EU MDR
& local country medical device advertising guidelines

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EU MDR and local country medical device advertising guidelines

One of the biggest concerns we hear from medical device companies is what can and cannot be said on digital platforms, particularly social media. To address this we have created a comprehensive and fully referenced table outlining the regulations applicable to selected countries.

An important starting point for any country in the EU is that advertising / promotional material (adverts) must follow the European Union Medical Device Regulation (EU MDR) in addition to local country requirements. The UK is different as it is not affected by the EU MDR, however local regulations apply.

Please note this document is for reference only and does not constitute legal advice.

Summary table of how the EU MDR and local country guidelines affect what can be done in seleted countries (subject to conditions outlined in tables 1-8)*/**

	EU MDR	Denmark	France	Germany	Italy	Netherlands	Spain	United Kingdom ***
Patients Can I advertise directly to patients?	Yes[24]	Yes[1]	Yes[2]	Yes[8]	Yes[11,12]	Yes[15]	Yes[17]	Yes[22]
HCPs Can I advertise directly to healthcare professionals (HCPs)?	Yes[24]	Yes[1]	Yes[3]	Yes[8]	Yes[11,12]	Yes[15]	Yes[17]	Yes[22]
Product comparisons Can I compare one product to another?	Yes[24]	Yes[1]	Yes[2]	Yes[7]	Yes[9,10]	Yes[13]	Yes[17]	Yes[18,20,22]
Regulatory text Is there additional that needs to be placed in advertisements?	No	Yes[1]	Yes[3]	No	Yes[11,12]	Yes[13]	Yes[17]	Yes[22]
Clinical data Is there any additional clinical data requirements for marketing?	No	No[1]	Yes[4]	Yes[8]	Yes[11,]	Yes[15]	Yes[17]	Yes[22]
Disease states Are there any diseases / devices that cannot be advertised?	No	Yes[1]	No	Yes[8]	Yes[11,12]	Yes[15]	Yes[17]	No
Online advertising to patients Are there additional regulations about advertising to patients online?	Yes[24]	Yes[1]	Yes[3]	No	Yes[11,12]	Yes[13]	Yes[17]	No
Online advertising to HCPs Are there additional regulations about advertising to HCPs online?	No	Yes[1]	No	No	Yes[11,12]	No	No	No

Updates are marked in GREEN
*This table will be updated as required
**Clinical data requirements differ per country.
See table 5 ***UK is not affected by EU MDR guidelines
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Can I advertise a medical device directly to patients?

When promoting to patients in the EU, you must first meet the EU MDR requirements and then any local country guidelines or regulations. The UK has its own regulations.

Table 1

EU MDR[24]	**Yes, but with conditions** You must ensure there is no misleading information regarding a device's intended purpose. This includes how you describe: • its features or outcomes • how it will treat or diagnose a patient • any 'likely' risks that may result from its use All aspects of your advert will be scrutinised for misleading information about the intended purpose, including: pictures • logos • text • names • trademarks
Denmark[1]	**Yes, but with conditions** Devices that are used exclusively by a doctor or dentist cannot be advertised to patients. For all other devices adverts cannot give the impression that • it's unnecessary to consult a doctor, dentist or other professionals who use the device as part of treatment or diagnosis • using the device is without risk which includes softening or omitting significant risks • patient's health will be negatively impacted if a device is not used, for example, not using the device could cause sadness, tiredness, depression, or reduced life quality Also, an advert cannot: • be directed exclusively or principally at children under 14 • lead to an incorrect self-diagnosis • use exaggerated, alarming or misleading terms, images, illustrations etc of changes in the human body • include recommendations by scientists, health professionals or other people whose prestige in health care could encourage the use of a device. Even implicit endorsements, such as the presence of a healthcare professional's image or a figure in a white coat, are prohibited. • mention, directly or indirectly a serious disease • refer to studies, literature or journals etc • provide inadequate information
France[3]	**Yes, but with conditions** Different rules apply for reimbursed vs non-reimbursed devices • For reimbursed devices, advertising to the general public is only possible for class I and IIa devices • For non-reimbursed devices advertising is allowed, however higher risk devices need pre-authorisation by the ANSM (National Agency for the Safety of Medicines and Health Products) Adverts must: • be adapted to the audience • ensure any quote is true and referenced • not use the term "new" after a year on the market Adverts must not: • suggest that a medical consultation or surgery is superfluous • lead to a false self-diagnosis • suggest using the device is without risk or adverse effects • suggest that a normal state of health can be improved by the use of the product or can be affected if the • product is not used • be aimed at children • refer to a recommendation from scientists or health professionals • use abusive, frightening or deceptive visual representations of alterations of the human body due to disease, injury or disability • show the action of the device on the human body in an excessive or misleading manner

Germany[8]	**Yes, but with conditions** Adverts cannot: • include publications that have an ambiguous purpose • suggest that a patient's health could be affective if the device is not used • be directly advertise to children under 14 • contain statements from third parties e.g. recommendations • suggests risks will occur if the device is not used
Italy	**Yes, but with conditions** Only devices that do not require a prescription or HCP use can be advertised or require a prescription, can be advertised and must be authorised by the Ministry of Health. If no response to an appliation for approval is recieved within 45 days, then an advert is deemed approved. Advertising for accessories for medical devices (such as eyeglass frames) and accessories for in vitro diagnostic medical devices is not subject to authorisation. [24] Adverts must also: • encourage rational use of a device[11] • be truthful, fair and not misleading[11] • have a clear advertising purpose which must not be hidden in too much information of a different nature[12] • be consistent with the label and instructions for use of a device[12] • not include anything that could lead to wrongful self-diagnosis[12] • not make the consultation of a doctor appear unnecessary[12] Also, an advert cannot: • infer that not using a device will be detrimental to a patient's health[12] • infer that the use of a device bears no contraindications or risks[12] • include misleading references to the healing capacities of a device[12] • be marketed to children[12] • include messages by scientists, medical practitioners, or notorious people[11]
Netherlands	**Yes, but with conditions** All adverts have to comply with the following regulations which provide that they must: • not be misleading[14] • be correct and verifiable[14] • not harm the accepted norms of good taste and decency or the industry's reputation, healthcare professionals or other devices[14] • include the appropriate evidence to substantiate the accuracy of statements[14] • not state or imply that a device is more than just a medical device[15] • not pose a threat to mental and/or physical public health[15] • not appeal to feelings of fear[15] • clearly be advertising[15] • not conflict with information in the instructions for use or device packaging[15] • be clearly identified as a medical device[15] • not equate to a medicine, health product, food, cosmetic product or other consumer goods[15] • be in a language that the consumer can understand[15] • not state that a device can be reimbursed on a doctor's prescription[15] • not deter or discourage the public from seeking medical treatment or seeking further medical examinations[15] • not give the impression that normal good health is affected if a device is not used[15] • not contain any statements that could lead to a false self-diagnosis by describing or presenting a detailed medical history[15] • not make false, deterrent or deceptive references to statements of recovery[15] • not use the phrases 'lasting results' and 'efficacy guaranteed'[15] • not be aimed exclusively or mainly at children[15] • not refer to recommendations by scientists or healthcare professionals[15] • not have secondary properties as the primary argument[15] • not use "new" after the first 2 years on the market. Changes to a device after 2 years can say "improved"[15]
Spain[17]	**Yes, but with conditions** Adverts can be directed at patients, but public marketing is not allowed for products funded by the Spanish National Health Service or those that are used by HCPs. Additional regulations provide that: • all side effects must be listed • there should be no mention of the Health Authority or any recommendations made by scientists, health professionals or other people who may, due to their reputation, encourage use • higher-risk devices requires pre-approval from the Spanish Health Ministry.

UK*	**Yes, but with conditions** Adverts must not: • be misleading[18] • invite patients to diagnose minor ailments[20] • encourage patients to use a device to excess[20] • falsely claim that a device can cure illness, dysfunction or malformations[22] • confuse patients by using unfamiliar scientific words for common conditions[22] • discourage essential treatment for conditions for which medical supervision should be sought[20] • say 'new' once a device has been in the UK for more than 12 months[22] Additionally, adverts must: • follow the device's CE Mark intended purpose[22] • be accurate, balanced, fair, objective and unambiguous, based on a fair evaluation of appropriate evidence and reflect that evidence clearly[22] • be legal, honest and not misleading (nor likely to mislead)[18] • be prepared with a sense of responsibility to patients[21]

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Can I advertise a medical device directly to HCPs?

When advertising to HCPs the rules tend to be less strict compared to direct patient advertising. However, if advertising in the EU you must still meet its requirements.

Table 2

EU MDR[24]	**Yes, but with conditions** You must ensure there is no misleading information in your advert regarding the intended purpose of a device (found in its IFU and technical file), which includes: • its features or outcomes • how it will treat or diagnose a patient • any 'likely' risks that may result from its use All aspects of your advert will be scrutinised for misleading information about the intended purpose, including: • pictures • logos • text • names • trademarks
Denmark[1]	**Yes, but with conditions** Adverts must contain adequate information for HCPs to understand when the medical device should or shouldn't be used. Adverts cannot give the impression that using a device is without risk which includes softening or omitting significant risks. Also, adverts cannot: • use exaggerated, alarming, or misleading terms, images, illustrations, etc of changes in the human body • include any competitions or prizes or any suggestion of gifts
France[3]	**Yes, but with conditions** Adverts need the following approvals and to adhere to certain criteria, including: • where a device could cause a serious health risk, it is subject to prior authorisation by the ANSM • adverts for all device types must be checked post-publication (the director of ANSM has the ability to remove them) • all information must be readable, accurate, up-to-date, verifiable and sufficiently complete to enable a HCP to form a personal opinion on the therapeutic value of a device

Germany[8]	**Yes, but with conditions** Adverts cannot: • be misleading • offer gifts or discounts unless of negligible value (typically 1 euro) • Include publications that have an ambiguous purpose • suggest that a patient's health could be affected if the device is not used • be directly advertised to children under 14 • contain statements from third parties for example recommendations
Italy[12]	**Yes, but with conditions** Adverts must: • have a clear purpose which must not be hidden in too much information of a different nature be consistent with the label and the instructions for use of a device • be written in easy to understand language with any medical terms explained. Online advertising to HCPs must be in restricted areas (e.g., password-protected websites), and users must be appropriately verified
Netherlands	**Yes, but with conditions** Adverts must: • not be misleading[14] • be correct and verifiable[14] • not harm the accepted norms of good taste and decency or the industry's reputation, healthcare professionals or other devices[14] • be written in a way that it is possible to substantiate the accuracy of statements with appropriate evidence[14] • not state or imply that a device is more than just a medical device[15] • not pose a threat to mental and/or physical public health[15] • not appeal to feelings of fear[15] • not conflict with the information contained in a device's instructions for use or packaging[15] • clearly be advertising[15]
Spain[17]	**Yes, but with conditions** Any supporting material in any format (eg. written or audio-visual) must be scientific in nature and directly distributed to HCPs. The information in an advert needs to be provided by trained personnel with sufficient knowledge of the device promoted and comprehensive guidance as to use.
UK*	**Yes, but with conditions** All adverts must: • be legal, honest and not misleading.[18] • follow the device's CE Mark intended purpose[22] • not falsely claim that a device can cure illness, dysfunction or malformations[20] • be accurate, balanced, fair, objective and unambiguous, and be based on and clearly reflect a fair evaluation of appropriate evidence[22]

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Can I compare one product to another in medical device advertising?

Yes, compartative advertising is allowed in Europe. In addition to the EU MDR, all countries listed have additional comparative adverting requirements which state that comparisons cannot be misleading and that competitor devices cannot be discredited.

Table 3

EU MDR[24]	**Yes, but with conditions** • devices being compared must meet the same needs or be for the same purpose • comparisions must be objective, relevant and verifiable when reviewing features,including price • comparisons must not create confusion between traders, and should • not discredit, imitate or take advantage of the trademarks or trade names of competitors

Denmark[1]	**Yes, but with conditions** • devices must be compared with all others with the same intended purpose except for those with a less than 3% market share
France[3]	**Yes, but with conditions** • comparisons can only be made directly to HCPs and need to include all device elements and primary safety and efficacy data
Germany[8]	**Yes, but with conditions** • comparison adverts must meet the same clinical data requirements as a standard advert including randomised, controlled and double-blind clinical trials with adequate statistical analytics published in peer reviewed journals
Italy	**Yes, but with conditions** • only for non-prescription devices and those that do not require the assistance of a healthcare professional. Pre-authorisation by the Ministry of Health is required for public advertisements.
Netherlands[13]	**Yes, but with conditions** • no competitor brand names can be listed, and all relevant features of all devices must be compared
Spain	**Yes**
UK*	**Yes**

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Is there any additional text that must be included in advertisements?

Under the EU MDR, adverts in the EU must list a product's CE mark.

Table 4

Denmark[1]	**Yes** • all adverts must state if a device needs to be used with another device or if additional parts need to be purchased
France[3]	**Yes** All adverts must include: • text in at least size 9 font, in a contrasting colour to the background • a message of caution • guidance to speak with a doctor, pharmacist or any other competent professional with regard to the nature of the device • the internal referencing number following authorization from ANSM • the date on which they were completed or last revised • the commercial name or reference for the device • the use, as well as the characteristics and performance claimed for such use • essential information for proper use • an express invitation to carefully read the instructions in the device leaflet or on the label given to the HCP • the following text on all patient material - Ce dispositif médical est un produit de santé réglementé qui porte, au titre de cette réglementation, le marquage CE For professionals the additional must be included: • the device class • if applicable, the name of the approved body which established the conformity assessment (in "CE XXXX" format) • reimbursement details

Germany	No
Italy	Yes Adverts must: • include the statement "E' un dispositivo medico CE" (it is a EC medical device)[12] • include the type of device and its class[12] • clearly urge the audience to read the warnings and/or the instructions for use (in at least size 9 font)[12] • be in Italian[11] • specify the sale price and conditions for reimbursement by the National Health Care Service
Netherlands	Yes Adverts must include: • the name of the medical device • the nature of the product • the data that is indispensable for the correct use of the medical device
Spain	Yes Adverts must: • provide the conformity of the product • include any contraindications • include any possible side effects that may arise from the use of the product
UK*	Yes Adverts must: • be clear that they are adverts[22]

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Clinical data in advertising: What level of clinical data is required?

As well as content requirements, you will need to be able to provide evidence for your claims. Each country has different requirements for the level of evidence required to support a claim.

Table 5

Denmark[1]	There is no level of clinical data required but the Danish Health Authority can require evidence of anything in an advert.
France[4]	Clinical data in adverts must be: • used objectively • The advert must focus primarily on the results of primary outcomes • The results of secondary outcomes can only be presented together with those of the main criteria, and provided they were published in the original article or abstract only from peer-reviewed publications, data within the marketing authorisation file, or that approved by the transparency committee • prospective, controlled, randomized and, if possible (and depending on the case) conducted blindly, with justified numbers allowing sufficient power to be obtained
Germany[8]	German courts require a high level of evidence to support a claim (this includes comparative advertising). Particularly: • the study design must be recognised as "gold standard". This includes randomised, controlled and double-blind clinical trials with adequate statistical analytics published in a peer-reviewed journal • case studies, retrospective analyses or meta-analysis collating less than gold-standard data will not be considered evidence for a claim

Italy[11]	Any articles, tables or illustrations taken from medical journals or scientific works must be reproduced in full and faithfully, with an exact indication of the source.
Netherlands[15]	Claims can be supported with data from studies, referrals to instructions for use and published articles - however acknowledgement of sources is important and must be made available.
Spain[17]	Any quotations, tables and other illustrations taken from medical journals or scientific works and used in adverts must be faithfully reproduced and the source accurately stated.
UK[22]*	The ABHI requires that: • clear references need to be provided for any studies that are referred to • graphs and tables are clear • peer-reviewed journals must be referenced • if a graph or table is reproduced from a published study, it should not be altered unnecessarily. In any event, the way material is used must not distort or give a false impression of the evidence published in that study. The advertiser must clearly state if the material has been modified.

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Are there any diseases / devices that cannot be advertised?

In some countries, certain classes of medical device, or disease types cannot be advertised. This will affect which symptoms can mentioned.

Table 6

EU MDR[24]	No
Denmark[1]	**Yes, but with conditions** Devices that exclusively require a doctor or dentist for use cannot be advertised. Serious illness cannot be mentioned in advertising. This will include anything that: • causes severe pain • leads to permanent deterioration in health • confines a person to bed • shortens a person's life • reduces a person's quality of life
France[3]	**Yes, but with conditions** For HCPs there is a long list of devices that require authorisation by the ANSM. The link to the whole list is available here.
Germany[8]	**Yes, but with conditions** Devices cannot be advertised if they relate to the detection, prevention, elimination or alleviation of: • notifiable diseases or infections • addictions, excluding nicotine • pathological complications of pregnancy, childbirth and puerperium
Italy	**Yes, but with conditions** The following devices cannot be advertised to patients: • those that must be ordered, chosen or used by a HCP[12] • custom made devices[11, 12] • devices that need to be used with a HCP
Netherlands[15]	**Yes, but with conditions** Self-care devices that require HCP help cannot be marketed to patients

Spain[17]	**Yes, but with conditions** You are not allowed to advertise devices that don't follow the Royal Decree or those that require a professional.
UK*	**No**

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Online advertising - Are there any additional regulations about advertising to patients online?

In most countries, the regulations governing advertising online are the same as any other form of marketing (as above). In some countries, however, there are additional regulations as below.

Table 7

Denmark[1]	**No** There are no specific rules for marketing online. Advertising of medical devices on the internet must satisfy the same requirements as advertisements in other media. The rules apply to banner ads, internet advertising and the like which clearly take the form of advertising and to the mention of medical devices. Also, employees' activities on social media can now be considered advertising of medical devices, even when acting in a personal capacity. Influencers and bloggers can be held responsible for advertising medical devices.
France[6]	**Yes, but with conditions** As well as the general advertising rules, additional requirements must be followed: • websites should clearly distinguish promotional pages from institutional pages • any operator who implements a discussion forum must implement true discussion moderation services • the promotion of health products on open social networks is forbidden unless such networks moderate internet users' comments and deactivate certain modalities (e.g. likes) • the downloading of mobile health applications on public platforms is forbidden unless such applications moderate the users' comments and deactivate certain modalities (e.g. comments, notations, recommendations of the application)
Germany[8]	Advertising of devices on the internet must satisfy the same requirements as advertisements in other media.
Italy[12]	**Yes, but with conditions** There are additional requirements which include: • websites and all adverts need approval from the Ministry of Health • once an advert is approved secondary approval is needed before it is posted online • Facebook, YouTube, and Instagram posts are allowed but comments must be deactivated, and the following statement added: The Ministry of Health authorises only the advertising content. Any comments are the sole responsibility of the user, and the company dissociates itself from the comments of the users • only links to websites approved by the Ministry of Health can be included
Netherlands[15]	**Yes, but with conditions** In the Netherlands the following additional regulation applies when advertising online: • all device-specific parts of any website must be inspected before going live by the Code for Public Advertising of Medical Devices Inspection Board
Spain[17]	**Yes, but with conditions** As well as general advertising rules, the following requirements must be followed: • advertising messages in the general media, including the internet, will be subject to prior authorisation by the Health Authorities of the autonomous communities • any other promotional text shall be made available to the Health Authorities concerned for at least three months after publication
UK*	**No**

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Are there any additional regulations about advertising to HCPs online?

For countries with stricter rules for patients vs. HCPs, "locking" HCP content online is common through the use of a separate website or password protected pages. Note: all HCP marketing online still needs to follow the rules for traditional marketing as outlined above.

Table 8

Denmark[1]	**Yes, but with conditions** These include: • online adverts to HCPs must be password protected or have an efficient method to ensure that only they gain access • it is not sufficient that users only enter a password to gain access to a web page. The minimum requirement is user identification, for example, a unique username, authorisation ID or an individual password
France[6]	**Yes, but with conditions** These include: • websites must clearly distinguish promotional pages from institutional pages • any operator who implements a discussion forum must include discussion moderation services • the promotion of devices on open social networks is forbidden unless such networks moderate internet users' comments and deactivate certain modalities (e.g. likes) • the downloading of mobile health applications on public platforms is forbidden unless such applications moderate the users' comments and deactivate certain modalities (e.g. comments, notations, recommendation of the application) • adverts targeting HCPs shall be displayed on sites that can only be accessed by HCPs
Germany	**No**
Italy[12]	**Yes, but with conditions** These include: • websites and adverts need approval from the Ministry of Health • once an advert is approved secondary approval is required prior to posting online • Facebook, YouTube, and Instagram posts are allowed but comments must be deactivated, and the following statement added: The Ministry of Health authorises only the advertising content. Any comments are the sole responsibility of the user, and the company dissociates itself from the comments of the users only links to websites approved by the Ministry of Health can be included • information intended for HCPs needs to come with a disclaimer that the information provided on the sites is only addressed to HCPs
Netherlands[15]	**Yes, but with conditions** These include: • all product-specific parts of a device website must be approved by the Code for Public Advertising of Medical Devices Inspection Board, before they are published
Spain[17]	**Yes, but with conditions** These include: • advertising messages in the general media, including the internet, will be subject to prior authorisation by the Health Authorities of the autonomous communities • any other promotional text shall be made available to the Health Authorities concerned for at least three months after disclosure
UK*	**No**

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UK is not affected by EU MDR guidelines*

This document will be updated with any changes made by the UK or EU after November 2024.

If there are any specific areas with which we can assist we will be pleased to do so on an informal basis (info@podymos.com).

This document is for reference only and does not constitute legal advice.

References

Denmark
1 Guideline on Advertising, etc. of Medical Devices

France
2 ANSM Comparative Advertising
3 Recommendations for advertising MDs/IVD
4 Data source
5 Communication way
6 Charter for communication and promotion of health products (drugs and medical devices) on the Internet and e-media

Germany
7 Gesetz gegen den unlauteren Wettbewerb, UWG
8 Law on Advertising in the Medical Sector (Heilmittelwerbegesetz - HWG)

Italy
9 Section 2598 of the Civil Code
10 Section 2.d of Legisaltive Decree no 145 dated 2 August 2007
11https://www.bakermckenzie.com/-/media/files/insight/publications/2016/01/promoting-medical-devices-globally/pmpg_italy.pdf?la=en#:~:text=This%20means%20that%20in%20Italy,or%20narcotic%20substances%20is%20prohibited.
12 https://cms.law/en/int/expert-guides/cms-expert-guide-to-advertising-of-medicines-and-medical-devices/italy

Netherlands
13 Dutch Civil Code
14 Code of Conduct Medical Devices
15 CODE PUBLIEKSRECLAME MEDISCHE (ZELFZORG) HULPMIDDELEN

Spain
16 Advertising Act
17 Royal Decree 1591 / 2009, Of 16 October, Which Regulates Medical Devices

United Kingdom
18 The Business Protection from Misleading Marketing Regulations 2008
19 The Consumer Protection from Unfair Trading Regulations 2008
20 The UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code)
21 The UK Code of Broadcast Advertising (BCAP Code)
22 ABHI Code of Conduct

Europe
23 DIRECTIVE 2006/114/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006
24 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices