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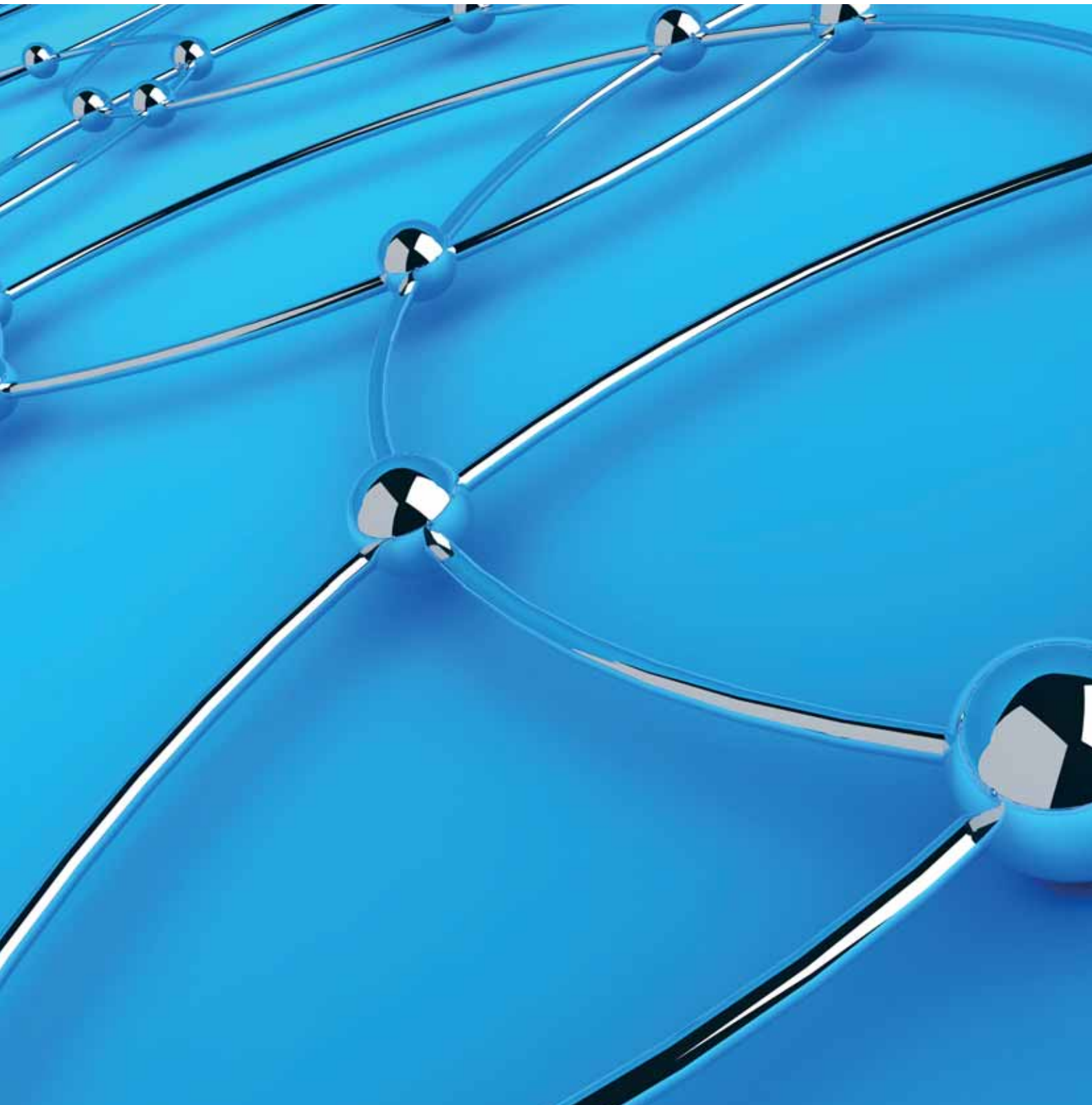
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IRISH MEDICAL TECHNOLOGY INDUSTRY

GUIDELINES ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Code of Ethical Business Practice



The Irish Medical Technology Industry Code of Ethical Business Practice consists of the Guidelines on Interactions with Healthcare Professionals and the Trade Associations' Guidelines and Competition Law.

This brochure contains only the Guidelines on Interactions with Healthcare Professionals.

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Code of Ethical Business Practice

These guidelines are intended to provide guidance on the interactions of **Irish Medical Device Association (IMDA)** and **IMSTA** members with individuals (clinical or non-clinical, including but not limited to, physicians, nurses, technicians and research co-ordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical devices ("Healthcare Professionals").

Members of the two Irish Medical Technology Industry associations recognise that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Healthcare Professionals.



All members should independently ascertain that their interactions with Healthcare Professionals comply with all current national and local laws, regulations and professional codes.

1. PREAMBLE

There are many forms of interactions between the members of the two Irish Medical Technology Industry associations and Healthcare Professionals that advance medical science or improve patient care, including:

- * **Advancement of medical technology:**
The development of innovative medical devices and the improvement of existing products require collaboration between members and Healthcare Professionals. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.
- * **Safe and Effective use of Medical Technology:**
The safe and effective use of medical technology requires members to offer Healthcare Professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.
- * **Research and Education:**
Members' support of bona fide medical research, education, and enhancement of professional skills contribute, amongst others, to patient safety and increase access to new technology.

Members of the two Irish Medical Technology Industry associations recognise that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Healthcare Professionals.

Members must encourage ethical business practices and socially responsible industry conduct related to their interactions with Healthcare Professionals. Members must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment.

The guidelines are based on the following key principles:

*** The Principle of Separation:**

Interaction between industry and Healthcare Professionals must not be misused to influence, through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of members' products.

*** The Principle of Transparency:**

Interaction between industry and Healthcare Professionals must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by requiring that prior written notification is made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.

*** The Principle of Equivalence:**

Where Healthcare Professionals are engaged by a member to perform a service for or on behalf of a member, the remuneration paid by the member must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.

*** The Principle of Documentation:**

For interactions between a member and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a member, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the member.

The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the member to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

Members should require that third party intermediaries, both sales intermediaries and other third party agents, including but not limited to, consultants, distributors, sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives, who interact with Healthcare Professionals in connection with the sale, promotion or any other activity involving members' products, comply with standards equivalent to these guidelines.

Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation imposes obligations upon the third party to comply with these or equivalent guidelines.

These guidelines set out the standards appropriate to various types of relationships with Healthcare Professionals. These guidelines are not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon members or Healthcare Professionals who engage in certain activities in those countries.

All members should independently ascertain that their interactions with Healthcare Professionals comply with all current national and local laws, regulations and professional codes.

Any hospitality should be reasonable in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Healthcare Professional is licensed to practise.



Members may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous.

2. MEMBER- SPONSORED PRODUCT TRAINING AND EDUCATION

Where appropriate, members should make product education and training available to Healthcare Professionals to facilitate the safe and effective use of medical technology. Such education and training programmes should occur at appropriate locations taking account of the convenience of the attendees and the nature of the training. In particular:

Programmes and events should be conducted in clinical, laboratory, educational, conference, or other appropriate settings, including members' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training. The training staff should have the appropriate expertise to conduct such training.

Members may provide attendees with reasonably priced meals in connection with the programme, and for educational programmes necessitating overnight stays, additional hospitality may be appropriate. Any hospitality should be reasonable in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Healthcare Professional is licensed to practise.

Members may pay for reasonable travel and accommodation costs incurred by an attending Healthcare Professional, in compliance with the regulations of the country where the Healthcare Professional is licensed to practise.

Members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for spouses or guests of Healthcare Professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

3. SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES

Bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective Healthcare. To these ends members may support such events provided the educational conference content promotes scientific knowledge, medical advancement and the delivery of effective Healthcare and is consistent with relevant guidelines established by professional societies or organisations for such meetings.

Irish Medical Technology Industry members may support such events by the provision of financial, scientific, technical, organisational and/or logistical assistance as follows:

* Healthcare Professional Sponsorship

Where permitted under national and local laws, regulations and professional codes of conduct, members may provide financial support to cover the cost of conference attendance by individual Healthcare Professionals. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event.

Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with such sponsorship and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, for example, by requiring that prior written notification of the sponsorship is made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority.

* Advertisements and Demonstrations

Members may purchase advertisements and lease booth space for company displays at conferences.

* Conference Support

Members may provide financial grants directly to the conference organiser to reduce the overall cost of attendance for participants and to cover reasonable honoraria, travel, meals and accommodation expenses of Healthcare Professionals who are bona fide conference faculty members. A written request must be made by the conference organiser, to the member and any sponsorship must be paid directly to the conference organiser or training institution. The conference organiser alone is responsible for the programme content and the faculty selection. Members may not have any detailed involvement in determining the content of the conference other than recommending speakers or commenting on the programme where requested to do so.

* Satellite Symposia

Members may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous. Members may determine the content of these events and be responsible for faculty selection.

The arrangement must be documented by written contract and the support of the member must be disclosed in all materials relating to the satellite event.

* Scholarships

Members may also provide educational grants to training institutions, Healthcare institutions or professional societies for medical education programmes by providing financial support for fellowships and similar scholarship awards. The selection of the grantee should be within the discretion of the institution at which they are enrolled or the teaching institution at which they will be trained. Grants must be provided to the teaching or professional institution, not to individual fellows, save at the prior written request of the institution. In no way should the funding be tied to an institution's purchase of a company's products, or otherwise be based on an institution's past or potential future use of the company's products or services.

Members may pay for reasonably priced meals for Healthcare Professional attendees in an environment that is conducive to the exchange of information.



Consulting arrangements with Healthcare Professionals must be described in a written agreement, signed by the parties and must specify the services to be provided.

4. SALES AND PROMOTIONAL MEETINGS

In the countries where it is appropriate for members to meet with Healthcare Professionals to discuss product features, conduct contract negotiations, or discuss sales terms, these meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business. In connection with such meetings, members may pay for reasonably priced meals for Healthcare Professional attendees in an environment that is conducive to the exchange of information.

Where plant tours or demonstrations of non-portable equipment are necessary, members may also pay for the reasonable travel and accommodation costs of Healthcare Professional attendees. However, members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for spouses or guests of Healthcare Professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

5. ARRANGEMENTS WITH CONSULTANTS

Healthcare Professionals may serve as consultants to members, providing meaningful bona fide services, including research, participation on advisory boards, presentation at member-sponsored training or third party educational conferences, and product development.

It is appropriate to pay Healthcare Professionals reasonable compensation for performing these services. The following factors support the existence of a bona fide consulting arrangement between members and Healthcare Professionals:

- * Consulting agreements must be entered into only where a legitimate purpose for the services is identified in advance.
- * Selection of consultants must be on the basis of the consultant's qualifications and expertise to address the identified purpose and should not be on the basis of volume or value of business generated by the consultant.

- * Consulting arrangements with Healthcare Professionals must be described in a written agreement, signed by the parties and must specify the services to be provided. Such arrangements must be consistent with the regulations of the country where the Healthcare Professional is licensed to practise.

- * The compensation paid to Healthcare Professionals engaged as consultants must be the fair market value for the services provided and must not be tied in any way to the value of medical devices which the consultants may use for their own practice. All payments made must comply with applicable tax and other legal requirements.

Members may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the engagement including reasonable and actual travel, meals and accommodation expenses incurred by consultants in attending meetings with, or on behalf of members. The written agreement should describe all expenses that can be claimed by the consultant in relation to the provision of the services.

- * Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with members engaging Healthcare Professionals as consultants. Where no such national requirements are prescribed, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, disclosing the purpose and scope of the consultancy arrangement.

- * All consultancy arrangements with Healthcare Professionals must be documented in writing even where the Healthcare Professional does not require payment for services or where the arrangement involves a one-day event only.

- * The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. The meetings should be conducted in clinical, educational, conference or other suitable settings, including hotel or other available meeting facilities, conducive to the effective exchange of information.

- * Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.

- * When a member contracts with a Healthcare Professional acting as a consultant for research services, the written agreement described above must reference a written research protocol or written schedule of work as appropriate and all required consents and approvals should be obtained.

- * When a member contracts with a Healthcare Professional for the development of intellectual property, there must be a written agreement providing compensation at a fair market value. However, under no circumstances may the Healthcare Professional receive any financial compensation in respect of medical devices he/she has prescribed in the past or may prescribe in the future, including medical devices which contain the novel intellectual property.

All required consents and approvals should be obtained, including from the hospital administration or the Healthcare Professional's superior (or locally-designated competent authority).

Members should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.



Members may make donations for charitable or other philanthropic purposes. Donations may be made only to charitable organisations or other non-profit entities entitled to receive them under applicable national or local laws and regulations.

6. GIFTS

Members occasionally may provide inexpensive, branded or non-branded items as gifts to Healthcare Professionals, if they are modest in value and in accordance with the national and local laws, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practise. Gifts must relate to the Healthcare Professional's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

7. PROVISION OF REIMBURSEMENT AND OTHER ECONOMIC INFORMATION

Members should support accurate and responsible billing to reimbursement authorities and other payors. In doing so, they provide economic efficiency and reimbursement information to Healthcare Professionals and third party payors regarding members' products. This information should be limited to identifying appropriate coverage, coding or billing of member products, or procedures using those products, or to encouraging the economically efficient delivery of member products. This section is not intended to address the legitimate practice of providing technical or other support intended to aid appropriate use or installation of the member's products

8. DONATIONS FOR CHARITABLE AND PHILANTHROPIC PURPOSES

Members may make donations for charitable or other philanthropic purposes. Donations may be made only to charitable organisations or other non-profit entities entitled to receive them under applicable national or local laws and regulations. Donations may be made to support the general activities of a bona fide organisation or may be made to support general fund raising drives for projects undertaken by such an organisation.

Charitable donations must not be tied in any way to past, present or potential future use of the member's products or services.

All donations to a charity or non-profit organisation should be appropriately documented. For example, a written request should be submitted by the charitable organisation, detailing the purpose of the charity and the nature of its activities. The payment should be made out in the name of the charity and paid directly to the charity. Charitable donations to a bona fide organisation should not be made in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the organisation and submits the request on behalf of the organisation. It would not be appropriate for a member to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional.

Members should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.

9. EDUCATIONAL GRANTS

Members may provide funds to support genuine independent medical research, advancement of medical science or education, or patient and public education. However, it is important that support of these programmes and activities by members is not viewed as a price concession, reward to favoured customers or inducements to recommend, prescribe or purchase members' products or services. Therefore members should ensure that they maintain appropriate documentation in respect of all educational grants made.

Educational grants must not be tied in any way to past, present or potential future use of the member's products or services.

Educational grants may be made only to organisations or entities entitled to receive them under applicable national and local laws and regulations and should not be made to individual Healthcare Professionals. (For guidance on how members may support the education of individual Healthcare Professionals refer to Section III Supporting Third Party Educational Conferences). Examples of appropriate educational programmes and related considerations are as follows:

* **Scholarships.**

Professional organisations, hospitals and universities where Healthcare Professionals are in training may be eligible to receive grants to support scholarships. For guidance on how members may support scholarships and similar awards refer to Section III Supporting Third Party Educational Conferences.

* **Advancement of Healthcare Education.**

Members may support Healthcare Professional education by donating funds to institutions or organisations for either accredited or non-accredited Healthcare education. For further guidance on how members may support such education, refer to Section III Supporting Third Party Educational Conferences.

* **Research.**

Research grants to support customer-initiated studies may be permitted for programmes involving clinical or non-clinical research in areas of legitimate interest to the member. The member may provide funds for documented expenses, in-kind services, or free product to support clearly defined bona fide research activities of Healthcare Professionals where permitted by national and local laws, regulations and professional codes of conduct. All requests for research grants must be in writing from the requestor stating the nature and objective of the research activity. No support should be provided until a written agreement is signed by both parties and said agreement should provide for adverse event reporting where appropriate. Full disclosure of the award must be made to the hospital administration, or the Healthcare Professional's superior, or other locally-designated competent authority as appropriate and the recipient of the grant shall be required to acknowledge the member's support of the research in all oral or written presentations of the results.

* **Public Education.**

Members may make grants for the purpose of supporting education of patients or the public about important Healthcare topics.



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