

APPLICATION FOR APPROVAL
OF PRODUCTS UNDER PART IX
OF THE DRUG TARIFF
FOR GP AND NURSE PRESCRIBING

1	PRODUCT NAME State the trade name under which the product is to be launched, or is already known in the UK.
2	DETAILS OF APPLICANT AND MANUFACTURER (if different)
	Names and address of applicant Name and address of manufacturer(s)
3	GENERAL DESCRIPTION OF PRODUCT (including Drug Tariff category, eg. Nebulisers)
4	PROPOSED PACK SIZES, PRICES AND ORDER CODES (eg. Five dressings – 100 pence – code 00123)
5	DOES THE PRODUCT CARRY A CE MARK UNDER THE MEDICAL DEVICES DIRECTIVE 93/42/EEC? Yes/no; if yes, please give the classification of the device under this Directive. (see appendix A for documentation)
	<p>Class I</p> <p>Class IIa</p> <p>Class IIb</p> <p>Class III</p>
6	DOES THE PRODUCT CARRY A CE MARK UNDER THE IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE? yes/no if yes, please give the category of the device under this Directive. (see appendix B for documentation)
	<p>General IVD (ie other than for self-testing of those appearing in annex II)</p> <p>Self-test IVD (other than those appearing in annex II)</p> <p>IVD appearing in annex II list B</p> <p>IVD appearing in annex II list A</p>

7	DETAILS OF COMPLIANCE WITH DRUG TARIFF SPECIFICATION, BRITISH STANDARDS OR BRITISH PHARMACOPOEIA IF ANY SUCH COMPLIANCE IS CLAIMED. Please attach a certificate of evidence from an accredited independent testing house (where appropriate).
8	DETAILS OF COMPLIANCE WITH QUALITY ASSURANCE SYSTEMS USED DURING MANUFACTURE (if any)
9	CLINICAL DEMAND indicate patient population and anticipated volume of sales
10	CONTRA-INDICATIONS AND ANY OTHER LIMITATIONS TO USE
11	PLEASE CONFIRM THAT THE PRODUCT WILL BE MADE READILY AVAILABLE TO THE COMMUNITY PHARMACIST EITHER THROUGH THE NORMAL WHOLESALE NETWORK OR ON EQUIVALENT TERMS
SIGNATORY	
The application should be signed by a senior person in the company	
Signature.....Date.....	
Name in block capitals.....	
Position in the company.....	
Please send a copy of this form together with one sample of the product to: Pharmaceutical Services Manager, NHS Business Services Authority, Prescription Pricing Divison, Bridge House, 152 Pilgrim Street, Newcastle-upon-Tyne, NE1 6SN.	

Appendix A. Documentation required for:

- a) Class I devices
 - A declaration of Conformity covering the Brand/Product name and,
 - Confirmation as to which Member State the manufacturer/Authorised Representative has registered in
 - For devices which are sterile or have measuring function the appropriate Notified Body approval

- b) Class IIa devices
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Notified Body Approval under Annex II **or**,
 - Notified Body Approval under Annex IV **or**,
 - Notified Body Approval under Annex V **or**,
 - Notified Body Approval under Annex VI

- c) Class IIb devices
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Notified Body Approval under Annex II **or**,
 - Notified Body Approval under Annex III and Annex IV **or**,
 - Notified Body Approval under Annex III and Annex V **or**,
 - Notified Body Approval under Annex III and Annex VI

- d) Class III devices
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Notified Body Approval under Annex II along with an EC Design Examination certificate **or**,
 - Notified Body Approval under Annex III and Annex IV **or**,
 - Notified Body Approval under Annex III and Annex V

Appendix B. Documentation required for:

- a) General IVDs
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Confirmation as to which Member State the manufacturer/Authorised Representative has registered in

- b) Self-testing IVDs
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Confirmation as to which Member State the manufacturer/Authorised Representative has registered in **and**,
 - Notified Body Product Design Examination Certificate under Annex III Section 6 **or**,
 - Notified Body Approval under Annex IV **or**,
 - Notified Body Approval under Annex V and Annex VI **or**,
 - Notified Body Approval under Annex V and Annex VII

- c) Annex II List B IVDs
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Confirmation as to which Member State the manufacturer/Authorised Representative has registered in **and**,
 - Notified Body Approval under Annex IV **or**,
 - Notified Body Approval under Annex V and Annex VI **or**,
 - Notified Body Approval under Annex V and Annex VII

- d) Annex II List A IVDs
 - A declaration of Conformity covering the Brand/Product name **and**,
 - Confirmation as to which Member State the manufacturer/Authorised Representative has registered in **and**,
 - Notified Body Approval under Annex IV, a Notified Body Product Design Dossier Examination Certificate and a Notified Body Batch or product Verification Certificate **or**,
 - Notified Body Approval under Annex V, Annex VII and a Notified Body Batch or product Verification Certificate.

Note: The IVD regulations came into force on 7 June 2000 and include a transitional period until 7 December 2003, after which date manufacturers must comply with the legislation. IVDs which conform with existing national legislation and are already in the distribution chain at the end of the transitional period can continue to be supplied to the end user for a further two years (ie until 7 December 2005).