

SDMA

SURGICAL
DRESSING
MANUFACTURERS
ASSOCIATION

**Code of Practice
for the Promotion of Wound Care
Products to Healthcare Professionals**



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Background Information on the SDMA



SECTION 1

- 1.1 The Surgical Dressing Manufacturers Association (SDMA) has as members the majority of manufacturers of wound care products supplying the UK health care market and therefore largely represents this sector of the health care industry.
- 1.2 The SDMA is dedicated to:
- (i) Encouraging the adoption of highly ethical standards of practice in the advertising and promotion of products.
 - (ii) Encouraging and expanding the use of safe and effective wound care and associated products in healthcare markets.
 - (iii) Creating an agenda whereby the development of technically appropriate products and concepts can be encouraged.
 - (iv) Working in partnership with healthcare professionals to develop the appropriate use of products.
 - (v) Influencing in a responsible way the creation of a beneficial regulatory environment.
- 1.3 Medical devices subject to this code are those materials and products which are used on wounds or the skin for one or more of the following purposes:
- as a mechanical barrier
 - for the absorption of or the transmission of exudates
 - to debride or to manage the micro-environment of a wound
 - for the support, bandaging, padding or splinting of limbs
 - for the prevention of hard or soft tissue injuries for medical reasons
- These devices can be used alone or in combination and are intended by the manufacturer for human use, solely or principally for the prevention, treatment or alleviation of disease, injury or handicap.
- 1.4 The SDMA Code of Practice specifically covers the promotion of wound care and associated products in the British Isles to bodies and individuals employed in the professional medical market where the decision maker could be; a healthcare professional (e.g. surgeon, doctor, hospital nurse, community nurse, pharmacist, dentist, chiropodist, physiotherapist, medicines management, pharmaceutical advisor, occupational therapist) or a health product buyer or a healthcare service provider.
- 1.5 The code applies to member company activities outside the British Isles when a customer based in the British Isles is involved. The code does not apply to member activities outside the British Isles when the customer is not based in the British Isles.
- 1.6 Compliance with the Code and respecting decisions of the Complaints Committee following the investigation of a complaint is mandatory for member companies of the SDMA. Failure to comply would render a member company liable to such sanctions as the General Committee thought fit, with any sanctions applied needing to be approved by a two-thirds majority.
- 1.7 All SDMA member companies agree to accept and abide by the results and decisions of the Complaints Committee following the investigation of a complaint and review.

Principals & Aims

SECTION 2

- 2.1 To promote high professional and ethical standards of business practice amongst SDMA member companies and their employees.
- 2.2 To encourage these standards as accepted practice across wound care and associated industries and make them widely known to healthcare professionals.
- 2.3 To encourage working in partnership with healthcare professionals and procurement organisations in an ethical and legal manner.
- 2.4 To promote standards of sales promotion and business activity that ensure the decision to purchase is made on the basis of the merits of the product or service acceptability for its intended purpose.
- 2.5 To ensure strong support is given to the code by SDMA member companies, with all companies devoting appropriate resources to ensure that their business activities comply with it.
- 2.6 To provide a complaints procedure for alleged breaches of the code which can be invoked by member companies, non member companies, healthcare professionals, or private individuals.



SECTION 3

3.1 GIFTS AND INDUCEMENTS

Gifts must be of benefit to patients or relevant to the recipient's practice and must not include items intended for personal use, such as items of apparel, cosmetics and home electronic devices. Gifts must be modest in value, i.e. up to a total value of £10.00 excluding VAT.

Specific gifts of an educational nature to an individual healthcare professional are permissible and have a maximum value of £25.00 excluding VAT.

Gifts must not take the form of cash or cash equivalents. Store vouchers, music tokens, retail discount schemes, and similar items are all considered as cash equivalents.

Gifts or donations must not be offered or given as an inducement to prescribe, supply, administer or buy a product.

Schemes that enable customers, healthcare professionals and their employees to obtain personal benefit and schemes that provide sums of money to an organisation in which an individual can obtain personal benefit are not acceptable.

Facilitation payments, which are payments to induce officials to perform routine functions they are otherwise obligated to perform, are not permitted.

3.2 BUSINESS COURTESIES

Business courtesies include meals, social events, travel, and living expenses. These courtesies, when provided to a customer, must be modest in amount and be related to a legitimate purpose (e.g. explanation or demonstration of a member's products, service capabilities, research work, or training). These must not exceed a level

normally associated with the customer's professional standing. Persons not involved in the use of product, e.g. spouses or partners, must be excluded from business courtesies.

3.3 REPRESENTATIVES

Companies are responsible for the activities of their representatives. It is expected that adequate training will be provided for all representatives to ensure they have sufficient technical knowledge to enable them to provide full and accurate information about the products they promote. It is also expected that suitable training in this Code of Practice is provided for all representatives. Appropriate training records must be kept by member companies.

For the purposes of this Code of Practice, any third party sales, marketing, clinical or consultancy company and their employees used by a member company will be considered to be representatives of that company and as such be subject to the requirements of the code. The member company employing such external organisations or individuals will be responsible for any breaches of the code made by them whilst representing the member company and their products and services and be subject to the complaints procedure.

Representatives must:

- (i) At all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the code.
- (ii) Not make claims for or comparisons with any product which are in any way inaccurate,

Areas Covered

misleading, disparaging, in poor taste or which discredit another company or the surgical dressings industry.

- (iii) Ensure that the frequency, manner, timing and duration of their calls on customers do not cause inconvenience.
- (iv) Pay attention to the wishes of individuals and organisations on whom representatives call – and ensure arrangements in force at any particular establishment are strictly observed.

3.4 ADVERTISING AND PROMOTIONAL MATERIALS

Advertising and promotional material covers all media, including electronically published materials but specifically excludes “broadcast” of independent scientific debate. Independent scientific debate includes non-company generated or sponsored data. All published company generated or sponsored data must be acknowledged, e.g. by the inclusion of a company name or logo.

Advertising and promotional material must at all times be legal, accurate, balanced, fair, objective and unambiguous and must not mislead or contain any exaggerated claims either direct or implied and must not misrepresent competitors’ products by the inaccurate or inappropriate use of data. Any product claim must be referenced and able to be supported by valid written evidence, which is either in the public domain, (e.g. through publication in a legitimate professional health or medical journal) or can be provided within twenty eight (28) working days, upon request. Failure to meet this time scale will constitute grounds for a complaint. Data on file is considered an acceptable source of information. The Code requires the release of the same information that would be given to a healthcare professional

if they asked for a claim to be substantiated.

Advertising and promotional material must not contain recommendation of a product by scientists or healthcare professionals without their prior written consent.

Advertising and promotional material which is unfair, misleading, disparaging or denigrating of a competitor’s products or services would be considered as a breach of the code.

Comparative advertising must be supported either by significant clinical data or by independently-validated objective data. Price and performance comparisons should be on a fair and appropriate like-for-like basis.

3.5 PROMOTIONS AND COMPETITIONS

No company will become involved in promotional schemes or competitions that are misleading or which may bring the industry into disrepute.

Where a competition involves a particular product, the questions and answers must test the skill or experience of the intended participants. All competitions must be conducted in a fair and transparent manner.

Promotional and competition materials will be considered in the same way as advertising and promotional literature and their content is governed by paragraph 3.4 of the code.

Competition prizes must be of benefit to patients or relevant to the recipient’s practice and must not include items intended for personal use, such as items of apparel, cosmetics or home electronic devices.

The value of individual competition prizes should have a combined value of not more than £200 plus VAT per event. They must be

educational in nature and relevant to the use of the product. Exceptionally, educational grants are acceptable as a prize – as described in paragraph 3.7.

Competition organisers must make employers of competition winners aware in writing of prizes that have been awarded to the employer and not the employee. A record of the notification should be retained, along with the request for acknowledgement of receipt.

3.6 **PRODUCT INFORMATION CLAIMS**

Where a product is a medical device, it is expected that claims made are supported in the documentation that shows conformity to the Essential Requirements of the Medical Devices Regulations S.I. 1994 No. 3017 as amended.

Information, claims and comparisons for all products must be accurate, balanced, fair, objective and unambiguous. They must not mislead either directly or by implication. Any information, claim or comparison must be capable of substantiation.

References for claims made in advertising and promotional literature should be readily available, for example by a web site link in the promotional material.

In vitro data must be labelled as such. Extrapolation into a clinical environment must be accompanied by sufficient evidence to demonstrate its clinical relevance.

Hanging comparisons, whereby a product is described as being better or stronger or suchlike, without stating to what it is compared, must not be made.

3.7 **EDUCATION AND TRAINING**

Companies have a responsibility, where relevant, to make available to customers, instruction, education and training to explain the safe, appropriate and effective use of their products.

If companies reimburse customers for travel, subsistence and refreshment expenses when participating in such instruction, education or training, such reimbursement must be modest in amount and related to the purpose.

Hospitality and travel must be secondary in purpose and not greater in value than the recipients would expect, if they were paying for themselves.

Member companies may provide funds to support genuine independent medical research, scholarships, advancements of medical science or education or patient and public education. Educational grants must not be tied in any way to past, present or potential future use of the member company's products and services. Research grants are permitted for investigations into areas of legitimate interest to the member company, provided that a full written description exists and is acknowledged by all parties.

3.8 **CONFERENCES, EXHIBITIONS AND SEMINARS**

Subsidies to underwrite the cost of conferences, exhibitions and seminars must be provided only to the organiser group, which may in turn use the money to reduce the costs of the event. Payment to defray the costs of an event must not be provided by the company directly to the attendees.

Companies may underwrite the costs of social events at a conference, exhibition or

Areas Covered

seminar. However, the social aspect should be of modest value, in proportion to the scale of the event and secondary to the educational purpose of the event.

Scholarships or other special funds may be provided or paid for by companies for the purpose of allowing appropriately qualified individuals to attend educational conferences and seminars. Attendance of such events must be approved by the institution employing the individual. The delegate fee must not be paid directly to that individual.

There must be no link between subsidies for conferences, exhibitions or seminars and the outcome of purchasing decisions.

3.9 PRODUCT TRIALS AND PROMOTIONAL SAMPLES

Samples left with customers should be sufficient to allow practitioners to become familiar with the product or to conduct an initial product evaluation, up to a maximum of ten (10) individual samples or one (1) standard pack.

Where samples are provided for clinical use in order that potential users may familiarise themselves with the product, the sample provided must be representative of the product itself and meet the appropriate regulations applying to the marketed product.

Stock swaps are permitted if they are part of a clinical trial or evaluation with an agreed protocol and an agreed timescale.

Stocks swaps of unused items are also permitted if they are carried out as part of a documented agreement.

Where product is being evaluated in a formal clinical trial or evaluation with an agreed protocol, samples and equipment

must only be supplied in accordance with that protocol. At the conclusion of a clinical trial, all equipment supplied must remain the property of the member company or be subject to a documented agreement.

3.10 SCIENTIFIC DEBATE AND CONFERENCE PAPERS

Brochures, leaflets and posters, handed out or made available by representatives of a company at conferences are, for the purposes of this code, regarded as advertising and promotional materials (see paragraph 3.4). A scientific paper presented at a conference and published in the official conference proceedings is regarded as scientific debate and outside the scope of this Code of Practice.

It must be clearly noted in conference proceedings and conference handouts that a speaker or the work presented by a speaker has been supported by a member company. For the purposes of this code such material must be regarded as promotional literature and advertising. Any possible conflicts of interest must also be disclosed.

For a scientific paper or data presented at a conference or meetings that are independent of company sponsorship or support and are published in the official conference proceedings, these will be considered as scientific debate and outside the scope of this code.

A member company A may request of member company B copies of papers to be presented at conferences or meetings sponsored or supported by company B if it believes that the papers may be critical of company A's products. Company A may then request the opportunity to respond at the conference or meeting. The opportunity to respond must not unduly be withheld by company B and in any case should not be less than 5 working days.

3.11 USE OF EXPERTS AND CONSULTANTS

Healthcare professionals may serve as consultants or experts for member companies providing the work is for a bona fide purpose, such as research, participation on advisory boards, and presentations at training events or conferences. It is acceptable to pay the healthcare professionals reasonable compensation for such work. However, a written agreement must be in place, signed by all parties, that fully describes the services to be provided and the remuneration and expenses payable. Where the service provided is research, then the written agreement must include a statement on how any Intellectual Property Rights are allocated.

Where healthcare professionals are engaged by a member company to perform a service, the remuneration paid must be commensurate and represent a fair market value for the service performed. Documentation must be retained to prove that the service had been adequately supplied.

3.12 CHARITABLE DONATIONS

Member companies may make donations for charitable or philanthropic purposes, provided that the recipient of the donations is a registered charity or another bona fide organisation. Charitable donations must not be tied in any way to past, present or potential future use of a member company's products or services.

3.13 ETHICAL STANDARDS

Member companies must not engage in any activity that would induce a healthcare professional to break their conditions of employment or their professional code of conduct.

3.14 SPONSORED HEALTHCARE PROFESSIONALS

Funding of healthcare professionals or the provision of nurses on an honorary contract are allowed if a written agreement is in place, signed by all parties, and that fully describes the required duties, the remuneration and expenses payable. Any use of products by such healthcare professionals or nurses should be fully in line with existing customer protocols – including clinical trial protocols



Areas Excluded

SECTION 4

4.1 MEDICINAL PRODUCTS

Products in respect of which a marketing authorisation has been granted pursuant to the Human Medicines Regulations 2012 are excluded from this Code of Practice. This area is already covered by the ABPI Code of Practice for the Pharmaceutical Industry.

For the avoidance of doubt, medical devices are not excluded, whether or not they contain medicinal substances.

4.2 VETERINARY PRODUCTS

Products sold for the treatment of animals are excluded from this Code of Practice. Amongst others, this area is already covered by the NOAH Code of Practice for the Promotion of Animal Medicines.

4.3 SALE TO THE GENERAL PUBLIC

Consumer advertising directed towards, and supply to, the general public. This area is already covered by the Sale of Goods and Services legislation and enforced by Trading Standards.

4.4 MEASURES OR TRADE PRACTICES

Measures or trade practices relating to prices, margins, or discounts which are in regular use by a significant proportion of the wound care industry. The exclusion extends to normal trade practices when supplying products solely for the OTC market.

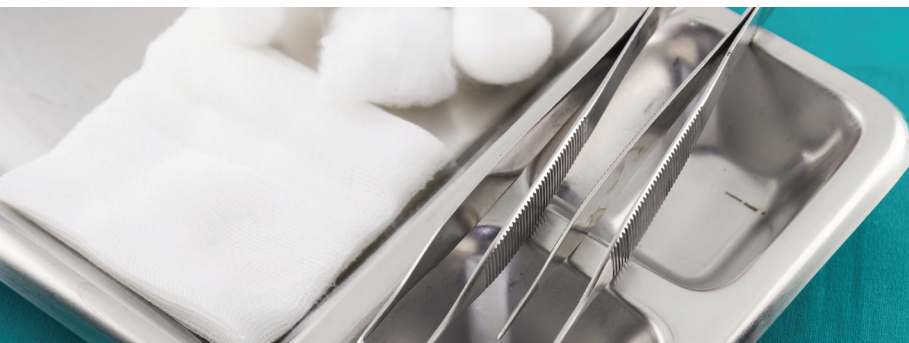
4.5 PRODUCT QUALITY AND ADVERSE REACTIONS

Complaints on individual product quality and adverse reactions are excluded from this Code, as described in paragraph 5.14 below.

4.6 LEGAL INVOLVEMENT

Any issue that is the subject of formal legal proceedings is excluded from the Code of Practice Complaints Procedure. Where legal activity is commenced in relation to a complaint already in progress the complaints procedure will immediately cease. Complaints cannot be raised or re opened when legal activities have ceased.

When the outcome of any legal proceedings conclude that activities have occurred which would amount to a breach of the Code, the findings will be published by the SDMA but additional sanctions will not be applied



Complaints Procedure

SECTION 5

- 5.1 Complaints of signatories to the code thought to be in breach of this code may be made by health care professionals, companies or private individuals. However, the parties involved should attempt to resolve the issue prior to any complaint being made.

Healthcare professionals or private individuals can make complaints directly to the SDMA without having to attempt a resolution of the issue with an SDMA member company. The SDMA will, at their request, maintain their anonymity. The SDMA secretary will act on behalf of such complainants if necessary.

For complaints related to competitions, a member company making a complaint is simply required to inform the member company that ran the competition that they consider a breach of the Code of Practice took place (stating their reasons) and that they will be registering a formal complaint with the SDMA Secretary. The Secretary will then ask the competition organiser for any statements they wish to make in justification of the competition or prize. After this, the complaint will be processed in the normal manner.

- 5.2 As they may be required to participate in Complaints Panel hearings, the SDMA Secretary and members of the Complaints Committee are not permitted to provide views on whether particular activities might breach the Code.

Questions or issues concerning the interpretation of the code should be taken to the General Committee for resolution.

- 5.3 Complaints must be made in writing to the Secretary of the SDMA indicating the clauses involved. When the complainant is a company, they must advise the company which is the subject of the complaint at the same time they raise the complaint with the SDMA. The requirements stated in paragraph 5.1 above must have been followed before a complaint will be logged.
- 5.4 The SDMA secretary must keep a log of all complaints. An alleged breach of the Code must be registered with the SDMA secretary within twelve (12) months of the incident occurring. Once a complaint has been registered in the log it cannot later be withdrawn.
- 5.5 The SDMA Secretary will immediately confirm receipt of a complaint, notify the company which is the subject of the complaint and refer the complaint to the Complaints Committee.
- 5.6 Complaints made by one company against another company must be signed by either the named General Committee representative or an executive director.
- 5.7 The SDMA Secretary must receive copies of all correspondence.
- 5.8 As soon as the relevant correspondence has been received, a panel from the Complaints Committee will be called together to consider and to pass an opinion. All complaints will be judged by the Complaints Committee on an individual basis.
- 5.9 All parties concerned with the complaint will be informed of the Complaints Committee's opinion in writing shortly after the meeting.

Complaints Procedure

- 5.10 SDMA member companies found in breach of the code will be responsible to bear the costs of the breach process in the form of a levy of £3,000 (or less if a reduced amount is recommended by the Complaint Committee and endorsed by the General Committee).

If there is found to be no breach of the code and a member company made the complaint, it will bear the costs of the complaint process in the form of a levy of £3,000 (or less if a reduced amount is recommended by the Complaint Committee and endorsed by the General Committee). If the complaint was made by an NHS or healthcare organisation, the SDMA will underwrite the costs incurred.

Companies who are not members of the SDMA can make complaints against member companies of the SDMA. However, non-member companies bringing a complaint will be asked to pay a levy of £5,000, 50% of which will be refundable if their complaint is upheld. Once the levy had been received the complaint will be processed in the normal manner.

All levies must be paid within thirty working days of the invoice date. If payment of a levy has not been made within thirty (30) working days, the matter will be referred to the General Committee.

- 5.11 The outcome of complaints made to the Complaints Committee will be published on the SDMA web site and in an appropriate journal (to be advised from time to time). The names of the companies involved will be included.
- 5.12 A decision of the Complaints Committee can be reviewed only if new evidence is presented in writing within thirty days. Reviews will be considered, where possible, by the same panel from the Complaints Committee with the fee structure described above applying.

- 5.13 Several complaints from different sources about the same activity will be regarded as one complaint with respect to a potential breach of this code.
- 5.14 Complaints that allege non-compliance to the Medical Device Regulations cannot be judged by the SDMA, which has a duty to forward all such complaints to the relevant Competent Authority.
- 5.15 The SDMA has a duty to report apparent breaches of the Bribery or Competition Acts to the relevant authorities.
- 5.16 The Complaints Committee will be entitled to note that a member company has persistently repeated an offence. In such circumstances the matter, along with any recommendations by the Complaints Committee, will be referred to the General Committee for further action or sanctions to be considered.
- 5.17 Whenever a complaint is discussed by the General Committee, any parties to the complaint must withdraw from the General Committee meeting for the duration of the discussion.
- 5.18 The SDMA Secretary, or any member of the Complaints Committee, must immediately report to the SDMA Chairman and Vice Chairman any actions by either party involved in a complaint that they deem to be an attempt to influence the outcome of that complaint.
- 5.19 Any decision made by the Complaints Committee will be considered final.

Complaints Committee

Complaints will be adjudicated by a panel chaired by an independent person nominated by the General Committee. The panel will consist of five (5) individuals drawn from a list of approved experts held by the secretary of the SDMA. The panel has full authority to consider, assess and decide all complaints.

Any individual having an interest in either the complainant or the company complained against must make a declaration of interest to the SDMA Secretary and withdraw from the panel.

The list of approved experts will be approved annually at the Annual General Meeting of the Surgical Dressing Manufacturers Association.



Appendix

Appendix

Background Information on the SDMA

The SDMA exists to serve companies who manufacture or distribute wound care and associated products within Europe with sales or distribution in the UK. Currently it has a membership of 16 companies and represents a combined turnover of over £0.5bn in wound care products. Member companies range in size from small family companies to major multinational organisations – but each company has an equal voice, regardless of size. One of the great strengths of the SDMA is the inclusive nature of its membership.

This Code of Practice has operated very successfully for many years and has succeeded in gaining a wide level of respect. Although there is strong encouragement for any issues under the Code to be resolved amicably between the parties concerned, an independent expert panel is available to adjudicate when necessary. The Code was introduced at the request of, and with the full support of all the SDMA member companies. It entered its sixth revision in February 2017. It is a condition of membership that companies abide by the code for promotional activities to healthcare professionals in the UK.



Notes



SURGICAL
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