutory auditor, if any, who will audit the accounts of the Association as well as approve the remuneration of the statutory auditor proposed by the Board of Directors, where applicable;

h. approve the annual budget proposed to it by the Board of Directors;

i. approve and accept donations and legacies for the Association;

j. bring legal proceedings on behalf of the Association against the directors and, as the case may be, the statutory auditor;

k. amend the statutes;

l. dissolve the Association on a voluntary basis;

m. decide, by unanimous approval, to modify the purpose of the Association with the aim of continuing the Association's activities; and

n. all other cases where the law or these statutes so require.

Article 12. Convening notice and meetings

12.1. An ordinary meeting of the General Assembly shall take place once a year, within six months as from the closing of the last financial year at the registered office of the Association or at any other place indicated in the convening notice.

The ordinary General Assembly is convened by the Board of Directors or the President of the Board or the Secretary General or by the statutory auditor, if any. The notice is sent by ordinary mail, fax, electronic mail or any other means of communication to each member at least thirty (30) calendar days before the date of the General Assembly meeting with the agenda. Documents to support decisions taken by the General Assembly may be made available later at least seven (7) calendar days before the date of the meeting. In such occurrence, it should be announced in the notice.

12.2 The Board of Directors, the President of the Board or the Secretary General may convene an extraordinary meeting of General Assembly whenever the interests of the Association so require or at the request of at least one-fifth of paid-up active members and not later than two (2) months after the request. The notice is sent by ordinary mail, fax, electronic mail or any other means of communication to each member at least fifteen (15) calendar days before the date of the extraordinary General Assembly meeting with the agenda. Documents to support decisions to be taken by the General Assembly may be made available later, at least five (5) five calendar days before the date of the meeting of the General Assembly. In such occurrence the fact that documents will be made available later on should be announced in the notice.

12.3 Convening notices must mention the date, time and place of the meeting of the General Assembly, as well as its agenda.

12.4 The General Assembly may meet physically, by conference call, videoconference, or any other means of telecommunication.

12.5 The Board of Directors may offer the members the possibility to remotely participate in the General Assembly (by audio or video conference) by means of an electronic means of communication provided by the Association. In that case, the members shall be deemed to be present at the place where the General Assembly is held.

The Association must be able to check the capacity and identity of the remote members by means of the electronic communication tool used, which allows the members and the members of the bureau of the General Assembly and the statutory auditor, if appointed, to hear each other simultaneously.

The electronic means of communication must at least enable the members to take direct, simultaneous and uninterrupted notice of the discussions at the General Assembly and, as far as the active members are concerned, to exercise their voting right with respect to all items on which the General Assembly is required to take a decision.

The electronic means of communication shall also enable members participating at a distance to take part in the deliberations and ask questions. The convocation to the meeting of the general Assembly shall include a clear and precise description of the procedures relating to remote participation.

Those procedures shall be made accessible to those who are entitled to participate in the meeting of the General Assembly. The minutes of the meeting of the General Assembly shall record any technical problems or incidents that prevented or disrupted electronic participation in the meeting or voting.

The members of the bureau of the General Assembly may not participate in the meeting by electronic means.

A representative of any active member may, by means of a document that bears the signature of the representative (including a digital signature in accordance with article 8.1, 3° of the Civil Code) and that has been communicated by ordinary mail, fax, electronic mail or any other means of communication, grant a power of attorney to another active member or someone from the same organisation than the representative of the active member, to represent such active member at a meeting

of the General Assembly and to vote for such active member. Each proxy holder may represent only one member at the same meeting.

12.6 The Board of Directors may determine the form of powers of attorney and require that they are deposited at the place indicated by it within a period of time to be determined by it.

12.7 Any member who is unable to attend the meeting of the General Assembly also has the possibility to cast its vote by ordinary mail, fax, electronic mail or any other means of communication before the meeting.

This written vote must be communicated at the latest on the working day before the meeting.

12.8 The General Assembly may only deliberate on items on the agenda, unless there is a unanimous agreement to the contrary from all members present or represented. Notwithstanding the above, the General Assembly is not entitled to adopt amendments to the statutes or to vote on voluntary dissolution of the Association, if such topics have not been mentioned in the agenda of the meeting of the General Assembly.

Meetings of the General Assembly are chaired by the President of the Board or, failing that, by the Vice-President of the Board or failing that, a director of the Board of Directors or the Secretary General or a permanent representative of an active paid-up member of the Association or an employee of the Association. If the number of persons present so permits, the chairman of the meeting of the General Assembly shall appoint a secretary, who will in principle be the Secretary General.

Article 13. Admission to the meetings of the General Assembly

Any paid-up member of the Association may participate to the meetings of the General Assembly.

Article 14. Decision-making

14.1 Attendance quorum

Unless the law or these statutes provide otherwise, deliberations of the General Assembly shall be valid only if at least fifty (50) % of all active members are present or represented. If this quorum is not reached, a second General Assembly shall be convened, at the earliest fifteen (15) calendar days later, for the same purpose. The General Assembly held after this second convocation shall be entitled to take decisions, no matter the number of active members present or represented.

14.2 Voting quorum

Each active member has only one vote.

Associate members have no voting rights. They may attend meetings of the General Assembly in an advisory capacity.

Members who abstain from voting count towards the attendance quorum.

Unless the law or these statutes provide otherwise stated in the Statutes, resolutions will be adopted by a simple majority of active members present or represented. Abstentions from voting, null and blank votes will not be taken into account for the calculation of the majorities.

In the event of a tie, the chairman of the meeting of the General assembly has a casting vote.

14.3 Minutes

All the members are informed of the resolutions adopted by the General Assembly, by ordinary or electronic mail within a month following the meeting of the General Assembly.

The minutes of the meetings of the General Assembly shall be recorded in a register kept at the registered office of the Association where they may be consulted by the members, whether active members or associate members. They shall be signed by members of the bureau and by the active members present who shall so request. Copies or extracts shall be signed by the President of the Board.

14.4 Written resolutions

The active members can by unanimous written resolution decide on any subject-matter within the powers of the General Assembly except for the amendment to the statutes of the Association or voluntary dissolution. In case of written resolutions, the convening formalities do not have to be fulfilled. The invite by the Board of Directors needs to set out the requirements for term and validity of this written decision making.

The member of the Board of Directors and, where applicable, the statutory auditor, may, at their request, take knowledge of these decisions.

Article 15. Amendments to the statutes – Voluntary dissolution of the Association

15.1 Proposal to amend the statutes or voluntarily dissolve the Association

Without prejudice to applicable legislation and article 14 of the statutes, any proposal regarding the amendment to the statutes or the voluntary dissolution of the Association, shall be made by the Board of Directors or by at least seventy-five per cent (75%) of the active members of the Association.

Regarding such proposal mentioned above in article

15.1, the Board of Directors shall inform the active and associate members of the Association of the date of the General Assembly meeting at least two (2) months in advance of the date of the General Assembly meeting.

15.2 Attendance quorum

The General Assembly can only legitimately deliberate on such a proposal if two-thirds (2/3rds) of active paid-up members of the Association are present or represented.

If this quorum is not reached, a second meeting of the General Assembly shall be convened at the earliest fifteen (15) calendar days later for the same purpose and shall then be entitled to take decisions, no matter the number of active members present or represented.

15.3 Voting quorum

Resolutions shall be approved by a majority of two-thirds (2/3rd) of the votes. In case

the General Assembly has to be reconvened for the same purpose in absence of quorum, resolutions are adopted by a majority of two-thirds (2/3rd) of active members present or represented.

In the event of a tie, the chairman of the meeting of the General Assembly meeting has a casting vote.

Abstentions are taken into account in the attendance quorum but not in the voting quorum. For the avoidance of doubt, abstentions from voting, null and blank votes will not be taken into account for the calculation of the majorities.

Amendments to the statutes will only be submitted to the Ministry of Justice, to the extent required by law.

IV. MANAGEMENT - CONTROL

Article 16. Composition of the Board of Directors

16.1 General

The Association is managed by a Board of Directors, which is composed of – at least three (3) – members or more from active paid-up members of the Association.

If a legal person is appointed as director, it shall be required to appoint a permanent representative, who shall be a natural person, to carry out the mandate in the name and on behalf of the legal person. This representative shall be subject to the same conditions and shall incur the same civil and criminal liability as if such person were performing this mandate in such person's own name and own account, without prejudice to the joint and several liability of the legal person the director represents. The legal person may only dismiss its representative by simultaneously appointing the successor. The appointment and termination of the functions of the permanent representative shall be subject to the same rules of publicity as if the director were exercising this mission in such director's own name and own account.

16.2 Appointment

The members of the Board Committee are appointed by the General Assembly for a period of four years which may be renewable. For the avoidance of doubt, permanent representatives of Board members may be nominated for a period of four years which may be consecutively renewed only once. However, this renewal rule limiting the number of consecutive mandates does not apply to Board members' permanent representatives of association members.

Notwithstanding the above and unless otherwise provided by the statutes or unless the General Assembly decides otherwise at the time of this appointment, the mandate of a director shall run from the meeting of the General Assembly that appointed the director until the ordinary meeting of the General Assembly that takes place in the financial year in which such director's mandate ends in accordance with the appointment decision.

Each active paid-up company member under the highest membership category has the right to nominate a candidate for a position on the Board of Directors. Active paid-up Association members have the right to nominate candidates among themselves for a position on the Board of Directors. They may have three seats on the Board. The candidates will be appointed by the General Assembly as provided in article 11. Each category of active members (i.e. companies or associations) will nominate their representatives.

16.3 Vacancy

When the position of a director becomes vacant before the end of such director's mandate, the remaining directors shall have the right to co-opt a new director. The first meeting of the General Assembly that follows must confirm the mandate of the co-opted director. In the event of confirmation, the co-opted director shall end the mandate of the predecessor, unless the

General Assembly decides otherwise. In the absence of confirmation, the mandate of the co-opted director shall end after the meeting of the General Assembly, without prejudice to the regularity of the composition of the Board of Directors until that date.

16.4 Resignation and dismissal

Any member of the Board of Directors may be dismissed at any time, with immediate effect and without cause, by the General Assembly by a two-thirds majority of active members present or represented, with a discharge of duties and liability for decisions of the directors or events which took place after the effective date of the dismissal.

Any director may resign by simply notifying the Board of Directors. At the request of the Association, such director shall remain in office until the Association can reasonably provide for a replacement.

16.5 Experts invited to the Board of Directors

By decision taken with a simple majority, the Board of Directors may invite one or more experts to attend one or more meetings of the Board of Directors to assist the directors to form an opinion on certain specialised or complex subject-matters. Each of these experts may render an advisory opinion, but under no circumstances shall an expert have any voting rights in the Board of Directors. The number of Board of Directors meetings that an expert is entitled to attend or the length of the time period that an expert may attend Board of Directors meetings shall discretionarily be determined by the Board of Directors. The authorisation granted to an expert to attend one or more Board of Directors meetings may be revoked at any time with immediate effect. The Board of Directors does not have to state reasons.

Article 17. Remuneration of the directors of the Board

Directors' mandates are not remunerated. Expenses incurred in the exercise of their function shall not be paid or reimbursed.

Article 18. Convening notice and meetings of the Board of Directors

18.1 The Board of Directors meets as and when necessary, but at least twice a year, and is convened by the President of the Board or the Secretary General or at least by one-third of the Directors of the Board.

18.2 Except in case of force majeure or urgency, duly justified by the Association's interests, convening notices are sent by ordinary mail, fax, electronic mail or any other means of communication at least five (5) calendar days before the date of the Board of Directors meeting.

18.3 Convening notices must mention the date, time and place of the Board meeting, as well as its agenda.

18.4 The Board of Directors may meet physically, by conference call, videoconference or any other means of telecommunication.

18.5 Any director may, by means of a document that bears the signature of such director (including a digital signature in accordance with article 8.1, 3° of the Civil Code) and that has been communicated by ordinary mail, fax, electronic mail or any other means of communication, grant a power of attorney to another director, to represent such director at a Board of Directors meeting and to vote in such director's place. Each proxy holder may represent only one director at the same Board of Directors meeting. This power of attorney may be given for one meeting.

Any director who is unable to attend the Board of Directors meeting also has the possibility to cast his vote by ordinary mail, fax, electronic mail or any other means of communication before the meeting. This written vote must be communicated at the latest on the working day before the Board meeting.

18.6 Meetings of the Board of Directors are chaired by the President of the Board or, failing that, by the Vice-President of the Board or their delegates.

Article 19. Powers of the Board of Directors

19.1 The Board of Directors shall have the power to perform all acts necessary or useful for the realization of the Association's purpose with the exception of those reserved by law or these statutes for the General Assembly.

19.2 In particular, the Board of Directors shall be responsible for organising the General Assembly meetings, drawing up the agenda and writing the minutes for each meeting, which shall be sent to all the members following the General Assembly meeting.

19.3 The Board of Directors is authorized to adopt internal rules. In case internal rules be adopted by the Board of Directors, a reference to it shall be mentioned

in these statutes.

19.4 The Board of Directors may delegate the day-to-day management of the Association, as well as the representation of the Association with regard to that management, to the Secretary General, a member of the Board of Directors or an employee of the Association or a third-party. In addition, it may, under its responsibility, confer special and defined powers to one or several special proxy holders.

19.5 The Board of Directors can set up one or more advisory committees under its responsibility. It defines their composition and their tasks.

19.6 The members of the Board of Directors are entitled to attend, ex officio, all meetings of the Association.

Article 20. Decision-making of the Board of Directors

20.1 Attendance quorum

Unless the law or statutes provide otherwise, deliberations of the Board of Directors shall be valid only if at least half of the directors are present or represented.

Each director may be represented by another director, upon providing proof of a written proxy. A director may only hold one such proxy.

Abstentions are taken into account in the attendance quorum.

20.2 Voting quorum

Each director has one vote. Unless the law or these statutes provide otherwise, resolutions of the Board of Directors are passed by a simple majority of the directors present or represented. Abstentions, null and blank votes are not taken into account for the calculation of the majorities. In the event of a tie, the President of the Board has a casting vote.

20.3 Conflict of interest

A director who, in the context of a decision to be taken, has a direct or indirect conflict of interest which is opposed to the interest of the Association, must inform the other directors before the Board of Directors takes the decision. The declaration and explanation of the nature of the conflicting interest must be included in the minutes of the meeting of the Board of Directors which has to take the decision. The director affected by the conflict of interest described in the previous paragraph may not take part in the deliberations of the Board of Directors concerning this decision, nor may such director take part in the vote on this point. If the majority of the directors, present or represented, are in a position of conflict of interest, the decision shall be submitted to the General Assembly. If the decision is approved by the General Assembly, the Board of Director may execute it.

20.4 Minutes

The minutes of the meetings of the Board of Directors shall be recorded in a register kept at the registered office of the Association, where they may be consulted by the members, whether active members or associate members. They shall be signed by the President of the Board and by the directors present who so request. Copies to be issued to third parties be signed by one or more members of the Board of Directors having the representation power.

20.5 Written resolutions

Decisions of the Board of Directors may be made by unanimous consent of the directors, expressed in writing.

Article 21. President

The President of the Board is appointed by the General Assembly amongst the members of the Board of Directors, for a four-year period and may be re-elected once by the General Assembly for a further non-renewable four-year period. The President of the Board represents the Association in external relationships with third parties.

Notwithstanding the above and unless otherwise provided by the statutes or unless the General Assembly decides otherwise at the time of the appointment of the President of the Board, the mandate shall run from the meeting of the General Assembly that appointed the President of the Board until the ordinary meeting of the General Assembly that takes place in the financial year in which the mandate ends in accordance with the appointment decision.

Except in case of reelection mentioned above in this article, one active member shall not provide Presidents for two successive periods.

The President of the Board may be dismissed at any time by the General Assembly, with immediate

effect and without cause, with a discharge of duties and responsibility for decisions of the directors or events which took place after the effective date of the dismissal.

The President of the Board in particular convenes and chairs the meetings of the General Assembly and the Board of Directors. Should the President of the Board be temporarily unable to perform duties assigned by the function, the Vice-President of the Board will act as a substitute. In case the Vice-President of the Board is unable to act as a substitute, the President of the Board will designate another director to this aim. In the event of death or if the President of the Board is unable to make this decision within a month, the Board of Directors shall designate a director to act as a substitute in a timely manner.

Article 22. Vice-President

The vice-president of the Board who shall be a director of the Board of Directors is proposed by the Board of Directors and appointed by the General Assembly. Should the President of the Board be temporarily unable to perform duties assigned by the function, the vice-president of the Board will act as a substitute under conditions mentioned in article 21.

Article 23. Treasurer

The Treasurer is proposed by the Board of Directors and appointed by the General Assembly. As a general rule, the Treasurer shall oversee the financial affairs of the Association and report in this respect to the Board of Directors. The Treasurer shall be a director of the Board of Directors.

Article 24. General Secretariat

The Secretary General is appointed by the Board of Directors. The office of the Secretary General may be remunerated.

The mandate of Secretary General may be for an indefinite term, or for a definite term.

Notwithstanding the above, the Board of Directors may revoke the Secretary General at any time and with immediate effect, without having to motivate its decision, unless otherwise contractually agreed or provided mandatory labour laws, if applicable. This applies whether the mandate is for an indefinite term or a definite term. In this case, the Secretary General shall not be entitled to any compensation, subject to contractual agreements or mandatory labour laws, if applicable.

The Secretary General may resign from office at any time by registered letter sent to the President of the Board. Subject to mandatory applicable labour laws, the Secretary General shall continue to perform duties assigned by the function until the earliest (i) the provision of replacement of the Secretary General or (ii) within ninety (90) calendar days from the date of receipt of the letter of resignation by the President of the Board, unless otherwise contractually agreed.

Should the Secretary General be temporarily unable to perform duties assigned by the function, the Secretary General shall designate an employee or a third-party to act as a substitute. In case of death or if the Secretary General is unable to make this decision or if the inability to perform duties assigned by the function lasts for more than a month, the Board of Directors shall act on behalf of the Secretary General or designate a substitute and/or revoke the Secretary General under the terms mentioned above.

The Secretary General is responsible for the day-to-day management of the Association, the implementation of the decisions of the General Assembly decisions and the preparation of the meetings of the General Assembly. The Secretary General is also responsible for the management of the financial resources of the Association, under the control of the Board of Directors and with the support of the Treasurer.

Unless otherwise agreed by the Board of Directors, the Secretary General is entitled to attend, ex officio, all meetings of the Association.

The powers and duties of the Secretary General are determined by the Board of Directors.

The Secretary General shall act under the responsibility of the Board of Directors and report regularly actions or activities performed to the Board of Directors or upon request of the Board of Directors.

Article 25. External representation of the Association

Without prejudice to the general representation power of the Board of Directors, the Association is validly represented vis-à-vis third parties in all acts, as well as in court:

- by the President of the Board acting alone
- by two directors jointly

- within the limits of the day-to-day management, by the Secretary General or by any person charged with the day-to-day management, acting alone or,
- by one or special proxy holders within the limits of their mandate.

Article 26. Committees

When necessary, the President of the Board or the Board of Directors may set up committees and working groups on either a permanent or temporary basis.

- Each committee has a chair (hereinafter the "Chair") and a Vice-Chair (the Vice-Chair).
- The Chair of such committee is responsible for the work of this committee. The Chair is in charge of the preparatory activities, the minutes of the meetings, the final reports and so on. The Chair is supported by the Secretary General or a person designated by the Secretary General.
- The Chair of the committee reports on the activities of this committee, to the Board.

Article 27. Control of the Association

The control of the financial situation, the annual accounts and the regularity of the transactions to be reported in the annual accounts shall, if necessary, in accordance with the criteria laid down in the Companies and Associations Code, be conferred to one or more statutory auditor(s), appointed for three years and eligible for reappointment.

V. FINANCIAL YEAR – ANNUAL ACCOUNTS

Article 28. Financial year and annual accounts

The financial year begins on 1 January and ends on 31 December of each year.

The Board of Directors draws up the annual accounts in accordance with the applicable legal provisions. The Board of Directors also draws up a budget proposal for the following financial year.

The Board of Directors shall submit for the approval of the General Assembly the accounts of the past financial year, as well as the budget for the next financial year.

In accordance with Article 3 :47§7 of the Companies and Associations Code, the annual accounts of the Association will be filed every year to the National Bank of Belgium.

The General Assembly may decide to create a reserve fund. The General Assembly shall determine the amount of the fund and the methods of making contributions due by each member.

If the Association were to generate a profit as a result of its activities, then it may never be distributed to the members of the Association.

VI. DISSOLUTION AND LIQUIDATION

Article 29. Dissolution and liquidation

The voluntary dissolution of the Association can only be decided by the General Assembly in accordance with article 15 of the statutes.

The liquidation shall be carried out by the liquidator(s) appointed by the general assembly or, in the absence of such appointment, by the Board of Directors in office at that time, acting as a liquidation committee.

The liquidator(s) shall have all the powers provided for by law, without special authorization from the General Assembly. However, the General Assembly may at any time limit these powers by a decision taken by simple majority.

The General Assembly shall determine, where applicable, the emoluments of the liquidator(s).

Article 30. Allocation of the assets of the Association

After settlement of all debts, charges and costs of liquidation or consignment of the sums necessary to pay them, the assets of the Association will be distributed to a non-profit association which pursue the same purpose than the Association, in accordance with law.

VII. GENERAL PROVISIONS

Article 31. Election of domicile

For the execution of these statutes, any member, director, statutory auditor, liquidator, domiciled abroad shall elect domicile at the registered office of the Association where all communications, summons, writs, notifications may be validly served to these persons mentioned above.

Article 32. Jurisdiction

For any dispute between the Association, its members, directors, statutory auditors and liquidators relating to the affairs of the Association and the execution of these articles of association, exclusive jurisdiction shall be attributed to the courts in whose jurisdiction the registered office of the Association is located.

Article 33. Languages

For interpretation of these statutes, the French version of the text will be considered the authentic and prevailing version, being understood that all versions in other languages are translations.

Article 34. General law

The provisions of the Companies and Associations Code which are not lawfully derogated from are deemed to be included in these statutes and clauses contrary to the mandatory provisions of the Companies and Associations Code are deemed to be unwritten.

Code of Conduct

November 2020.

STATEMENT BY ALL COMPANY MEMBERS OF COCIR

COCIR is dedicated to the advancement of medical science and the improvement of patient care.

As participants in an industry largely funded from public funds, COCIR Company Members recognise that adherence to the highest levels of integrity and ethical standards and compliance with all industry laws are critical.

Accordingly, the Company Members of COCIR adopt this Code of Conduct, which represents our collective commitment to the highest standards of integrity. It is intended to supplement and not supersede any legal requirements and individual Company Member codes.

1. INTRODUCTION

This Code of Conduct becomes effective on 1 January 2015 and governs COCIR company members' ("Members") interactions with Healthcare Professionals. This Code of Conduct was amended in 2017. This amended Code of Conduct becomes effective on 1 January 2019.

"HEALTHCARE PROFESSIONALS" refers to individuals (and the institutions for which they work) involved in the decision-making process resulting in the procurement of Members' products or services. This includes doctors, nurses, hospital managers, and consultants employed by hospitals.

This Code applies to Healthcare Professionals in geographic Europe.

Members agree to pass on the responsibility to comply with the principles contained in this Code to their distributors and agents.

This Code is not intended to replace or supersede supranational, national or local laws or regulations or professional codes (including company codes) that may impose particular requirements upon Members or Healthcare Professionals.

2. BASIC PRINCIPLES

The following fundamental principles form the foundation of this Code:

2.1 The Separation Principle - A clear separation should exist between any advantages or benefits granted by Members to Healthcare Professionals and the decision- making process resulting in the procurement of Members' products or services. The purpose of this principle is to prevent undue, improper advantages or benefits influencing such procurement.

2.2 The Transparency Principle - Advantages or benefits to Healthcare Professionals should be disclosed to their institution's administration or management and also, if required, to local authorities.

2.3 The Proportionality Principle - Any consideration given to a Healthcare Professional in exchange for a service or other performance should not exceed fair market value.

2.4 The Documentation Principle - The granting of any advantages or benefits to Healthcare Professionals by Members should be documented.

3. MEETINGS - ORGANISED BY MEMBERS

3.1 Purpose. The meeting should have a genuine educational, scientific or business purpose as its primary purpose and there must be a legitimate reason for inviting each Healthcare Professional to the relevant event.

3.2 Meeting locations. All Member organised meetings should be conducted at an appropriate location and venue.

3.3 Permitted Expenses. Members may pay for reasonable travel and lodging costs incurred by Healthcare Professionals for attending Member organised meetings.

3.4 Separation from Sales. It is always inappropriate for Members to organise hospitality for the purpose of inducing Healthcare Professionals to enter into a business transaction. It is also inappropriate for Members to arrange hospitality contingent upon past, present or future business transactions.

3.5 Guests. It is inappropriate for Members to invite to a meeting any other person without a professional interest in the meeting, such as the spouse or guest of a Healthcare Professional. Members will ensure that their invitations will not be interpreted as extending to such individuals. It will always be inappropriate for Members to pay for the travel or lodging expenses for such individuals. In addition, it will be inappropriate for Members to pay for the expense of meals and hospitality for such individuals.

4. CONFERENCES - ORGANISED BY THIRD PARTIES

4.1 Financial support to Conferences. Members may support conferences organised by third parties. Members may provide financial support to third parties under the following conditions:

1. the conference is primarily dedicated to promoting objective scientific and educational activities;
2. the third party is responsible for and controls the selection of program content, faculty, educational methods, and materials;
3. the third party independently invites and selects individual Healthcare Professionals who will participate in the conference or training and determines the payment of their expenses, as the case may be;
4. the third party independently selects speakers and determines the payment of their expenses;
5. the support of a conference by a Member is clearly stated in advance of and at the meeting; and
6. the support is not specifically granted for any entertainment or hospitality.

4.2 Financial support to individual Healthcare Professionals Members may not provide financial support to any individual Healthcare Professional for his/her passive attendance or active participation as a speaker in a third-party conference. Therefore, Members may neither pay for registration fee, travel and lodging costs nor for honoraria for a speaking engagement.However, Members may provide financial support to an individual Healthcare Professional for registration fee, travel and lodging costs to:

1. attend a hands-on procedure training, organised by a third party, which is typically performed in a clinical environment or
2. speak or provide a professional training at a satellite symposium organised by a Member in the margins of a thirdparty conference; in this case, Member may also pay honoraria for a speaking engagement.

5. HOSPITALITY

5.1 In connection with Meetings or Conferences. Members may pay for reasonable hospitality in the form of meals, drinks, receptions and entertainment (e.g. a music, sports or theatre event) in connection with the program of a meeting or conference. However, any such hospitality should be in accordance with local law, subordinate in both time and focus to the purpose of the meeting or conference.

5.2 Unconnected with Meetings or Conferences. Members may pay for business meals and drinks that take place in a setting that is conducive to business discussions and is not selected because of its leisure or recreational facilities. However, Members may not pay for any other kind of hospitality, for example in the form of entertainment as described in 5.1.

6. CONSULTANCY

6.1 Agreements in writing. Consultancy agreements between Members and Healthcare Professionals must be in writing, signed by both parties, and specify all the services to be provided. Services may include clinical and scientific advice, speaking engagements, participating on advisory boards, advising on new product development, conducting demonstrations and writing abstracts.

6.2 Separation from sales. Consultancy agreements between Members and Healthcare Professionals should not be made on the basis of the volume or value of business generated by Healthcare Professionals or the institution with which the Healthcare Professional is affiliated or be contingent on past, present or future business transactions.

6.3 Management approval. Consultancy agreements between Members and Healthcare Professionals must be approved by the administration or management of the institution with which the Healthcare Professional is affiliated.

6.4 Fair market value compensation. Compensation paid to Healthcare Professionals for consultancy should not exceed fair market value for the services provided.

6.5 Legitimate need. Members should only enter into consultancy agreements where a legitimate need and purpose for the contracted services has been identified in advance.

6.6 Consultant qualifications. Selection of consultants should be made on the basis of the Healthcare Professionals' qualifications and expertise to address the identified purpose.

7. GIFTS

7.1 Limitation on gifts. Generally, gifts are discouraged. However, if given, they should be in accordance with local law, occasional and of modest value, and must never leave the recipient in a position of obligation or be perceived to affect the outcome of a business transaction or potentially expose the business to undue influence.

7.2 Never cash or cash equivalent. A gift shall never consist of cash or cash equivalent.

8. CHARITABLE DONATIONS

8.1 Charitable Purpose & Recipient. Members may make donations for a charitable purpose. Donations should be made only to charitable organisations.

8.2 Separation from Sales. It is inappropriate for Members to make charitable donations for the purpose of inducing Healthcare Professionals to enter into a business transaction. It is also inappropriate for Members to make charitable donations contingent upon past, present or future business transactions.

8.3 Transparency. The recipient of the donation and the recipient's planned use of the donation should be documented Members must be able to justify the reason for the donation at all times.

8.4 Evaluation & Documentation. Members are recommended to establish a process whereby they can ensure that requests for charitable donations are evaluated separately from the Members' commercial activities and such requests are consistently documented.

9. PUBLIC PROCUREMENT

9.1 Main principles. Members value the main principles of public tendering laws: transparency of tendering processes and fair and equal treatment of all bidders.

9.2 Improper influencing. It is always inappropriate for Members to offer, directly or indirectly, gifts or other benefits in order to improperly influence Healthcare Professionals in the public tendering process. Members shall refrain from any activities that are likely to be seen as aimed at improperly influencing Healthcare Professionals.

9.3 Technical specifications. Members acknowledge that it is important that Contracting Authorities formulate open an objective technical specifications to afford fair and equal access to bidders.

9.4 Exemptions from public tendering procedures. Members understand that Contracting Authorities have only limited possibilities to exempt themselves from public tendering procedures. Members should not encourage Contracting Authorities to unduly seek such exemptions.

9.5 Consultants, use of third parties. Where a Member, as part of a technical dialogue or otherwise, acts as an independent consultant for the Contracting Authority, that Member shall do so only in a way that would not violate the principle of equal treatment of bidders.

9.6 Notice of future tenders. More specifically, where a Member, acting in a role of an independent consultant for the Contracting Authority, is or reasonably should be aware of the likelihood of a future tender arising as a result of the consulting services the Member provides to the Contracting Party, and which the Member intends to participate in, that Member shall request that the Contracting Authority issues an appropriate notice of any such future tender so that all potential bidders may have equal and fair notice of that tender opportunity and are aware of the role of the Member in a transparent way.

9.7 Amendments to contract or scope of supply. Members understand that during or after the tendering procedure, Contracting Authorities will have only limited possibilities to make changes to tender documentation, contractual terms or scope of supply.

10. RESEARCH AGREEMENTS

10.1 Research services. When a Member contracts with a Healthcare Professional for research services, there must be a written agreement specifying all services to be provided and a written protocol for a genuine research purpose.

10.2 Research to be legitimate and documented. The research should be a legitimate scientific work. Well-defined milestones and deliverables must be documented in a detailed written agreement. Selection of the Healthcare Professional should be made on the basis of qualifications and expertise to address the identified purpose.

10.3 Separation from sales. The research support should not be contingent upon past, present or future sales of the Member's products or services to the Healthcare Professional. A condition that the research support is contingent upon the Healthcare Professional's purchase of products or services from the Member is only permissible if the said products or services are being purchased for specific use within the research or are requested as part of a tender.

10.4 Management approval. Research Agreements must be approved by the administration or management of the institution with which the Healthcare Professional is affiliated.

10.5 Fair market value compensation. Compensation paid to Healthcare Professionals for research services should not exceed fair market value for the services provided.

11. EDUCATIONAL GRANTS

11.1 For defined purposes only. Members may make an educational grant to support:

1. the advancement of genuine medical, clinical or technological education;
2. the advancement of public education, that is, the education of patients or the public about important healthcare topics.

11.2 No grants to individuals. Educational grants should not be made to or for individual Healthcare Professionals.

11.3 Recipient independently controls. The recipient of the grant should independently control and be responsible for the selection of program content, faculty, educational methods, materials, any scholarship awards and any individual Healthcare Professional who may benefit from the grant. The grant may not be used to directly fund endowments of professors, chairpersons of departments or other similar position, nor replace departmental budgets.

11.4 Separation from Sales. It is inappropriate for Members to make educational grants for the purpose of inducing Healthcare Professionals to enter into a business transaction. Educational grants should not be contingent upon past, present or future sales of Members' products or services to the Healthcare Professional.

11.5 Evaluation & Documentation. Members are recommended to establish a process whereby they can ensure that requests for educational grants be evaluated separately from Members' commercial activities and such requests be consistently documented.

11.6 Grants must be documented. Members should maintain appropriate documentation in respect of all educational grants made, to show that the grant was used for a genuine educational purpose.

12. DEMONSTRATION AND EVALUATION EQUIPMENT

12.1 Limited duration. Members may offer equipment for demonstration and evaluation to Healthcare

Professionals free of charge and for a reasonable period of time, which shall normally be less than 6 months. Written approval by Healthcare Professionals' administration or management is required and should be filed alongside the appropriate documentation.

13. INDEPENDENT THIRD PARTIES

13.1 Use of independent third parties. Members may use independent third parties for the promotion, importation and sale of their products and services to Healthcare Professionals, such as agents, distributors or consultants.

13.2 Select with care. In order to find trustworthy individuals or organisations, Members should only select and award business to independent third parties that are committed to act with integrity and comply with applicable laws and regulations.

13.3 Monitor and control. Members should therefore (i) conduct due diligence on proposed independent third parties, (ii) impose obligations in contracts with independent third parties to comply with anti-bribery laws and the duties of the COCIR Code and (iii) monitor significant independent third parties as part of a Member's regular review of relationships with them and subject significant independent third parties to appropriate controls.

14. COMPLIANCE WITH THE CODE

Role of Code of Conduct Committee. COCIR has established a mechanism for anyone concerned that a Member may have breached this Code to report such concern directly to COCIR. Such concerns will be referred to senior legal or compliance officers within the relevant Member for proper investigation, handling and resolution. COCIR has established a Code of Conduct Committee consisting of one senior legal or compliance officer from each Member. The Members shall disclose to the Committee, on an aggregated basis, how concerns relating to that Member have been addressed and resolved.

COCIR DO'S

DO ADHERE TO THE 4 BASIC PRINCIPLES OF COCIR'S CODE OF CONDUCT

1

SEPARATION
between benefits & decision-making

2

PROPORTIONALITY
of remuneration for services provided

3

TRANSPARENCY
in the management of HCPS

4

DOCUMENTATION
of benefits provided

Photo from Behzad Ghaffarian / Unsplash

COCIR DO'S

CONSULTANCY & RESEARCH AGREEMENTS

- Ensure a legitimate need for the contracted services based on the HCP's qualifications and expertise.
- Specify services and deliverables in a signed contract.
- Document approval of HCP's institution.
- Compensate consultancy at fair market value.

DEMONSTRATION & EVALUATION EQUIPMENT

- Offer equipment for demonstration/ evaluation only for a reasonable period, usually less than 6 months.
- Get approval from the HCP's institution.

INDEPENDENT THIRD PARTIES (ITPS)

- Select ITPs that are committed to act with integrity and comply with the law
- Conduct due diligence on proposed ITPs
- Impose obligations in contracts with ITPs to comply with anti-bribery laws and the COCIR Code
- Monitor and control ITPs

MEETING, HOSPITALITY & CONFERENCES

- Ensure a legitimate reason for the meeting and appropriateness of location.
- Reimburse reasonable travel and lodging expenses to individual HCPs only for educational and scientific conferences organised by Members. For third-party conference, provide financial support to individual HCPs only if (1) the event organised by the third party is a procedure training which is a hands-on training typically performed in a clinical environment or (2) if the individual HCP is a speaker or a professional trainer invited by a Member to speak at a satellite symposium organised by the Member in the margins of a third-party conference .
- Ensure hospitality related to a meeting is subordinate in time and focus.
- Limit meetings and related hospitality strictly to persons having a professional interest in the meeting
- Contribute financial grants to conferences for scientific or educational activities only to conference organiser, be transparent with respect to the support provided.

COCIR DO'S

GIFTS & CHARITABLE DONATIONS

- Discourage gifts
- Restrict yourself to occasional gifts of modest value
- Donate only for a charitable purpose to a charitable organisation
- Ensure through your internal evaluation process that donations are not linked to past, present or future business transactions

SPONSORSHIP

- Make sponsorship for third-party conference or professional training to a professional conference organiser
- Allow the professional conference organiser to independently (i) control the program content, faculty, educational methods, materials, scholarship awards and (ii) select individual HCPs who may benefit from the grant

EDUCATIONAL GRANTS

- Make grants to a healthcare institution only to advance genuine medical, clinical or technological education or to educate patients or the public about important healthcare topics
- Allow grant recipient to independently (i) control the program content, faculty, educational methods, materials, scholarship awards and (ii) select individual HCPs who may benefit from the grant
- Ensure grants are not contingent upon past, present or future sales
- Ensure to establish a process whereby requests for educational grants be evaluated separately from commercial activities and be consistently documented

PUBLIC PROCUREMENT

- Allow Contracting Authorities to formulate open and objective technical specifications without interference
- Recognize that Contracting Authorities have only limited possibilities to exempt themselves from public tendering procedures
- Respect the principle of equal treatment of bidders when acting as an independent consultant for a Contracting Authority
- Recognize that Contracting Authorities have limited possibilities to make changes to tender documents or scope of supply

COCIR DONT'S

DO NOT NEGLECT THE 4 BASIC PRINCIPLES OF COCIR'S CODE OF CONDUCT

1

SEPARATION
between benefits & decision-making

2

PROPORTIONALITY
of remuneration for services provided

3

TRANSPARENCY
in the management of HCPS

4

DOCUMENTATION
of benefits provided

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COCIR DONT'S

CONSULTANCY & RESEARCH AGREEMENTS

- Engage HCPs without a legitimate need, without consideration of their capabilities and without evaluating their scientific contribution
- Link research funding with sales of members' products (unless product is specifically for use in research or linked by tender)
- Keep deliverables and timelines unclear
- Conceal the agreement from the HCP's institution
- Fix compensation without consideration of the fair market value

DEMONSTRATION & EVALUATION EQUIPMENT

- Loan equipment without a proper reason nor for a period exceeding 6 months
- Conceal the loan from the HCP's institution

INDEPENDENT THIRD PARTIES (ITPS)

- Fail to conduct due diligence on proposed ITPs
- Fail to monitor and train ITPs

MEETING, HOSPITALITY & CONFERENCES

- Invite to meetings in inappropriate locations
- Pay financial support to individual HCPs to attend third-party educational conference
- Contribute to conferences with no apparent scientific or educational content or value
- Treat the HCP in a lavish way
- Arrange for hospitality for Member's meeting or thirdparty procedure training which is excessive in relation to the meeting
- Extend invitations to others in addition to the HCP (e.g. spouses)
- Conceal your contribution from the HCP's institution

COCIR DONT'S

GIFTS & CHARITABLE DONATIONS

- Treat HCPs with multiple or excessive gifts
- Give cash or cash equivalents
- Donate for non-charitable causes or to non-charitable organisations
- Donate with the intent to influence a business transaction
- Conceal your donation from the HCP's institution

SPONSORSHIP

- Request the selection of certain speakers or individual HCPs for the conference organised by the professional conference organiser

EDUCATIONAL GRANTS

- Make grants to individual HCPs
- Use grants to directly fund endowments of professors, chairpersons of departments or other similar position, the attendance of named individual HCPs to thirdparty conferences or replace departmental budgets
- Make grants which are not restricted to medical education with no control of the use of grants by recipients of the grants
- Request the selection of certain speakers or individual HCPs for the third-party conference

PUBLIC PROCUREMENT

- Unduly influence technical specifications
- Offer, directly or indirectly, gifts or other benefits in order to improperly influence HCPs in the public tendering process
- Encourage Contracting Authorities to unduly seek exemptions from public tendering procedures

GUIDELINES GOVERNING COCIR MEETINGS & TELECONFE-RENCES

COCIR'S MISSION

COCIR's aim is to represent the interests of its radiological, electromedical, radiotherapy and healthcare IT industry members in Europe and abroad. COCIR also provides services to its embers and acts as a communication channel for key stakeholders including the European institutions and other regulatory bodies.

COCIR operates in Europe and has an office in China. COCIR also covers matters of common interest to its members beyond Europe.

COCIR seeks to promote the development of harmonised international standards and regulatory control which respect the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users and promote the free worldwide trade in these products.

GUIDELINES

COCIR offers a neutral platform that allows its members to discuss matters of common interest. However, meetings or teleconferences at which competing COCIR members participate give rise to a risk of competition law infringement.

These guidelines provide a general summary of the competition law rules and do not intend to be exhaustive. They are provided for informational purposes only and cannot be considered as legal advice. For further assistance or clarification, please contact a specialised lawyer.

BEST PRACTICE

- **DO** ensure that for any meeting organised by COCIR that an official COCIR representative is present.
- **DO** ensure that meetings and teleconferences have a legitimate purpose.
- **DO** ensure that agendas are agreed and circulated in advance of any formal meetings, and that accurate minutes are circulated thereafter.
- **DO** ensure that the attendance list is signed at the beginning of each physical meeting, and in the case of a teleconference, that it is properly documented.
- **DO** ensure that membership of working groups / participation criteria to meetings are transparent and nondiscriminatory.
- **DO** inform the COCIR meeting organiser if you have competition law concerns about the appropriateness of any discussion and/or any topic on the agenda.
- **DO** stop the discussion of any topic if you reasonably believe that it does not comply with competition/antitrust laws until such concerns can be ruled out, either during the meeting or afterwards. If efforts to stop the discussion are not successful, leave the meeting under protest and request that your protest be documented in the minutes.

WHAT MAY BE DISCUSSED

AMONG OTHERS, THE FOLLOWING MAY BE DISCUSSED:

- Non-confidential, technical issues relevant to the industry, such as standards, environmental concerns, matters related to corporate social responsibility, health and safety matters, regulatory policy developments.
- Public policy, educational and scientific developments.
- Publicly available information (e.g. trade press, newspapers and company websites) on industry trends or general market conditions, provided the information is not company specific and relates to the industry as a whole

Benchmarking exercises or market surveys provided these activities do not result in an exchange of competitively and/or commercially sensitive information among the participants; results must be presented in an aggregated form which does not allow the identification of individual companies

DO NOT DISCUSS

Any discussions, whether in a formal or informal context including mere information exchanges, could constitute an anti-competitive agreement or practice. To avoid liability, **DO NOT** reach understandings or agreements or even discuss any of the following commercially sensitive matters:

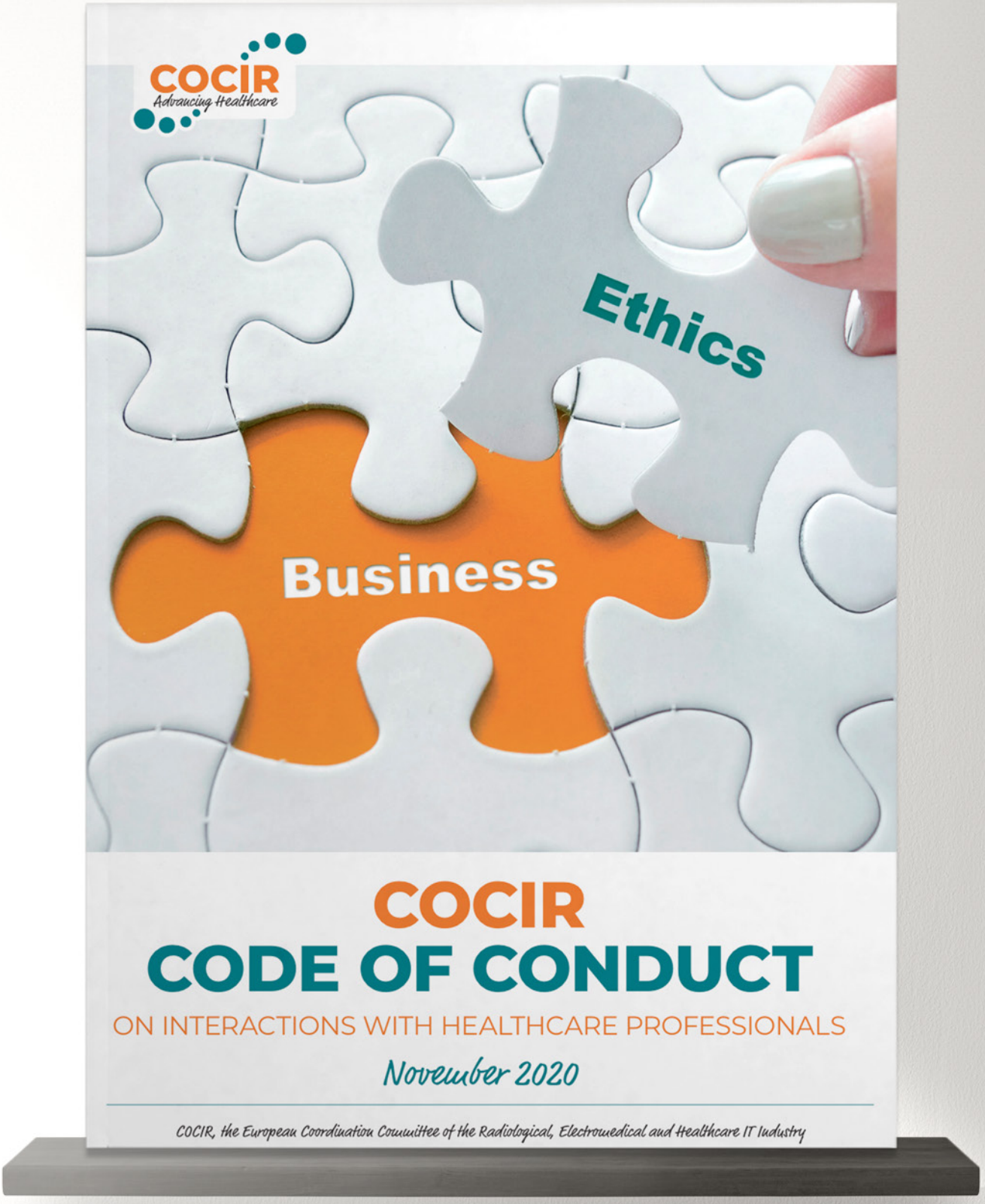
- Pricing strategies including price ranges, margins, discounts, rebates or any other element of pricing.
- Supply costs, operating costs or other overhead costs.
- Invoicing practices and payment terms.
- Market partitioning such as the allocation of customer groups, types of products or territories between competitors.
- Markets for expansion and investment.
- Commercial business plans, marketing or sales initiatives, development roadmaps and product portfolio plans.
- Any arrangement to avoid direct competition, or joint action to exclude competitors or new entrants to the market and/or to COCIR.

GUIDELINES ON MARKET STATISTICS INFORMATION EXCHANGE

COCIR collects market statistics data and strict confidentiality rules govern what information may be exchanged. The exchange of statistical information is typically **PERMITTED** when:

- only aggregated statistical information is shared with individual companies; and
- it does not allow the identification of individual companies.

However, it is **PROHIBITED** to exchange company-specific information between competitors, such as data on prices, costs, market shares, order and sales volumes (by units and/or values), marketing plans or inventories.



For more info and Q&As visit:
www.cocir.org/services/code-of-conduct

Our members
2024

COCIR COMPANY MEMBERS

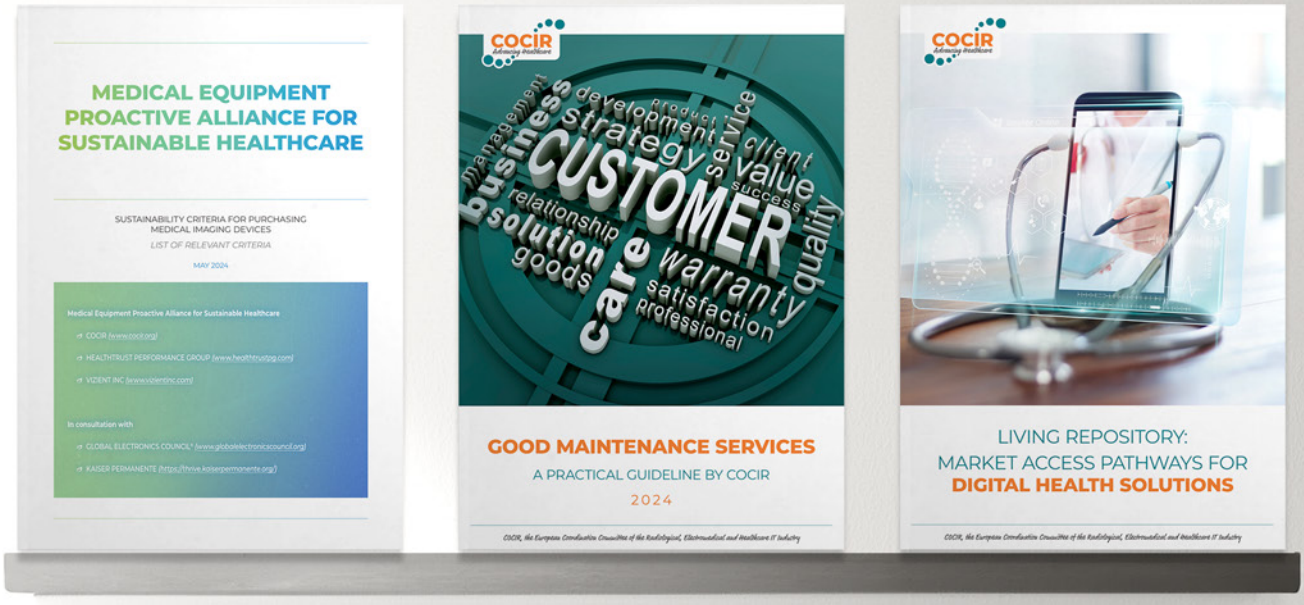
ACCURAY
AGFA HealthCare
AGFA
aidence
human sense in artificial intelligence
Alcon
BARCO
BAYER
Canon
CANON MEDICAL
Carestream
CMR SURGICAL
Dedalus
HEALTHCARE SYSTEMS GROUP
Elekta
EOS imaging
Epic
esaote
FUJIFILM
GE HealthCare
HOLOGIC
The Science of Sure
HUAWEI
iba
KONICA MINOLTA
LUXIUM SOLUTIONS
PHILIPS
SAMSUNG
SIEMENS Healthineers

NATIONAL TRADE ASSOCIATIONS MEMBERS:

Healthtech Finland — FINLAND
LE DISPOSITIF MÉDICAL SNITEM Pour faire avancer la santé — FRANCE
bvitg — GERMANY
zvei electrifying ideas — GERMANY
ETOSZ ASSOCIATION OF HEALTH TECHNOLOGY SUPPLIERS AND MEDICAL DEVICE MANUFACTURERS — HUNGARY
CONFINDUSTRIA Dispositivi Medici — ITALY
Associação Portuguesa das Empresas de Dispositivos Médicos apormed tecnologias para a saúde — PORTUGAL
FMed FEDERATIE VAN MEDISCHE TECHNOLOGIEBEDRIJVEN — THE NETHERLANDS
FME POWERED BY DUTCH TECHNOLOGY — THE NETHERLANDS
Fenin — SPAIN
SWEDISH Medtech — SWEDEN
TIP GÖR DER — TURKEY

www.cocir.org/members

Latest publications



Find all our publications on:
www.cocir.org/latest-news/publications

Acronyms

AI - Artificial Intelligence

AISBL - Association international sans but lucrative

BSS - Basic safety standards

COCIR - Comité Européen de Coordination des Industries Radiologiques, Électromédicales et d'informatique De Sante / European Coordination Committee of the Radiological, Electromedical and Healthcare Information Technology (IT) Industry

CT - Computed tomography

DHS - Digital Health Solutions

DITTA - Global Diagnostic imaging healthcare IT & radiation therapy trade association

EFTA - European Free Trade Association

EHDS - European Health Data Space

eHealth - Electronic health

GDPR - General Data Protection Regulation

HCP's - Healthcare Professionals

ICT - Information and Communication technology

IAEA - International Atomic Energy Agency

IHI - Innovative Health Initiative

ITPS - Independent Third Parties

LMICs - Low and Middle Income Countries

MDR - Medical Device Regulation

MFF - EU Multiannual Financial Framework

MI-PET - Molecular Imaging-pet

MRI - Magnetic Resonance Imaging

RRF - EU Recovery and Resilience Facility

RT - Radiation Therapy

SDGs - Sustainable Development Goals

SMEs - Small and medium-sized enterprises

WGs - Working Groups

ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association. Our industry delivers innovative, data-driven, safe and efficient diagnostic imaging, radiotherapy and digital health solutions.

COCIR's core objectives are:

To support the transformation of European health systems, enabling better health outcomes and better experiences for patients and professionals.

To promote the critical role of our industry as providers of essential or life-saving products and solutions for patients.

To strive for the best innovation climate for our industry in Europe.

COCIR aisbl | Bluepoint Building
Boulevard A. Reyerslaan 80
1030 Brussels | Belgium

Tel +32 (0)2 706 89 60
info@cocir.org
www.cocir.org | @COCIR

COCIR
Advancing Healthcare