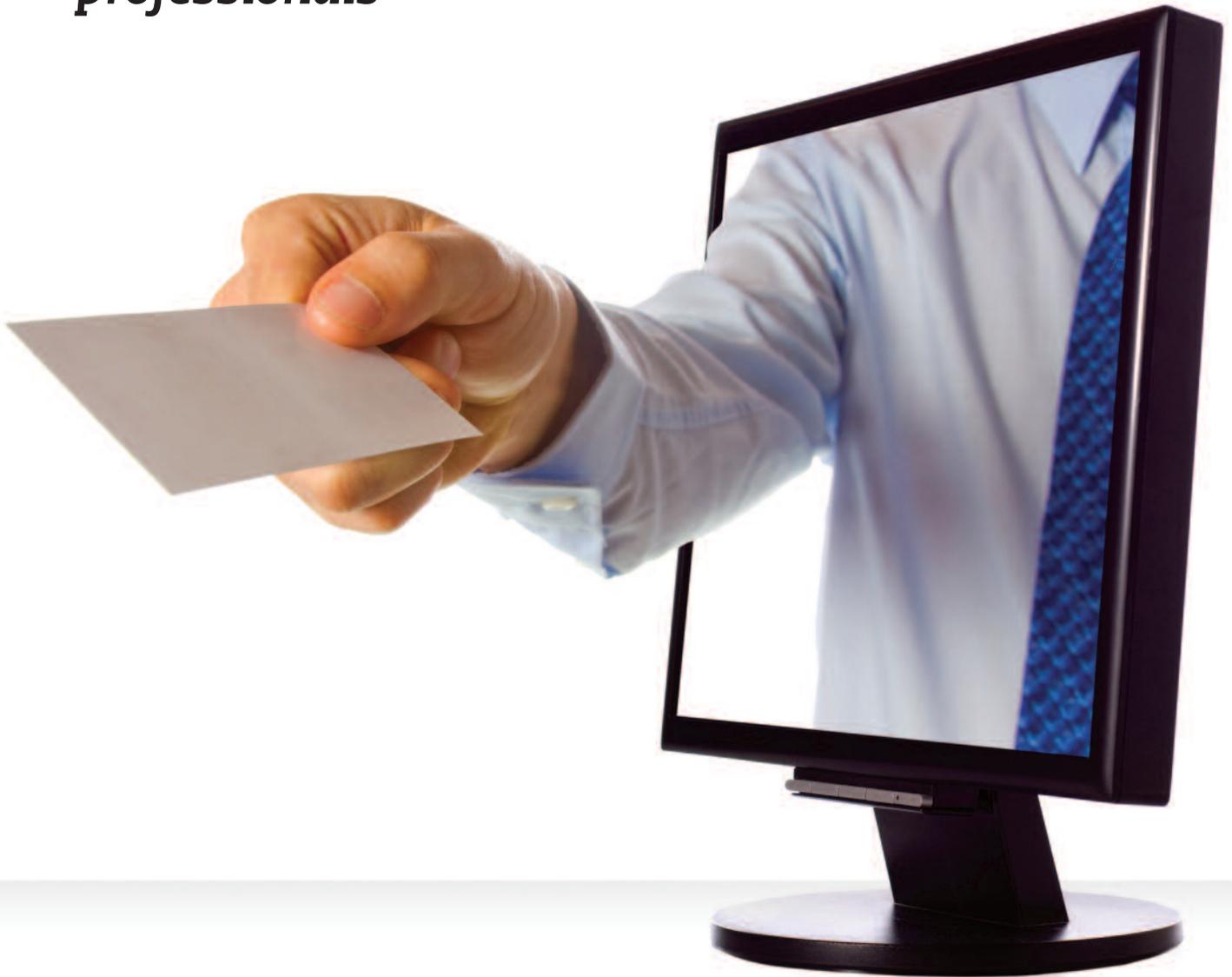




Direct-to-consumer medical advertising in Ireland

***Informing and empowering
patients, doctors and healthcare
professionals***



Irish College of
Ophthalmologists
Eye Doctors of Ireland
Protecting your Vision

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Summary

Healthcare and health outcomes have advanced significantly in the past 20 years. Diagnostics and treatments for medical conditions have improved, and advances have also been made in methods to improve aspects of our physical appearance. The procedures, techniques, and principles of cosmetic surgery are entirely focused on enhancing a patient's appearance. As the areas being treated already function properly, cosmetic surgery is classed as elective.

All surgery contains a certain element of risk and it is essential that consumers are reliably informed of both the risks and benefits of any procedure before making a decision to proceed. Due to the elective nature of cosmetic procedures, in many cases they are provided by, and undertaken in, private clinics. It can be difficult for prospective patients to know which practitioners or what procedures are safe or appropriate for them. Patients are often reluctant to approach their general practitioner (GP) for advice on elective procedures and may be particularly influenced by advertising or marketing material.

With regard to the powerful impact of advertising, the following points should be noted:

- **Direct-to-consumer advertising of medical procedures is currently unregulated in Ireland.**
- **Advertising that only emphasises the benefits of such procedures can lead to unrealistic expectations.**
- **Unmet expectations can predispose patients to take legal action.**
- **The increasing incidence of litigation and the cost of professional indemnity is driving doctors out of practice**
- **Medical or surgical procedures must not be regulated in the same manner as consumer or lifestyle goods**

The Irish College of Ophthalmologists (ICO) has raised concerns with the Advertising Standards Authority for Ireland (ASAI) about what it regards as inappropriate medical advertising, including incentives such as the chance to win free surgery or discounts for multiple procedures.

The ICO, together with its medical colleagues from the specialties of plastic and reconstructive surgery and dermatology, has cautioned that a lack of regulatory oversight impacts on prospective patients' access to unbiased information, and that the appropriateness of certain direct-to-consumer advertising of medical procedures is questionable.

A factor that must also be considered is whether advertising that only states the benefits of medical procedures is leading to raised and, at times, unrealistic expectations among the patient population, thus contributing to a more litigious environment. The cost of claims to the State is considerable and the continued increases in professional indemnity costs for medical practitioners are unsustainable.

This report explores some of the issues involved and concludes that tighter guidelines or formal legislation controlling direct-to-consumer medical advertising is required in order to safeguard and promote patient safety and enhance the consumer's ability to make a fully informed decision before undertaking a procedure.

The Irish College of Ophthalmologists (ICO) is the training and professional body for eye doctors and the medical authority on eye care in Ireland.

1. Introduction – an overview of the current situation in Ireland and abroad

Advances in medical technology have made the provision of treatment of certain conditions commercially attractive. Coupled with the rapidly growing cosmetic intervention sector, this commercialisation of medicine and the increase in the dissemination of information to the public has particularly impacted on the specialties of plastic and reconstructive surgery, dermatology and ophthalmology.

Medical service providers use advertising and marketing to compete for consumers. While advertising has a legitimate role in providing information it can, however, have an adverse impact particularly if it trivialises the risks of procedures, targets vulnerable consumers, or misleads people by portraying an outcome that may not be attainable for all.

There is some evidence that unrealistic expectations prior to surgery increase the likelihood of malpractice litigation following surgery, regardless of the medical outcome.

The decision to have a medical or surgical procedure can have a profound impact on the health and well-being of both the patient and their family. While there is little doubt that a procedure can be positive for patients when undertaken by trained specialists with appropriate aftercare, it is essential that patients receive balanced information and are fully informed of the potential risks and benefits.

For some, the cost of certain procedures can be a deciding factor in influencing their choice of service provider, even more influential than the qualifications of the person performing the procedure and the quality of care they provide. Trivialising surgery to the point where the decision to proceed is solely based on cost or convenience is not compatible with the prioritisation of patient safety and quality outcomes.

Currently, in Ireland, there are no regulatory requirements for advertisements or marketing material to provide any information on the health risks of procedures.

The Fine Gael/Labour Programme for Government committed to the introduction of a national licensing system for healthcare facilities. The Department of Health and Children is currently drafting proposals relating to the development of a licensing framework for health and social care facilities. The Framework which will be included in the **Patient Safety (Licensing) Bill** will provide for a mandatory system of licensing for public and private health and social care providers. It will be designed to improve patient safety by ensuring that providers do not operate below standards which are applied in a consistent and systemic way.

The ICO proposes that this legislation, which will impose controls on the operation of the facilities and clinics, includes responsible advertising and marketing standards.

The proposed licensing system is in addition to other patient safety policy initiatives in progress by the Government, including recently completed work on the Code of Conduct for employers that clearly sets out employers' responsibilities in relation to achieving an optimal safety culture, governance and performance in their organisation.

It is the shared view of the ICO, the Irish Association of Dermatologists (IAD) and the Irish Association of Plastic Surgeons (IAPS) that medical advertising should concentrate on educating the public rather than be used as a medium to entice prospective patients through the use of attractive or reduced pricing, along with competitions and time-limited offers.

International context

Discussion of this topic is not unique to Ireland. Healthcare stakeholders across the United Kingdom (UK), Europe and Australia among others have deliberated, and continue to deliberate, on these issues.

In the UK, Sir Bruce Keogh, Medical Director of the National Health Service (NHS), led an expert group which reviewed the regulation of cosmetic interventions. The final report of the group was published in April 2013 and included recommendations for responsible advertising and marketing.¹

In response to the report, both the UK Government and the Department of Health said they fully accepted the principles of the review and the overwhelming majority of its recommendations for protecting people who choose cosmetic procedures.

In Australia, the Cosmetic Surgery Working Group for the Australian Health Ministers' Advisory Council reviewed the adequacy of consumer safeguards regarding cosmetic medical and surgical procedures including those in relation to advertising, marketing and recruitment. The Working Group made recommendations on the need for, and nature of, additional safeguards for consumers and developed a framework for progressing such safeguards, including advertising restrictions.²

In France, aesthetic plastic surgery cannot be advertised or promoted to the public in any form, direct or indirect. The changes initiated in France were in response to public demands following a breast implant recall which drew attention to the lack of traditional safeguards for patients; the implants manufactured by Poly Implant Prothèse (PIP) were found to contain unauthorised silicone gel instead of a more expensive medical-grade silicone.

Current Irish guidelines

To practise in Ireland a doctor must be registered with the Irish Medical Council. The Medical Council publishes a *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, which includes guidelines for the provision of information to the public and advertising.³ The Guide advises doctors that they must ensure that the information they publish is true, verifiable, does not make false claims or have the potential to raise unrealistic expectations, and should include information about any inherent risks associated with the services provided.

The ASAI, the independent self-regulatory body set up and financed by the advertising industry, implements a code of standards for advertising and marketing in Ireland. It applies to commercial marketing communications and to promotions designed to boost the sale of goods or services.⁴ The Code contains a set of general rules, which are supplemented by additional requirements for particular products or sectors including the health and beauty sector. Following a review by the ASAI, an updated Code was launched on 17 September 2015 for implementation from 1 March 2016. The new seventh edition of the Code has been retitled *Code of Standards for Advertising and Marketing Communications in Ireland*. While the ICO welcomes and acknowledges the amendments made to the health and beauty section, the ICO's view is that specific regulation of advertising of medical and surgical procedures is required.

In February 2015, the ICO published *Guidelines for Refractive Surgery in Ireland* as a reference for the public, patients and healthcare professionals.⁵ The guidelines, which were developed to assist people in making an informed decision, include a section on advertising, discouraging time-limited deals and the promotion of unrealistic expectations.

In formulating the guidelines, the ICO worked closely with its members and with the other relevant expert bodies, including the Medical Council, patient associations and the ASAI, in order to ensure that they set the appropriate standard.

The guidelines provide the public with information on what to expect during the process, from decision-making to post-operative care. This document is an important step in the ICO's continued efforts to safeguard patients and provide accurate information to the public.

'Medical Advertising in Ireland' Conference – Multi-stakeholder consultation

In September 2014, the ICO convened a multi-stakeholder meeting at the Royal College of Surgeons in Ireland (RCSI) to facilitate a review of the current practice of direct-to-consumer medical and surgical advertising in Ireland.

The discussions at the 'Medical Advertising in Ireland' meeting focused on whether tighter guidelines or formal legislation controlling direct-to-consumer medical advertising are required to safeguard and promote patient safety and enhance a patient's ability to make a fully informed decision before undertaking a procedure.

¹ *Review of the Regulation of Cosmetic Interventions, Final Report Department of Health, April 2013, available at <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>*

² *Cosmetic Medical and Surgical Procedures: A National Framework, Australian Health Ministers' Conference 2011, available at <http://www.health.nsw.gov.au/publications/Documents/cosmetic-surgery.pdf>*

³ *GUIDE TO PROFESSIONAL CONDUCT AND ETHICS FOR REGISTERED MEDICAL PRACTITIONERS Medical Council 2009, available at <http://www.medicalcouncil.ie/News-and-Publications/Publications/Information-for-Doctors/Guide-to-Professional-Conduct-and-Ethics-for-Registered-Medical-Practitioners.pdf>*

⁴ *Manual of Advertising Self-Regulation with the Code of Standards for Advertising, and Marketing Communications in Ireland ASAI 2015 available at http://www.asai.ie/wp-content/uploads/ASAI-CODE_2015.pdf*

⁵ *Guidelines for Refractive Surgery in Ireland Published by the Irish College of Ophthalmologists, February 2015 [http://eyedoctors.ie/medium/files/ICO_Guides_Refractive_Surgery_Final_\(web\)-r.pdf](http://eyedoctors.ie/medium/files/ICO_Guides_Refractive_Surgery_Final_(web)-r.pdf)*

The aim was to enable the exchange of views between those working in the specialties whose patients are most impacted by this form of advertising, alongside consideration of the views of the regulators and the patient advocacy bodies in order to reach a consensus on what the next steps should be.

Stakeholder's involved in the discussions on the day included representatives from the ASAI, Irish Medical Council, Health Service Executive (HSE), Injuries Board, Royal College of Physicians of Ireland (RCPI), Royal College of Surgeons in Ireland (RCSI), Law Society of Ireland, Broadcasting Authority of Ireland (BAI), Irish Patients Association, and medical press.

The ICO has previously raised concerns and highlighted examples of what it regards as inappropriate medical advertising with the ASAI, including the activities of companies that offer incentives such as the chance to win free laser eye surgery.

The ICO, together with its medical colleagues from the specialties of plastic and reconstructive surgery and dermatology, has expressed concern that the lack of regulatory oversight impacts negatively on patients' access to unbiased information and that the appropriateness of certain direct-to-consumer advertising of medical procedures is questionable.

This report reflects the views given by the experts invited to the multi-stakeholder meeting and the conclusions drawn from the discussions and debate.

2. Medical perspective on direct-to-consumer medical advertising

The three specialties of medicine on which direct-to-consumer advertising is particularly focused are ophthalmology, dermatology and plastic and reconstructive surgery. The medical practitioners in these specialties unanimously agree that the patient should be in a position to make the most informed choice, without unrealistic advertising influencing their decision.

Advertising and marketing practices should not trivialise the seriousness of procedures or encourage people to undergo them hastily. Any claims made about the effects of treatments must be based on high-quality evidence and should not raise unrealistic expectations.

Areas of particular concern relating to coercive and inappropriate direct-to-consumer sales techniques include:

- Financial inducements
- Time-limited deals to promote interventions
- Surgery being offered as a raffle prize
- Celebrity endorsements
- Package deals, such as 'buy one get one free' or reduced prices for two people such as mother and daughter deals, or refer a friend.

In the area of cosmetic surgery advertising, the use of photographs of models who have never undergone the cosmetic treatment being advertised is creating unrealistic expectations for consumers. The use of such models and/or airbrushed photographs has been banned in some countries, including France and Denmark. There are misleading advertisements on websites, in beauty salons and in pharmacies promoting treatments that claim to eradicate wrinkles; these advertisements use before and after photographs portraying results that cannot possibly be achieved by the treatment suggested.

Incentives such as "reductions for a friend" and "special price for a limited time" are contrary to the concept of informed consent, which is a legal requirement for any surgery or medical treatment. In other jurisdictions, these practices are seen as "incentivising" the consumer and considered not to be in their best interests, and both the practice and the advertising of such offers have been banned.

It is mandatory for all doctors practising in Ireland to be registered with the Irish Medical Council, including those doctors in training. Marketing material often includes the statement "fully registered with the Medical Council", as if to suggest some specialist level of registration, which is misleading. As registration is a statutory requirement, this statement cannot be used in advertising to imply a higher level of registration. The distinction is not clear to the public. In the area of dermatology, concerns in relation to direct-to-consumer advertising include the marketing of mole mapping and pigmented skin lesions, laser and light devices, and cosmetic injectables and treatments.

It is the shared view of the three specialties referred to above that the current regulatory system needs to be revised to provide clearer rules under which advertisers can be held to account, which also reflect the changing market, particularly the enormous growth in non-surgical procedures and the increasing use of digital marketing. Standards must ensure that any advertising is conducted in a socially responsible manner. The ICO propose that responsible advertising and marketing standards must be included in the new licensing for healthcare facilities legislation.

The legislative prohibition on the underage use of sunbeds in Ireland, coupled with a ban on advertising the benefits of sunbed use, is an example which highlights how regulation can be successfully implemented in the interests of patient safety.

Key recommendations from clinicians:

1. Regulation of direct-to-consumer advertising for medical or surgical procedures is required.
2. Inclusion of responsible advertising and marketing standards in the new licensing of healthcare facilities legislation
3. Standards and safeguards must apply equally in the public and private sectors.
4. Financial inducements must not be used to entice patients to undergo procedures, and providers should not offer financing for procedures they will subsequently provide.
5. Marketing materials must be designed to safeguard patients from unrealistic expectations. Claims must be objectively substantiated.
6. Advertisements should not offer discounts linked to a deadline date for booking appointments for surgery, or other date-linked incentives.
7. Advertisements should not offer surgery as a competition prize or trivialise surgery by offering it as a package deal (e.g. refer a friend, reduced price for two people).
8. Profit motivation must not override safety.
9. Listing of qualifications of practitioners must be mandatory.

3. Regulatory perspective

Regulation of advertising

Currently, there are no regulatory requirements for advertisements or marketing material to provide any information on the health risks of procedures.

Advertising in Ireland is self-regulated. The ASAI is the independent, self-regulatory body set up and financed by the advertising industry to promote and monitor the standards of marketing communications, promotional marketing and direct marketing. It does this primarily through its *Code of Standards for Advertising and Marketing Communications in Ireland*.

The ASAI's Complaints Committee comprises six advertising representatives and seven independent members (a secondary school teacher, three civil servants, a psychotherapist, a psychologist/academic and the CEO of a State body).

The activities of the ASAI include: the enforcement of the *Code of Standards for Advertising and Marketing Communications in Ireland*; the handling of enquiries and requests for advice; the investigation of complaints and the publication of its adjudications; monitoring advertising; providing copy advice (free and confidential); issuing guidelines on particular trends or problems; and operating information/educational programmes.

There are three grounds on which a review of the Complaints Committee's decision may be requested: new evidence, decision clearly and manifestly in error, or substantial procedural flaw.

Regulatory issues have arisen in relation to:

- Qualifications required for medical/surgical procedures
- Initial consultation and aftercare
- Suitability of premises for surgical procedures
- Marketing and promotions for medical services

In September 2014, the ASAI participated in the consultation process with the ICO and other key stakeholders at the 'Medical Advertising in Ireland' meeting to review the practice of direct-to-consumer advertising in this country. The ASAI acknowledged that discussions at this meeting were instrumental in informing the review group on the views of key stakeholders and as they prepared the seventh edition of the Code.

While the ICO welcomes and acknowledges the amendments made to the health and beauty section of the new Code, the position remains unchanged and distinct regulation of advertising of medical and surgical procedures is required.

The ASAI compiled its own report on the appropriate steps to reflect the following points:

- The current regulatory system needs to be updated to provide clearer rules under which advertisers can be held to account.
- Regulatory standards need to reflect the changing market, particularly the enormous growth in non-surgical procedures and the increasing use of digital marketing.
- Standards must ensure that any advertising is conducted in a socially responsible manner.
- Advertising and marketing practices should not trivialise the seriousness of procedures or encourage people to undergo them hastily.
- Any claims made about the effects of treatments must be based on high-quality evidence and should not raise unrealistic expectations.
- A requirement for listing the qualifications of practitioners should be introduced.
- Promotions/prizes related to advertising for medical procedures to be performed by a registered medical practitioner should be curbed.
- The requirement for substantiation for all claims related to the efficacy of medical products and services should be emphasised.

Regulation of medical practitioners

To practice in Ireland a doctor must be registered with the Irish Medical Council – Medical Practitioners Act (2007)⁶. The Medical Council publishes a 'Guide to Professional Conduct and Ethics for Medical Practitioners'.⁷

In the seventh edition of the Guide, published in November 2009, guidelines for the provision of information to the public and advertising were further refined in paragraph 54 and in particular paragraph 54.4 (Appendix 3). It advises doctors that they must ensure that the information they publish is true, verifiable, does not make false claims or have the potential to raise unrealistic expectations and should include information about any inherent risks associated with the services provided. The guidelines stipulate that information communicated to the public in relation to the availability of medical services should be in the public interest and be factually accurate, evidence based and not misleading.

While the provisions relating to the dissemination of information in the Ethical Guide are acknowledged, it must be stressed that currently in Ireland there is no regulation **specific to the advertising and marketing of medical procedures**. Due to the nature and sensitivities of medical advertising and the potential risk of a negative outcome for patients, existing controls including those set out in the ASAI voluntary code, are insufficient.

Marketing and advertising for elective medical procedures has increased considerably in recent years and it is the view of the ICO, the IAPS and the IAD that advertising of medical procedures cannot be managed in the same way as consumer advertising. The end product and outcome of the two are not comparable. Protection for prospective patients must be introduced.

As a first step to address this, the ICO has devised specific advertising guidelines.⁸

The ICO is also proposing to Government that provisions specific to the responsible advertising of medical and surgical procedures be included in the forthcoming Patient Safety (Licensing) Bill. This will ensure that all medical facilities offering such services are regulated in this regard.

Regulation of solicitors

Solicitors practising in Ireland are regulated by the Law Society of Ireland. The rules of professional conduct are derived both from statutory and non-statutory sources. The Solicitors Acts 1954 to 2011, and the regulations made under these Acts, are the legislative framework for the regulation of solicitors. Advertising by solicitors is subject to statutory regulation. *S.I. No. 518 of 2002. Solicitors (Advertising) Regulations 2002* details the very specific criteria that solicitors must meet with regard to the advertising of their services.⁹ The legislation provides that when a solicitor is advertising he/she

should ensure that the advertisement does not encourage personal injury litigation. Advertising should be couched in terms which do not give offence to members of the public or to members of the profession. A solicitor should not advertise in a manner which brings the profession into disrepute. The legislation also details that a direct, unsolicited approach may not be made to any person who is not an existing client with a view to being instructed to provide legal services, where this is likely to bring the solicitors' profession into disrepute. In particular, approaches should not be made at inappropriate locations, for example, adjacent to a calamitous event or in the vicinity of a Garda station, prison or courthouse.

The Law Society publishes *A Guide to Good Professional Conduct for Solicitors*, which includes information on the advertising and marketing regulations and restrictions.¹⁰

The regulations were brought into force in response to concerns regarding inappropriate advertising, particularly with respect to personal injuries claims, which were seen to have the effect of encouraging people to pursue claims. Initially, the Law Society's role was primarily reactive, one of responding to complaints received. However, in the recent past, the Society has adopted more of an enforcement role with regard to inappropriate advertising and has become much more proactive in its monitoring of external media to identify those who are transgressing the regulations.

The regulation of solicitors' advertising and marketing activities provides a very good example of how formal regulation can be implemented in the area of direct-to-consumer communications.

4. Consumer perspective

The view of the Irish Patients' Association is that the current system of regulation is not robust enough to protect the patient and it gives rise to a patient safety issue that requires urgent action. The eight years of campaigning that was necessary to instigate a ban on the underage use of sunbeds in Ireland was an unacceptable time to have to wait for this protection for the public to be put in place. The Association is of the opinion that legislation governing the advertising and carrying out of medical procedures and treatments is necessary and that the Department of Health has a key responsibility, alongside other stakeholders, to develop a public awareness campaign to help inform and empower people.

The medical media has written extensively about the issues involved. In 2014, *The Medical Independent* published a series of investigative articles by journalist Catherine Reilly on the increased commercialisation of medicine in Ireland. The series highlighted the fact that, currently, the self-regulating ASAI adjudicates on complaints associated with advertisements; however, in cases where communications are deemed by the Authority to have broken rules, the usual remedy is that the advertisement be withdrawn or amended. In the case of medical-related advertisements, which may have already influenced vulnerable consumers, this would appear to be 'too little, too late'.

The Medical Independent series raised a number of issues including:

- Having unregulated people performing particular procedures is not merely an advertising matter.
- While the ASAI can draft a code, these recommendations have to be submitted to the National Consumer Agency and the Competition Authority for approval, before they can be adopted.
- The Irish Medical Council has no jurisdiction over the way these commercial medical entities are being run or the standards they employ, and this is a major defect.

The series concluded that stronger regulation and sanctions are required and that a new or adapted structure to monitor standards associated with the advertising of elective medical treatments may need to be considered, and that the Department of Health should have a role in this area.

⁶ *Medical Practitioners Act (2007)*, Irish Medical Council, available at <http://www.irishstatutebook.ie/2007/en/act/pub/0025/>

⁷ *GUIDE TO PROFESSIONAL CONDUCT AND ETHICS FOR REGISTERED MEDICAL PRACTITIONERS* Medical Council 2009, available at <http://www.medicalcouncil.ie/News-and-Publications/Publications/Information-for-Doctors/Guide-to-Professional-Conduct-and-Ethics-for-Registered-Medical-Practitioners.pdf>

⁸ *ICO Advertising and Marketing Guidelines* available at http://www.eyedoctors.ie/medium/files/ICO_Advertising_Marketing_Guidelines-x.pdf

⁹ *Solicitors (Advertising) Regulation, The Solicitors Act 2002*, available at <http://www.irishstatutebook.ie/2002/en/si/0518.html>

¹⁰ *A Guide to Good Professional Conduct for Solicitors, The Law Society of Ireland*, available at <https://www.lawsociety.ie/Documents/committees/conduct-guide.pdf>

5. Realistic outcomes and unmet patient expectations

There is considerable research regarding the impact on the public's health, both beneficial and harmful, of the advertising of medicines. On the one hand, it can inform, educate and empower patients; on the other hand, it may also misinform them by, for example, overemphasising a drug's benefits. This can strain the relationship between a patient and their doctor by diminishing a patient's trust in their doctor's clinical decisions.¹¹ There are similar concerns regarding the advertising and marketing of surgical procedures. Information can be both empowering and, at the same time, biased and the impact of advertising on consumer decision-making has also been well documented. The research has shown that when evidence about quality in a product category is ambiguous, advertising has the potential to be quite persuasive.¹² The sequence in which we encounter information influences our subsequent judgements; first impressions matter, therefore patients' expectations of the treatment process and its likely outcome have a significant impact on the level of satisfaction subsequently experienced.

The cost of insurance to indemnify doctors against potential personal injuries claims is spiralling, and is becoming unsustainable for many doctors. The processes by which patient expectations are formed must be examined, in order to determine whether they are a contributing factor to the surge in medical malpractice legal cases in Ireland. The increasingly litigious environment is also a significant cost to the state. In *Patient expectations: How do they Matter?* Jayasankar (2009) discussed the fact that unrealistic expectations are preventable triggers for claims.¹³

It is crucial that management of a patient's expectation as to the outcome of their surgery is addressed during every stage of the treatment process. Patients must be aware of both the risks and the potential benefits of the procedure and, in the case of elective surgery, whether the individual is deemed a suitable candidate by the surgeon.

Elective procedures are routinely advertised with 'before and after' photographs; through the use of computer-generated images, models who have not undergone the specific treatment are often used. Before and after photographs create an image of the end product and before a patient has even had their initial consultation with the doctor, they often have a very definite perceived expectation of their outcome.

Jayasankar (2009) recommends prudent use of computer imaging, warns against overzealous representation of a surgeon's skill, and advises that less-than-favourable outcomes must also be depicted to show the full range of possible results. This new technology becomes a liability if a clinician escalates expectations without providing the full picture of risks and benefits.

Jayasankar's study cites that a patient's disappointment with an unexpected turn of events or outcome is a key driver for medical liability claims. Integral to quality care and among the risk-prevention efforts under our control is, according to Jayasankar, appropriate patient education to ensure that patients have realistic expectations about the risks, rehabilitation, and outcome of a (in this case orthopaedic) procedure.

Jayasankar examines how a patient develops expectations and observes that in this information era, patients 'learn' from a growing number of sources with varying validity. In addition to hearing from family, friends, and others who have experienced the surgery or treatment, patients can be influenced by conventional news sources and internet sites with information of variable quality and potential bias or sensationalism.

According to the Medical Protection Society (MPS), 'the protracted and challenging process of responding to a litigation claim can make it a distressing experience. The paradox is that, in general, outcomes from healthcare in Ireland have never been better, and yet doctors have never been more likely to receive a complaint, claim or be referred to the Medical Council.'¹⁴

¹¹Connors, AL. (2009) 'Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics', *Albany Law Review*, 73(1), pp. 243–282 and Abel GA., Penson RT., Joffe S. et al. (2006) 'Direct-to-Consumer Advertising in Oncology', *Oncologist*, 11(2), pp. 217–226.

¹²Hoch, S. and Young-Won, Ha. (1986) 'Consumer Learning: Advertising and the Ambiguity of Product Experience', *Journal of Consumer Research*, 13(2), pp. 221–233.

¹³Jayasankar, S. (2009) 'Patient Expectations: How do they Matter?' *Journal of the American Academy of Orthopaedic Surgeons* <http://www.aaos.org/news/aaosnow/mar09/managing6.asp>

¹⁴Dinwoodie, M. 'Why Patients Sue... and How to Try and Avoid it'. *Medical Protection Society* <http://www.medicalprotection.org/ireland/casebook/casebook---may-2014/why-patients-sue-and-how-to-try-and-avoid-it>

Most clinicians believe that litigation arises when patients are treated outside accepted standards of care resulting in an adverse outcome. However, the causes of litigation are much more complex.¹⁵

The MPS says that analysis of claims tends to revolve around the precipitating clinical factors, such as a delay in diagnosis, incorrect surgical technique or medication error. However, the risk of complaint and litigation appears to have much more to do with predisposing factors such as clinicians' communication skills, sensitivity to patient needs and management of expectations, than with the complexity of the patient's condition, patient characteristics or technical and clinical skills.¹⁶

If the patient has an experience that is very different from what they are expecting, these unmet expectations lead to a 'disappointment gap', which can be a powerful 'predisposing factor' in a decision to take some sort of action. The patient's perception of the outcome or experience may be very different from that of the clinician, or even reality, but it is the patient's perception that matters in terms of dissatisfaction. In commercial terms, this is equivalent to 'over-promising and under-delivering'.

Advertisements which assure 'life-changing' results from surgery are, in the view of the ICO, the IAD and the IAPS, inappropriate. No surgery is risk free and controls on advertising which indicates the contrary are required. All medical interventions imply risk and while those risks may be infrequent or rare, prospective patients must be fully informed.

A medical or surgical procedure cannot and must not be regulated in the same manner as other lifestyle consumables.

The Medical Council's *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* outlines the importance of the full disclosure to the patient of the risks and benefits of the procedure. While this is welcomed it does not, in the view of the ICO and the other medical representative bodies that are seeking tighter regulation, go far enough in addressing the increasing advertising by commercial entities of medical procedures. Regulation is required to ensure an environment of transparency and full disclosure.

6. Conclusions and recommendations

In the interests of patient safety and transparency, regulation of direct-to-consumer medical advertising is urgently required.

Standards and safeguards must apply equally in the public and private sectors. It is essential that patients receive balanced, unbiased information in order for them to be in a position to make fully informed decisions.

Best patient outcomes must be held at the highest priority level and the medical training bodies, the Medical Council, the advertising regulators, the legal professions, the Department of Health, and Government must collaborate to ensure that the appropriate actions are taken.

Next Steps:

- Medical training and professional bodies to publish guidelines on advertising and marketing
- Collective effort by the medical training and professional bodies in tandem with the ASAI, the Department of Health/Government/politicians to ensure action is taken
- Regulation of commercial entities and organisations providing medical treatment
- Statutory requirement for adequate professional indemnity
- Licensing of institutions and standard setting – The ICO suggest the inclusion of responsible advertising and marketing standards in the new licensing of healthcare facilities legislation

¹⁵Brennan, T. et al. (1991) 'Incidence of Adverse Events and Negligence in Hospitalized Patients', *New England Journal of Medicine*, 324(6), pp. 370–376 and Cydulka, RK., Tamayo-Sarver, J., Gage, A. and Bagnoli, D. (2011) 'Association of Patient Satisfaction with Complaints and Risk Management Among Emergency Physicians', *The Journal of Emergency Medicine*, 41(4), pp. 405-11.

¹⁶Ibid 13.

APPENDICES

Appendix 1: Conference Programme and Biographies of Speakers

Medical Advertising in Ireland

CONFERENCE PROGRAMME

College Hall, Royal College of Surgeons in Ireland, Dublin
Wednesday, 24 September 2014

9.20am	Welcome and Overview from Conference Moderator <i>Caroline Murphy, RTÉ</i>
9.30am	Welcome address from ICO President <i>Miss Marie Hickey-Dwyer</i>
9.45am	Frank Goodman, Chief Executive, Advertising Standards Authority of Ireland <i>"The Regulation of Commercial Advertising for Medical Services"</i>
10.05am	CLINICAL PANEL Billy Power – Consultant Ophthalmologist <i>"Medical Advertising – Is Regulation Necessary?"</i> Patrick Ormond – Consultant Dermatologist and Mohs Micrographic Surgeon <i>"Does it do what it says on the tin?"</i> Margaret O'Donnell – Plastic, Reconstructive and Aesthetic Surgeon <i>"Cosmetic Surgery Advertising"</i>
11am	Stephen McMahon, CEO, Irish Patients' Association
11.30am	Catherine Reilly, Journalist, The Medical Independent <i>"Flattering to Deceive?"</i>
11.45am	John Elliot, Director of Regulation, Law Society of Ireland <i>"Regulation of Solicitors' Advertising"</i>
12pm	William Kennedy, Director of Regulation, Irish Medical Council

Biographies of speakers

Marie Hickey-Dwyer – *Ophthalmic Surgeon, President of the Irish College of Ophthalmologists*

Marie Hickey-Dwyer is a Consultant Ophthalmic Surgeon at the University Hospital Limerick. Dr Hickey-Dwyer commenced her ophthalmology training in the Royal Victoria Eye and Ear Hospital in Dublin in 1985 and subsequently moved to continue her training in St Paul's Eye Unit in the Royal Liverpool University Hospital specialising in diseases of the retina and vitreous.

Dr Hickey-Dwyer has been running a dedicated retinal specialist clinic for the past 17 years, treating patients suffering from retinal detachments, complicated vitreoretinal disease, macular degeneration and diabetic eye disease. She is currently the Head of the Department of Ophthalmology, the President of the ICO and an examiner for the European Board of Ophthalmology. She is an examiner on behalf of the ICO for the Membership Examination in Ophthalmology of the RCSI and for Undergraduate Ophthalmology at University College Dublin.

Frank Goodman – *Chief Executive ASAI*

Frank Goodman is Chief Executive of the Advertising Standards Authority for Ireland (ASAI). Frank previously served as a nominee of the Director of Consumer Affairs on the Complaints Committee of the ASAI and was a member of the Executive Committee of the European Advertising Standards Alliance.

Prior to joining the ASAI Frank served as a board member and Chief Executive of the Legal Aid Board. He also worked with the Revenue Commissioners and was subsequently Director of the Office of the Ombudsman from 1990 to 1995.

Billy Power – *Consultant Ophthalmologist*

Consultant Ophthalmologist at the Royal Victoria Eye and Ear Hospital, St Vincent's University Hospital and The Blackrock Clinic, Mr William Power has been a Consultant Ophthalmologist practising laser eye

Biographies of speakers (continued)

surgery, cataract and corneal surgery for 20 years. He was appointed Assistant Professor of Ophthalmology, Harvard Medical School and consultant eye surgeon in the Massachusetts Eye and Ear Infirmary (MEEI) in 1995 and appointed Chief of Ophthalmology, Brigham and Women's Hospital, Boston in 1996. He returned to Dublin in 1998.

He is a Member Royal College of Physicians, Ireland (MRCPI) Fellow Royal College of Surgeons, Glasgow (FRCSGlasg), Fellow Royal College of Ophthalmologists (FRCOphth), Masters in Surgery (TCD). Professional memberships include American Academy of Ophthalmology, American Society of Cataract and Refractive Surgeons, International society of Refractive Surgeons, European Society of Cataract and Refractive Surgeons, Irish College of Ophthalmologists.

Patrick Ormond – Consultant Dermatologist

Dr Patrick Ormond, FRCPI, Consultant Dermatological and Mohs Micrographic Surgeon at St James's Hospital, Dublin and Senior Lecturer, University of Dublin, TCD. Dr Ormond set up the only centre for Mohs Micrographic Surgery in the public health service in Ireland. He was also chairman of the skin cancer expert skin group for the National Cancer Control Programme.

Dr Ormond is a Member of the Irish Association of Dermatology, British Association of Dermatology, British Society of Dermatology Surgery, American Society of Mohs Surgery and the Royal College of Physicians of Ireland. He is also a founding board member of the Irish Skin Foundation.

Margaret O'Donnell – Consultant in Plastic and Reconstructive Surgery

President of the Irish Association of Plastic Surgeons, Ms O'Donnell is a Plastic, Reconstructive and Aesthetic Surgeon based in Blackrock Clinic and St Vincent's Private Hospital. For ten years she was a Consultant in St Vincent's University Hospital and in St James's Hospital where she was in charge of the National Burns Unit.

She is a Special Lecturer in the RCSI in Human Factors and Patient Safety to BST & HST trainees in all the surgical specialties including Ophthalmology. She has promoted the development of European Standards in Aesthetic Surgery Services, an EU project with multi-disciplinary representation.

Stephen McMahon – CEO, Irish Patients' Association

Stephan McMahon is Chairman and co-founder of the Irish Patients' Association (IPA). The IPA works alongside many healthcare organisations and educational centres in Ireland, ensuring that the patient remains at the very centre of healthcare. The Association is involved in education, research, and works in partnership at many levels within the Irish healthcare system. Stephen is currently Campaign Lead for the Patients First Campaign.

Catherine Reilly – Journalist, The Medical Independent

Catherine Reilly is a staff journalist with The Medical Independent and a former freelance journalist with the Irish Medical Times. Before entering the medical press in 2012, Catherine wrote for national and specialist media on immigration and ethnic minority issues. She is a graduate of University College Dublin and Dublin Institute of Technology.

William Kennedy – Director of Regulation, Irish Medical Council

William Kennedy joined the Medical Council in November 1997 as Head of Professional Standards and Legal Adviser. Professional standards includes responsibility for fitness-to-practise inquiries, ethics and monitoring of conditions attached to doctors' registration.

William provides advice to Council, generally, in relation to disciplinary processes and to other sections in relation to their functions, in particular to the Registration, Education and Training and Professional Competence Sections. He is also tasked with providing advice to Council in relation to all of its statutory obligations.

John Elliot – Registrar of Solicitors and Director of Regulation, Law Society of Ireland

Solicitor John Elliot has been the Registrar of Solicitors and Director of Regulation of the Law Society of Ireland since 2004. He is responsible for the statutory duties of Registrar and management of the regulatory functions of the Law Society. These functions include the regulation of solicitors' advertising.

Appendix 2

IGO GUIDELINES FOR REFRACTIVE SURGERY IN IRELAND

RECOMMENDATIONS FOR DIRECT-TO-CONSUMER ADVERTISING AND MARKETING FOR MEDICAL AND/OR SURGICAL PROCEDURES

- (a) All advertising must adhere to the relevant Advertising Standards Authority of Ireland (ASAI) Standards¹⁷ and the Medical Council (Ireland) Guidelines¹⁸. It must be legal, factual and not misleading.
- (b) Marketing materials must be drafted and designed to safeguard patients from unrealistic expectations.
- (c) Advertisements should not offer discount linked to a deadline date for booking appointments for surgery, or other date-linked incentives.
- (d) Advertisements should not offer surgery as a competition prize or trivialise surgery by way of offering it as a package deal (e.g. refer a friend, reduced price for two people).
- (e) Promotional events such as open evenings should not include financial incentives for potential patients to book a consultation appointment, at the event.
- (f) All staff and speakers at promotional events should be clearly identified with regard to their profession and role within the organisation.

RECOMMENDATIONS FOR PATIENT INFORMATION LITERATURE PRE-PROCEDURE

- (a) Information for patients should be written in concise, plain, non-technical language.
- (b) Information for patients should include:
 - 1. The range of procedures, stating which ones are available at the facility.
 - 2. Eligible criteria for patients.
 - 3. Treatment options, including advantages and disadvantages.
 - 4. General and procedure-specific risks and complications associated with surgery, their frequency, management, course and outcome.
 - 5. Statistical information regarding the achievements of the desired goal or of needing more than one procedure.
- (c) Information for patients should include details regarding the experience and qualifications of the operating surgeon and his or her relevant training.
- (d) Information for patients should include a price list of procedures and should be explicit about what is and is not included in the quoted fees. It should also give details about payments of deposits, their refund, and any penalty that may be incurred by cancellation.
- (e) Written post-operative instructions should be given to patients to take home after the procedure/operation. They should include a contact number for the hospital/clinic and a 24-hour emergency number.

¹⁷ASAI: *Manual of Advertising Self-Regulation, with Code of Standards for Advertising, Promotional and Direct Marketing in Ireland* (6th Edition Jan, 2007, Chapter 1, Para 8.1).

¹⁸Section E PARA 54, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners*, Irish Medical Council, 2009.

Appendix 3: ICO ADVERTISING AND MARKETING GUIDELINES

The Irish College of Ophthalmologists (ICO), the training body for eye doctors in Ireland and the medical experts on eye care, has devised these guidelines for the advertising and marketing of surgical and medical procedures.

The ICO places the highest priority on patient safety and urges all healthcare providers to refer to and abide by the following guidelines.

The guidelines apply to any marketing or advertising material (broadcast, print or online) that could be interpreted as or deemed to potentially influence the decision making process of a prospective patient.

The Irish College of Ophthalmologists make the following recommendations for advertising and marketing of surgical and medical procedures

- (a) Material must be truthful, legal and not misleading.
- (b) All material must adhere to the Medical Council (Ireland) Guidelines¹⁹ and the relevant Advertising Standards Authority of Ireland (ASAI) standards²⁰.
- (c) Ensure that the information published is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.
- (d) Marketing materials must be composed and designed to safeguard patients from unrealistic expectations. Claims must be objectively substantiated.
 - I. Materials must not minimise or trivialise the risks of interventions and must not exploit patients' vulnerability. Marketers should not imply that invasive surgery is a "minor procedure" or similar if that claim is likely to mislead as to the complexity or duration of the operation, the pain experienced either during or after the operation, the length of the recovery time or the potential side-effects.
 - II. Materials must not mislead as to the likely commitment required for pre-consultation, surgery, recovery and post-operative assessments.
 - III. Marketers wishing to make secondary claims about an intervention, such as that it is "suitable for all", "pain-free", "without side-effects" or similar must hold evidence to that effect.
 - IV. References to a "consultation" must not mislead as to the purpose of that appointment. Marketers should take care not to give the impression that such an appointment will be with a medical professional if that is not the case.
 - V. Claims that imply superior skill such as "leading surgeons", "best surgeons", "foremost surgeons" and "surgeons of the highest calibre", if used, must be provable. Showing that the surgeons have held high administrative posts in the medical profession is unlikely, on its own, to be enough to substantiate such claims.

- VI. Marketers must not imply unrealistic benefits, for example that the permanent removal of localised areas of fat will prevent subjects from gaining fat elsewhere, that tattoos can be removed without trace, that laser eye surgery can achieve better than 20/20 vision or that surgically replaced hair will last permanently or with minimal risk of untoward complications.

Use of Before and After photographs

- I. Marketers must hold documentary evidence that the before and after photographs used in their marketing communications are genuine and hold signed and dated proof from the subject shown.
 - II. While marketers might be able to show that before and after photographs are genuine they still need to hold evidence which substantiates the level of efficacy implied by the photos.
 - III. Marketing communications must not mislead consumers by exaggerating the capability or performance of a product.
- (e) Advertisements must not offer discount linked to a deadline date for booking appointments for surgery, or other date linked incentives.
 - (d) Advertisements must not offer surgery as a competition prize. Offering medical or surgical interventions as prizes may cause prospective patients to make decisions about having a particular intervention sooner than they otherwise would have done, or to choose certain interventions (included in the promotion) over others that might be more suitable. Offering medical or surgical interventions as prizes shows irresponsible disregard for patient safety, which could damage public confidence in the medical profession.
 - (e) Advertisers must not trivialise surgery by way of offering it as a package deal (e.g. refer a friend, reduced price for two people).
 - (f) Promotional events such as open evenings must not include financial incentives for potential patients to book a consultation appointment at the event.
 - (g) All staff and speakers at promotional events must be clearly identified with regard to their profession and role within the organisation.
 - (h) If pricing is quoted in marketing or advertising material, it must be clear about what is included in quoted prices and what other charges might be payable, including possible charges for revision or routine follow-up.
 - (i) Listing of qualifications of practitioners must be mandatory.

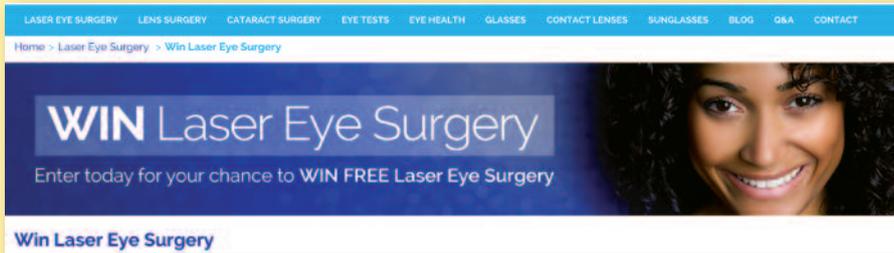
*Guidelines for Advertising and Marketing of Surgical and Medical Procedures in Ireland, Irish College of Ophthalmologists
September 2015*

¹⁹Section E PARA 54, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners, Irish Medical Council, 2009.*

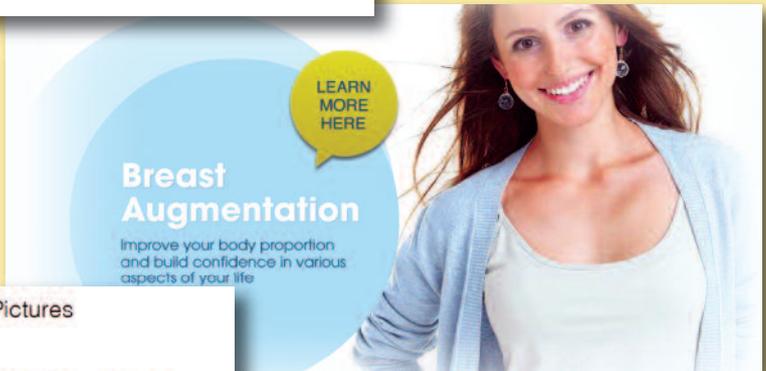
²⁰A.S.A.I.: *Manual of Advertising Self-Regulation, with Code of Standards for Advertising, Promotional and Direct Marketing in Ireland (6th Edition Jan, 2007, Chapter 1, Para 8.1).*

Appendix 4

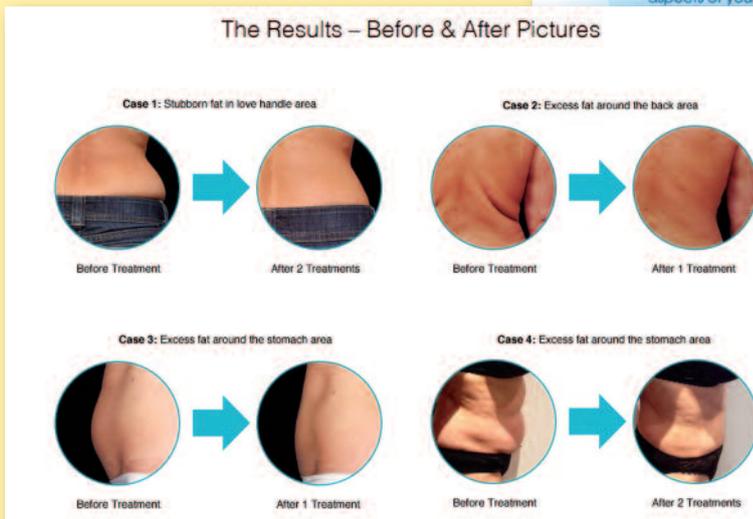
Direct-to-consumer advertising – Samples of advertisements



Inducements by competitions

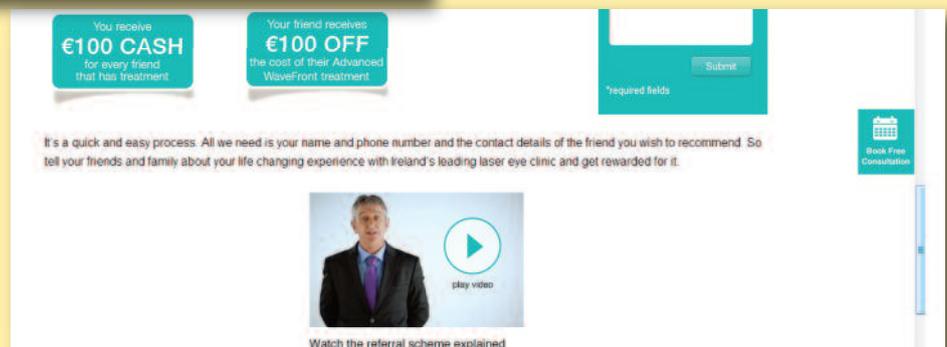


Unrealistic expectations



Financial inducements for referring a friend

Before and after



Refer a friend

Appendix 4

Direct-to-consumer advertising – Samples of advertisements

Unrealistic expectations

Targeting vulnerable audience

Financial inducements special offers

Unrealistic expectations

Unrealistic expectations

Misleading information

Appendix 5: Guide to Professional Conduct and Ethics – Irish Medical Council

Ethical Guide (6th Edition)

14.1 Educating the Public

Doctors have an important part to play in educating the public in medical matters and in disseminating medical knowledge. However, doctors must not imply that they have unique solutions to health problems.

Doctors are reminded that if they work in a clinic or any healthcare setting that makes unfounded claims about special expertise not found elsewhere they may be held responsible for such claims.

14.2 Information for the Public

Information given to the public should be expressed in clear and factual terms. It must never cause unnecessary public concern or personal distress nor should it raise unrealistic expectations.

Doctors dealing with the media on social, ethical, political, or research aspects of medicine must take responsibility for the views they express and establish the basis for them.

14.3 The Balance of Benefit

In adjudicating on complaints concerning doctors in the media, the Medical Council will consider whether the benefit to the doctor has been greater than that to the public and whether there has been an element of self-advertisement or a claim of possession of special skills, either of which could be interpreted as canvassing for patients. In all circumstances benefit to the patient must outweigh any incidental advantages to the practitioner concerned. Self-advertisement, or publicity to enhance or promote a professional reputation for the purpose of attracting patients is unacceptable; paragraphs 6, 7, 13 and 14 refer to all forms of communication.

Ethical Guide (7th Edition)

- 54.1 The provision of information about the availability of medical services through the media, internet or other means is generally in the public interest provided that the information is factually accurate, evidence-based and not misleading.
- 54.2 You may advertise your practice by publicising the name and address of the practice, the practice hours and contact details. You may include your area of specialty if it is one that is recognised by the Medical Council and you are entered for that specialty in the Specialist Division of the Register.
- 54.3 The fees you charge should be appropriate to the service provided. Patients should be informed of the likely costs before the consultation and treatment.