MEDICAL DEVICES DIRECTORATE

DIRECTIVES BULLETIN

THE CITIZEN'S CHARTER AND DEREGULATION

A CODE FOR ENFORCEMENT

Bulletin number 9

August 1993

DEPARTMENT OF HEALTH

Introduction

This information Bulletin is the ninth in a series. It sets out, in broad terms, the principles for regulatory and enforcement bodies in their dealings with the healthcare industry, particularly in relation to the implementation of the EC Directives concerning medical devices. It is part of the Prime Minister's initiative on deregulation and the Citizen's Charter.

Regulatory and enforcement bodies

The regulatory and enforcement bodies covered are those under direct Government control. These are Government departments, Agencies and non-Departmental Public Bodies and they include, therefore, the Medical Devices Directorate (MDD).

The principles for regulation and enforcement

It is necessary for the Medical Devices Directorate to be aware of the needs of industry and, with other enforcement bodies, we strive to behave in a way that is helpful to business.

Also, it is essential that industry should have easy access to simple guidance about regulations and should be able to complain without fear if it is unhappy with the way a regulation has been enforced.

Accordingly, it is intended that administrative procedures shall be streamlined as far as possible and that regulations should aim for simplicity.

How will this be done?

A **Code for Enforcement**, embodying both deregulation and Citizen Charter principles, will apply to MDD immediately. Other organisations which enforce areas of regulations, such as Notified Bodies responsible for enforcing legal requirements on business, are not under the direct control of Government. However, they will be actively encouraged to adopt the principles in the Code.

Timescale

Each enforcement body will publish its Code stating how it is putting the principles into practice. The Code will include information about the responsibilities of the enforcement body and the standards it will work to. MDD, the Competent Authority for medical devices regulation, has been charged with producing its Code for enforcement by 1 January 1994.

The Code

The Code will cover the following areas:-

* **Publication of Standards**

  Publication of clear statements of standards setting out the level of service that business people should be able to receive. Standards will include the time taken to respond to enquiries and the effectiveness of complaints procedures. Performance against the standards will be monitored and published annually.

* **Information and Openness**

  Provision of information and advice in plain language on the rules that are being enforced. Advice will distinguish between practices which set out the obligatory requirements on business and those improvements which are not mandatory. (These Bulletins already go some way towards satisfying this requirement.). Charges for advice and for enforcement will be set out sufficiently in advance to allow for consultation. Enforcement bodies will be open about how they set about their work.

* **Consultation and Communication**

  Consultation with business to discuss compliance failures or difficulties. This will help the enforcement body to understand the concerns of business and business to recognise why the particular regulation is important.

* **Courtesy and Helpfulness**

  Provision of a courteous and efficient service. Enforcement staff will indentify themselves by name. (The names of officials presently working on Competent Authority activities are included with this Bulletin.).

* **Complaints**

  The establishment of well publicised, swift and effective complaints systems that are easily accessible to business. An element of independence will be included so that business can complain without fear and enforcement bodies can carry out their duties impartially.

* Value for Money

The costs of compliance imposed on business by enforcement to be minimised. As far as possible, enforcers will aim to ensure that compliance costs are proportionate to the risk and take account of the particular needs of small firms. Clearer information and more focused enforcement will also deliver better value for money.

Benefits

The Code for Enforcement is expected to benefit business by -

* cutting the overall cost of complying with regulations;

* reducing the uncertainty to business about whether they are complying completely and correctly; and

* assuring business that they are competing with one another on level terms.

The Code is also expected to benefit ordinary citizens, and patients, by -

* ensuring that regulations achieve their intended purpose;

* improving their protection; and

* reducing the burden on the taxpayer.

Further information

Further information about the Code for Enforcement and the EC Directives concerning medical devices can be obtained from:-

Mr R M Gutowski
Department of Health
Medical Devices Directorate
14 Russell Square
LONDON WC1B 5EP

Telephone: (071) 636 6811 Extn 3199/3039
Fax: (071) 436 2128.

MEDICAL
DEVICES
DIRECTORATE

Medical Devices Directorate
Department of Health
14 Russell Square, London WC1B 5EP
Telex 883669 DHSSHQ G
Fax 071-637 8990
Telephone 071-636 6811 Ext.

Your reference:

Our reference:

Date: 27 July 1993

Following a comprehensive review, Ministers have approved the Medical Devices Directorate as a candidate for Next Steps Agency status. The aim is to launch the new Agency on 1 April 1994.

The Next Steps initiative is designed to improve management and to deliver better quality central Government services within available resources, for the benefit of taxpayers, customers and staff. As the Medical Devices Agency we will seek to achieve that aim.

A Chief Executive will be appointed in the next few months by open competition. She or he will be accountable to Parliament and directly to Ministers for the Agency's performance.

The document setting out the parameters within which the new Agency will operate (the Framework Document) will be available from 1 April 1994. It will include the targets and performance indicators by which the Agency's success will be measured. You can order a copy by contacting Pamela Durham by fax on 071-436 0851 or by writing to the address given above. (Please note that from 27 September the fax number will be 071-972 8104). Your name will be added to our mailing list and the document will be sent out when the Agency is launched.

As a user of our services we very much value your views on our current performance and any improvements we could make. We will be surveying our customers as part of our move towards better focussed services. If, meanwhile, you have any comments, please write to me now.

Alan Barton

ALAN BARTON
Director

— MEDICAL —
DEVICES
DIRECTORATE

Medical Devices Directorate
Department of Health
14 Russell Square, London WC1B 5EP
Telex 883669 DHSSHQ G
Fax 071-637 8990
Telephone 071-636 6811 Ext.

Your reference:

Our reference:

Date:

New telephone numbers from 27 September 1993:

Switchboard: 071 972 2000

Direct Lines:

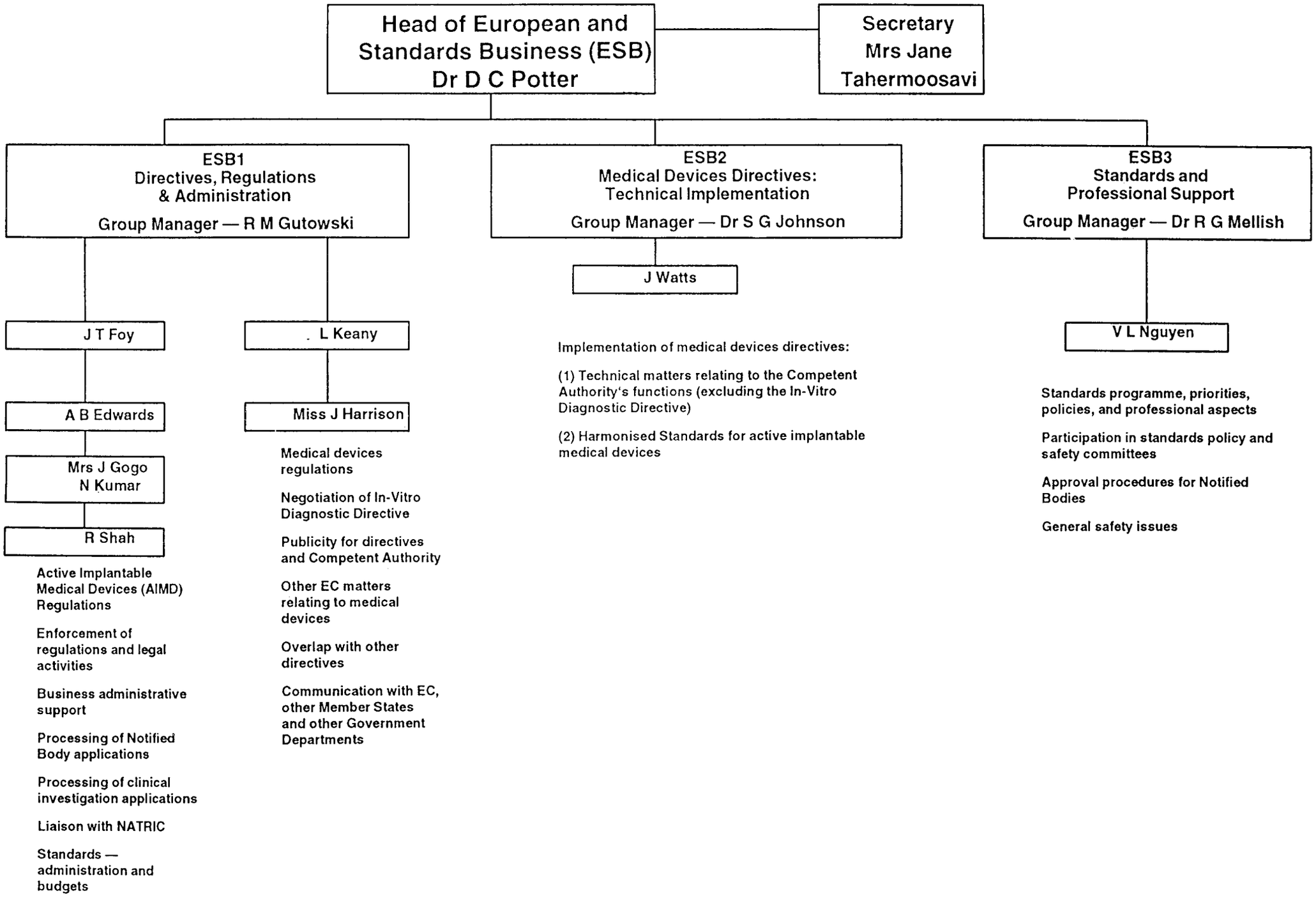
European Directives	071-972 8300
NATRIC	071-972 8080
Evaluation Publications	071-972 8181
Manufacturer Registration Scheme	071-972 8200
Competent Authority	071-972 8282
Device Technology and Safety Enquiry Point	071-972-8100

Our new telephone system will provide **Direct Dialling In** please ask our staff to give you their direct line numbers if you expect to make regular contact.

Fax Numbers:

European Directives	071-972 8112
NATRIC	071-972 8109
Evaluation Publications	071-972 8105
Manufacturer Registration Scheme:	
Administration Services	071-972 8107
Professional Services	071-972 8110
Competent Authority	071-972 8111
Device Technology and Safety:	
General Enquiries, Non-Acute and Diagnostic Imaging Services	071-972 8106
Acute Care services	071-972 8113
Corporate Management	071-972 8104
Medical and Nursing	071-972 8103

MEDICAL DEVICES DIRECTORATE, EUROPEAN AND STANDARDS BUSINESS



MEDICAL DEVICES DIRECTORATE, DEVICE TECHNOLOGY AND SAFETY (DTS)

Business Manager
Miss M N Duncan

Adverse Incident Reporting

Group Manager — J Worroll

National Reporting and Investigation Centre (NATRIC)
Manager — A C Wheeler

NATRIC

Office Manager— Mrs M Bahadur

Initial Data Collection & Processing

S Visvanathan
Mrs J Wallen

Community & Non-Acute Care Devices & Services
Group Manager — A D C Shipley

Acute Care Devices & Services

Group Manager — C S Bray

Professional specialists providing in-depth investigations and advice concerning:

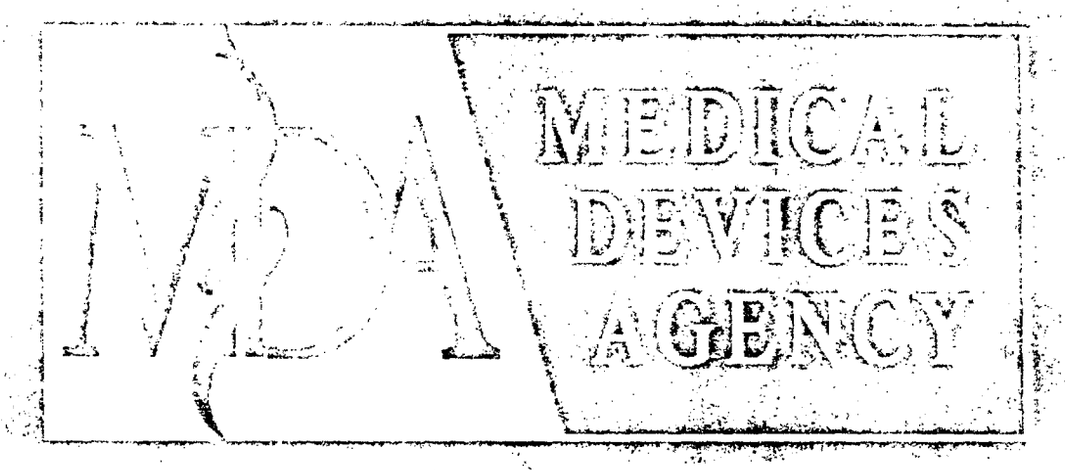
- Community and non-acute care devices
- Mobility aids and equipment
- Non-acute care diagnostic imaging and measurement devices

- External life support devices
- Implants and toxicology
- Acute service therapy, surgical devices & in-vitro diagnostic devices

MEDICAL & NURSING ADVICE

Dr S Ludgate

Mrs P A Collinson



Enforcement Policy

Compliance Inspections and Action

Your Rights

Medical Devices Agency's (MDA) Enforcement Responsibilities

1. The Secretary of State for Health is responsible for administering legislation relating to medical devices and for ensuring the safety and quality of devices. The relevant legislation is:

(a) The Active Implantable Medical Devices Regulations (SI 1992 No 3146) as amended by SI 1995 No 1671;

(b) The Medical Devices Regulations (SI 1994 No 3017). For the purposes of enforcement, these Regulations are safety regulations under the Consumer Protection Act 1987.

2. MDA have a duty to enforce this legislation on behalf of the Secretary of State and have delegated responsibility for England, Wales, Scotland and Northern Ireland. This involves establishing that the Medical Devices Regulations have been complied with and ensuring that the appropriate action is taken wherever necessary to prohibit or restrict unsafe products being placed on the market.

3. The above obligation is met by MDA in 4 basic ways.

(i) Any complaints about CE marked products which are drawn to our attention will be investigated;

(ii) Selection for inspection of a sample of manufacturers who have CE marked their products on the basis of self - assessment to determine compliance with the essential requirements specified in the Medical Devices Regulations and manufacturers of custom-made devices, assemblers or sterilisers who are also required to register under the Regulations;

(iii) Regular monitoring of the activity of Notified Bodies designated by MDA to assess the compliance of products not subject to self-declaration;

(iv) Inspections will be undertaken where warranted as a result of vigilance reports.

4. The investigations in (i), (ii) and (iv) above will normally be initiated and resolved in writing by requesting technical and other information for documentary review. Inspection visits will only be undertaken where the documentation indicates it is merited to confirm compliance, or where technical documentation can only be properly reviewed on site as for custom-made devices.

Immediate enforcement action may be required in some instances to protect public health. The following paragraphs explain MDA's role and a manufacturer's rights in these circumstances.

Inspection Visits

5. The undertaking of an inspection visit does not necessarily mean that there has been a breach of the Regulations.

6. MDA have no legal obligation to give prior notice of an inspection visit. However, manufacturers will normally be informed 14 days before the date. One of the aims of the visit is to confirm that the essential requirements are being complied with in practice. There will, therefore, be no need to disrupt the manufacturing process and it will not be essential for senior management to be present or for any special preparation to be made. The date of the visit will only be changed in exceptional circumstances.

7. The inspection visit will be undertaken by an authorised inspector supported, as necessary by product specialist staff. They have been fully trained to carry out inspection duties and carry an authorisation card which will be shown on request.
Inspectors make their own travel, accommodation and catering arrangements and will not accept any offers that could possibly be construed as affecting their judgement.

8. Compliance Officers are designated by MDA's Chief Executive on behalf of the Secretary of State to determine whether a contravention of any safety provision has taken place. Under Section 29 of the Consumer Protection Act they have the right to:

(a) enter premises and inspect goods;

(b) examine manufacturing procedures and testing arrangements;

(c) require the production of any records for examination and to take copies of, or of an entry in, the records, if required;

(d) seize and/or detain suspect goods which may be required as evidence in proceedings for an offence in respect of a contravention.

9. The visit will normally last for no more than a day and, as outlined above, access will be required to any records, technical specifications or parts of the manufacturing site to confirm compliance with the essential requirements specified in the Regulations. It is an offence under Section 32 of the Consumer Protection Act 1987 to fail to give such an officer any other assistance or information that they reasonably require for the purposes of exercising their function under the Act.

10. Any information provided will be treated in confidence in accordance with Article 20 of the Medical Devices Directive (93/42/EEC) which is implemented in the UK by the Medical Devices Regulations.

Enforcement Action

11. If a possible offence is detected any interview will be undertaken under caution, as required by the Police and Criminal Evidence Act 1984 (PACE). If detection occurs during an inspection, the visit will normally be terminated and an interview under caution arranged for a later date at MDA's offices. However, an inspector may conduct
such an interview on the spot if appropriate. Company representatives will be informed of their rights at relevant stages under the Police and Criminal Evidence Act 1984 Code C and E of the Code of Practice. PACE under the Code of Practice sets out the investigations of an offence and includes safeguards and protections for members of the public.

12. As well as prosecution, the MDA has a range of other enforcement powers under the

Consumer Protection Act:

(a) Offences against the safety regulations (Section 12) - these set out the potential safety non-compliances;

(b) Prohibition Notices (Section 13) - these prohibit the supply of any goods which are considered to be unsafe or are not in compliance with Regulations;

(c) Notices to Warn (Section 13) - these require a manufacturer to issue at his own expense a warning about any relevant goods which are considered unsafe;

(d) Suspension Notices (Section 14) - these limit the supply of a good for a period of up to six months where it is suspected that a safety provision has been contravened. Compensation may be payable if it is later established that there was no contravention;

(e) Forfeiture Orders (Sections 16 and 17) - Enforcement authorities may apply for an order for the forfeiture of goods where there has been contravention of a safety provision;

(f) Obtaining Information (Section 18) - MDA, on behalf of the Secretary of State, has the power to serve a notice requiring a person to furnish information or to produce records for the purpose of deciding whether to serve, vary or revoke a prohibition notice or notice to warn;

(g) Test purchases (Section 28) - this gives enforcement authorities the power to make test purchases for the same purposes as above.

In addition, regulation 19 (7) of the Medical Devices Regulations and regulation 10 of the Active Implantable Medical Devices Regulations (as amended) provide powers to issue notices for non-compliances with the Regulations. These powers are in the main for technical breaches of the Regulations such as where a device is thought not to conform with an essential requirement, but where it does not compromise health or safety. The notice requires the person on whom it is served to ensure the device conforms with the period stated in the notice.

Notification

13. Where an inspector informs a manufacturer that he should take remedial action before the question of formal action arises, you have the right to request a written statement expressing clearly what action is necessary and why.

14. Unless immediate action is merited on safety grounds, you will be notified of an intention to take formal enforcement action. You have the right, within a specified period of not less than 14 days, to make formal written representations to MDA before action is taken.

15. Where immediate action is necessary, a written statement explaining the reasons for the action will be provided as soon as practicable

16. The above are all measures introduced to improve enforcement procedures and to make them less burdensome on industry in line with the Quality Regulation Initiative.

Appeals

17. At the time an enforcement notice or summons is issued, manufacturers will be informed of their right of appeal and how they should go about it.

18. Appeals against conviction are through the Courts but there are a variety of different means of appeal against other enforcement decisions, some of which are prescribed in the Consumer Protection Act, the Appeals Procedures, and others which are applied administratively by MDA. A guidance document will be available shortly.The following applies to action taken under both the Active Implantable and Medical Devices Regulations.

19. Prohibition Notices: a manufacturer may make written representations to MDA's Chief Executive (acting on behalf of the Secretary of State). The Chief Executive will decide whether to revoke the notice outright or to appoint an Independent Adjudicator to consider the manufacturer's views and report back. Only the Chief Executive can make the final decision but he has a duty to consider the Adjudicator's findings and, if necessary, seek the Secretary of State's approval. The final decision could uphold the notice, revoke it completely or make variations to it. In the case of the latter, the variation may not be more onerous than the original notice.

20. Notices to Warn: before a notice of this type is issued MDA are required to provide the manufacturer with a draft of the notice and a written statement of why it is necessary. At that stage the manufacturer may make written representations to MDA's Chief Executive who will consider the appeal in the same way as prohibition notices above.

21. Suspension Notices or Forfeiture of Goods: an application to set aside a suspension notice can be made to a Magistrate's Court in England, Wales and Northern Ireland or by summary application to a Sheriff's Court in Scotland.

22. Forfeiture Orders: these are issued by a Magistrate's Court, on application by MDA or through the Procurator Fiscal to the Sheriff in Scotland. The Court can only issue the order if it is satisfied that there has been a contravention of the safety provision in relation to those goods. If a manufacturer is aggrieved by the making of such an order he can appeal through the Crown Court in England and Wales, the County Court in Northern Ireland and to the High Court by Bill of Suspension in Scotland.

23. Notice to Produce Documents: requests for information will be covered by administrative appeal procedures being introduced by MDA which will be similar to the Independent Adjudicator system for prohibition notices. The first step is for a manufacturer to make written representation to MDA's Chief Executive.

24. Decisions to inspect goods, enter premises, examine procedures, require the production of goods, seizure and detention of goods or records and require the opening of containers or vending machines. If the occupier of premises does not voluntarily permit entry or where it is anticipated that permission will not be granted to enter the premises or for other powers of search necessary, the enforcement authority must go to a Justice of the Peace for a warrant. The criteria that the Justice of the Peace has to be satisfied are being met before issuing a warrant are laid down in Section 30(2) of the Consumer Protection Act 1987. Appeals against (or where no proceedings have been brought a complaint about) the retention of goods following seizure can be made to Magistrates' Courts in England, Wales and Northern Ireland or by summary application to the Sheriff in Scotland.

25. Non-compliance with the Regulations: these notices will also be the subject of the appeal procedure being introduced which will be similar to the Independent Adjudicator system for prohibition notices. The first step is for a manufacturer to make written representation to MDA's Chief Executive.

26. Complaints about the conduct of MDA personnel: any complaints about the behaviour of MDA personnel or advice given by them other than on enforcement decisions (see the section on appeals above) will be covered by MDA's complaints procedure. A complaint against a member of MDA's staff may be initiated by writing to his or her senior officer or to the Chief Executive. Full details of the procedure will
be published in MDA's revised Code of Practice.

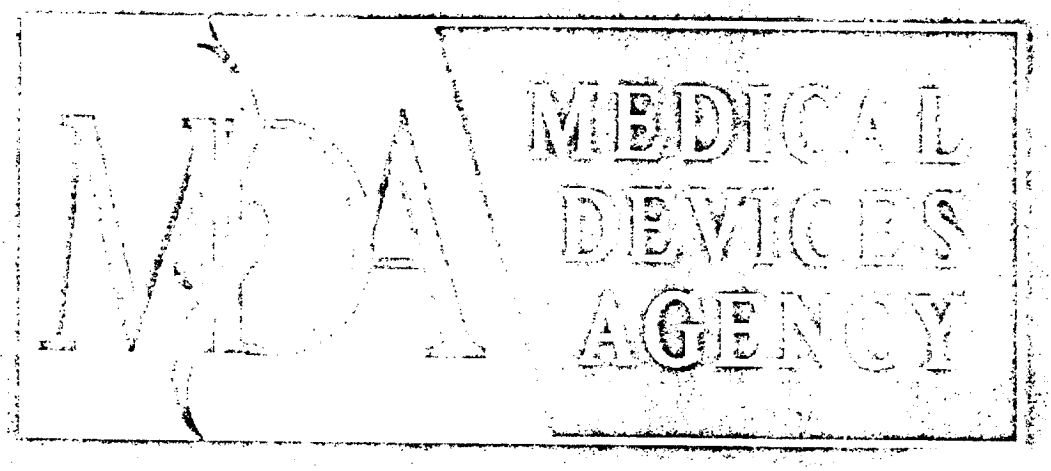
27. Clinical Investigation Applications and Notified Body Designations: the decisions taken by the Secretary of State about whether to object to a clinical investigation or issues relating to the designation of Notified Bodies are not currently subject to any appeal. The only appeal a manufacturer or Notified Body has in this respect is by seeking Judicial Review. This will change and the MDA appeal procedure detailed above for prohibition notices will apply.

Further Information

28. If you require any further information on the above please contact:-

Stephen Wilson
Medical Devices Agency
European and Compliance Section
11N8
Hannibal House
Elephant and Castle
London SE1 6TQ

Tel: 020 7972 8207
Fax: 020 7972 8112



Enforcement Policy

Your Questions Answered

What is the MDA?

The Medical Devices Agency (MDA) as the UK'S Competent Authority under the Medical Devices Regulations has a legal duty to ensure that manufacturers conform to the provisions of those Regulations before placing their products onto the UK market.

How does MDA fulfil this role?

In addition to investigating claims that products do not meet necessary requirements, MDA also selects manufacturers of medical devices which have been CE marked on a self-declaration basis (ie without an independent assessment being made by a Notified Body). MDA then reviews relevant technical documentation kept by the manufacturer in support of the named device's CE marking. The manufacturers of custom-made products, assemblers and sterilisers required to register under the Regulations will also be subject to this programme of inspection.

How was I selected?

Your name was obtained from MDA's Register of manufacturers who self-declare compliance with the Regulations.

This does not imply any suspicion that you have not conformed fully with the various Regulations.

What Regulations are involved?

The relevant legislation is

Medical Devices Regulations (SI 1994 No 3017).

For the purposes of enforcement these Regulations are safety regulations under the Consumer Protection Act 1987. These implement Directive 93/42/EEC.

Do I have to give you the information requested?

Yes. Regulation 7 of the Medical Devices Regulations together with Annex VII to the Directive requires you to keep relevant documents available for inspection by the national authorities. Enforcement action may be taken if you do not provide this information when asked unless you have a good reason for not doing so.

Will the information I give you be safe?

Any information provided will be treated as confidential. Once we have finished with it we will either return it to you or destroy it depending on your wishes.

What will you do with the information?

MDA experts will examine the information to confirm that the
relevant essential requirements in the Regulations have been complied with. In some cases this will not be possible from an examination of paper records alone and a site visit will be

necessary. However, in most cases we expect to be able to resolve any outstanding issues with you by correspondence.

What happens if you discover a breach of the Regulations?

This will depend upon the nature of the breach. However, in the majority of cases we would expect to reach an agreement with you to put the defect right within an acceptable time. Where such an agreement is reached no further action is likely. In a very few cases, for example, where public health and safety are being jeopardised or a manufacturer refuses to take corrective action, MDA has the power to initiate a range of enforcement action including prosecution.

Do I have any rights in this process?

Yes. These are described in further detail in the leaflet "Compliance Inspections and Action: Your Rights." The leaflet also sets out your rights of appeal against any enforcement action taken.

What enforcement role do Trading Standards Officers (TSOs) have?

Under the Medical Devices Regulations, Trading Standards Officers also have enforcement responsibilities for over - the - counter devices available from retail outlets.

How will duplication of any enforcement action with Local Authority TSOs be avoided?

Under the Home Authority Principle, the Local Authority TSO has a co-ordination function to minimise duplication and reduce public expenditure. MDA will, wherever possible, liaise with the Local Authority Trading Standards Office to ensure that such duplication is avoided.

Where can I obtain more information about MDA or its enforcement policy?

You can obtain more information from:

Stephen Wilson
The Medical Devices Agency
European and Compliance Section
11N8, Hannibal House
Elephant and Castle
London SE1 6TQ

Tel : 020 7972 8207
Fax : 020 7972 8112