

Mail

*The MHRA updating service
for medicines*



Medicines and Healthcare products
Regulatory Agency

Safeguarding public health

No. 136 March/April 2003

- ICH standards for electronic reporting
- MHRA fees for human medicines 2003/2004
- New Regulations on Good Clinical Practice in clinical trials



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Items in *MAIL* give general guidance and must not be treated as a complete and authoritative statement of the law on any particular case. Copies of the Medicines Act and of the Orders and Regulations made under the Act are available from The Stationery Office bookshops.

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WELCOME to *MAIL* 136, the first issue to be published under our new name, the Medicines and Healthcare products Regulatory Agency (MHRA). Details of the reason for the change are given on page six. This month as our leading issue we have an update on the progress we have made towards implementation of standards for electronic reporting. We have information on the proposed implementation of the Clinical Trials Directive (2001/20/EC) into UK law, and also the new MHRA fees for medicines, which came into force on April 1. Finally we have news of a new flat-rate fee for the assessment of changes to labels and leaflets.

EDSCULLY
The Editor, *MAIL*, 10th floor, Market Towers.
Telephone 020-7273 0345.



Leading issues

Update on MHRA status on implementation of electronic standards for electronic reporting

THE MHRA is currently enhancing its pharmacovigilance systems to comply with the requirement to implement the International Conference on Harmonisation (ICH) standards for the electronic transmission of Individual Case Safety Reports (ICSRs) and the move to electronic transmission of ICSRs.

Specifically (as of March 2003):

- The MHRA's pharmacovigilance database (ADROIT) is in the process of being migrated to the MedDRA terminology (originally ICH M1) which will be the required medical terminology for electronic reporting. This migration requires extensive testing and is expected to be completed in the first quarter of 2003.

- The MHRA currently has the ability to receive electronic reports from market authorisation holders (MAHs) and send reports to the EMEA in version 2.0 of the ICSR Message Specification (ICH ICSR DTD version 2.0). The latest version of this specification (and the version that will be used in live operation) is version 2.1 and we expect to have migrated to this version by end March 2003. We can also return the standard XML acknowledgement message to MAHs on receipt of an electronic report.

- The MHRA currently does not have the ability to send reports to MAHs. We are developing this capability.

The MHRA have implemented the Cyclone secure gateway (also used by the EMEA) and can receive electronic reports from MAHs using this mechanism.

We are aware that not all MAHs are able to report ICSRs electronically at present and are working to amend their systems to ensure that the electronic reporting requirements are met. We would like to issue the following advice:

ICSRs can be sent to the MHRA by the following ways and will be accepted with or without

MedDRA (any version of MedDRA can be used):

- Via the Secure Gateway– (a fully compliant E2B(M) file)
- On Paper
- Via AEGIS (for those MAHs that subscribe to AEGIS)

All MAHs are requested to report all ICSRs directly to the MHRA following reporting requirements as stated in Directive. We will then send the report to EMEA as required. However, while the MHRA is migrating their system, we request that all MAHs contact the MHRA for direct advice on this issue before they start sending parallel reports to the EMEA to determine whether a parallel report to the EMEA is necessary.

The MHRA is ready to start testing the receipt of ICSRs from individual MAHs:

- Via the Secure Gateway
- Via AEGIS (as a backup mechanism)

Please note that we will require the electronic ICSRs to be in DTD version 2.0 format until we have migrated to version 2.1 (see above). During testing the MHRA will provide feedback to MAHs on any errors detected in the electronic reports (we can not, however, provide specific advice on how to implement the requirements on the MAHs individual pharmacovigilance system).

The MHRA would like to discuss the options available to smaller and medium sized MAHs who are currently not in a position to report ICSRs electronically.

MAHs are encourage to read the following documents:

Continued on page 3

Leading issues

Continued from page 2

- | | | |
|--|--|---|
| <p>1. Volume 9 – <i>Pharmacovigilance guidelines on medicinal products for human and veterinary use</i> (www.europa.eu.int).</p> <p>2. <i>Policy paper on the implementation of the electronic ICSRs for medicinal products for human use authorised in the European Union</i> (www.eudravigilance.org).</p> <p>3. <i>Note for Guidance on regulatory electronic transmission</i></p> | <p>of ICSRs in pharmacovigilance (www.eudravigilance.org).</p> <p>4. <i>Maintenance of the ICH Guideline on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Report</i> document version 4.4.1, for descriptions of the data elements and how to use them in the transmission of ICSRs (www.ich.org or www.fda.gov/cder/m2).</p> <p>5. <i>Electronic Transmission of Individual Case Safety Reports</i></p> | <p><i>Message Specification (ICH ICSR DTD version 2.1) document version 2.3, for instructions on how to use the DTDs in preparing structured data sets</i> (www.ich.org or www.fda.gov/cder/m2).</p> <p><i>Please contact Mrs Shelley Gandhi on 020-7273 0209 for general enquiries on electronic reporting. For advice on testing please contact Mr Shaun Fiddes on 020-7273 0708.</i></p> |
|--|--|---|

Clinical Trials

New Regulations on Good Clinical Practice in clinical trials (Directive 2001/20/EC)

ON 21 February 2003, a consultation exercise was launched on the UK's proposed implementing regulations which are required to transpose the Directive into UK law. Member States are required to bring the provisions of the Directive fully into force by 1 May 2004. The proposed Regulations will apply to the whole of the United Kingdom as is the case with existing legislation relating to medicines control.

The proposed Regulations would set standards for conducting clinical trials and will also allow for the establishment of ethics committees on a legal basis and provide legal status for certain procedures, such as times within which an opinion must be given. In addition, they cover procedures for commencing a clinical trial. They also propose standards for the manufacture, import and labelling of investigational medicinal products. To ensure compliance with these standards, the MHRA would set up inspection systems for Good

Manufacturing Practice (GMP) and Good Clinical Practice (GCP). The proposed regulations do not distinguish between commercial and non-commercial trials. Significant changes to current arrangements in the UK and proposals to comply with the Directive are set out in the consultation documents.

Copies of the documents have been circulated widely and are available on the MHRA's and the Department of Health websites (www.mhra.gov.uk and www.doh.gov.uk respectively). Comments are invited by no later than 16 May 2003.

The MHRA is planning to host a conference on 14 May 2003 at the end of the consultation period. Further information, including an outline programme for the event is available on the MHRA's website.

For further information please contact Ms Caroline Brennan on 020-7273 0525.

Medicines and Healthcare products Regulatory Agency (MHRA) licensing fees for human medicines 2003/2004: proposals to be implemented from April 2003

CONSULTATION letter MLX 289 was issued on 22 November 2002 to around 3,200 licence holders and other interested parties. The letter proposed an across-the-board increase in fees of 8%, and other proposals for new fees for new work and some for currently unremunerated work. The specific new fees proposed included:

- a new flat-rate fee of £350 for assessment of labels and leaflets (PLPI applications are included in this proposal with a flat-rate fee of £270);
- a new fee for ad hoc / non-routine inspections;
- a new fee for pharmacovigilance inspections;
- a new fee for inspection of importers of unlicensed medicines;
- a new fee for inspection of manufacturers of investigational medicinal products (IMP) in readiness for the Clinical Trials Directive coming into force in 2004;
- An amendment to the variations categories introducing Type IA and new extended Type II complex variations to reflect the new European variation regulations.

We also asked for views on the introduction of new fees for pre-application company meetings, at a cost of from £1,000 to £2,000 depending on the level of advice requested.

Responses to the consultation letter

The consultation period ended on 14 February 2003 and a total of 55 replies were received. 22 of respondents agreed the proposals without comment or accepted that the increases were appropriate. 15 of the responses, including the main trade associations, wanted demonstrable improvements in

levels of service and without it, did not support the increase of 8%. Some were concerned about the effects of the merger and stressed that the finances should be fully transparent with none of the industry's fees being used to support the other work of the newly merged Agency. Other main comments included: specific fees should help provide a better

service on labels and leaflets; complaints that the method of charging for pharmacovigilance inspections will be inequitable, particularly to generic companies with large portfolios.

We considered the replies and reported the issues raised to Ministers who approved the proposals. Subject to Parliamentary process, the changes to the fees

proposed came into force on 1 April 2003. The changes proposed can be seen in Appendix 3.

Delays in implementing some proposals

Proposals for the *new variation categories* are delayed until the European Regulation is adopted and will be implemented through a further amendment to the Fees Regulations during the coming year.

The new fee for *inspection of manufacturers of investigational medicinal products* (IMP) will be implemented through separate clinical trials regulations later in the year.

New fees for *pre-application company meetings* for companies seeking scientific advice in connection with the quality, safety or clinical development for a medicinal product will be introduced from 1 July 2003. The proposal to introduce these fees was generally welcomed by those responding to the consultation. The fees will range from £1,000 up to £2,000 depending on the level and amount of advice requested. Further

Continued on page 5

We considered the replies and reported the issues raised to Ministers who approved the proposals. Subject to Parliamentary process, the changes to the fees proposed came into force on 1 April 2003.

Fees

Continued from page 4

details of these fees can be found in Appendix 3, Annex A1. Clear protocols for these meetings will be issued prior to the July implementation date.

Comments on the responses

The 8% increase from April this year will cover costs, but even with this level of increase, fees will still remain around 9% lower than they were in 1992/93 in real terms. However, this increase is also needed to take us from a deficit in year 2002/2003 to a small surplus in 2003/2004. We acknowledge the reservations some respondents have about the level of new fees that have been introduced. These new fees will be monitored and reviewed during the year to ensure that they are set at the right level. The pharmacovigilance inspection fees were set following experience of undertaking

such inspections. The more marketing authorisations a company has, the longer it takes to undertake the work. The legal status of the products held is immaterial. The inspection team will be specifically targeting black triangle products as suggested by one respondent.

We acknowledge that although the MCA's level of service was good in many areas, it was not uniformly high. There is room for improvement and MHRA will be actively addressing this issue in the coming year, by continuing the MCA customer satisfaction surveys begun last year and by working with our own staff and trade associations.

Further information on fees can be obtained from Mrs Lavinia O'Brien, Fees Policy Unit, Room 16-160 Market Towers, Telephone 020-7273 0884, e-mail: lavinia.obrien@mhra.gsi.gov.uk.

Labelling and leaflets

Assessment of labels and leaflets – new fees from 1 April 2003

UNDER Title V of Directive 2001/83/EC, approved labelling and a patient information leaflet must accompany all medicines supplied to the public. Article 61(3) provides that all proposed changes to the label or leaflet covered by the Directive, and not connected with the summary of product characteristics (SPC), must be submitted for review. From 1 April 2003 we are introducing a flat rate fee of £350 for the assessment of these changes to labels and leaflets.

A single fee will cover the assessment of all changes to a single version of the label and leaflet for one product, submitted at the same time. As for variations, bulk fee discounts of one full fee with a 50% reduction in further fees for applications submitted together will be implemented. These will apply where identical changes are being made across a range of different

strengths of the same dosage form. Where changes are proposed to a second or subsequent version of the label and leaflet, a separate application must be submitted accompanied by the appropriate fee. Where the changes to a subsequent version of the packaging components are identical to those proposed to the first version of the packaging, and are submitted at the same time, the bulk fee provisions will apply.

There will be no additional fee for assessing changes to labels and leaflets required as a result of variations to the SPC since the appropriate variations fee covers these. However, if the Product Information Unit, consequent to the variation application is required to undertake a separate assessment, then a separate fee will be levied. Should it be necessary to undertake a separate assessment of the packaging components you will be advised in the variation approval letter that this is the case, the reason for this

and a reminder that a fee will be charged. The Agency will not levy a fee when revisions to the label or leaflet are submitted solely in order to incorporate safety changes requested by the Agency.

An application form for submission of label and leaflet applications is included in Appendix 4. This should accompany all applications submitted from 1 April 2003. Where bulk provisions apply, one application form should be completed together with an accompanying list of products affected.

Please send two copies of the application form and accompanying data to Mr D Jarman, 14-139, Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

Further information is available from Mrs Jan MacDonald on 020-7273 0267.

MHRA

Medicines and Healthcare products Regulatory Agency

ON 1 APRIL 2003, the Medicines Control Agency (MCA) merged with the Medical Devices Agency (MDA) to form the Medicines and Healthcare products Regulatory Agency (MHRA). Telephone and fax numbers for Market Towers and the regional offices will **not** be changing; the number for the Central Enquiry

Point will remain 020-7273 0000. E-mail addresses will adopt the form: Name.Surname@mhra.gsi.gov.uk. However, for the foreseeable future, e-mails addressed to Name.Surname@mca.gsi.gov.uk will reach the intended recipient. The new Agency's website can be found at <http://www.mhra.gov.uk>.

Enforcement

Prosecutions

REGINA V Beijing Tong Ren Tang

FOLLOWING a guilty plea on 6 February 2003, at Bow Street magistrate court, District Judge Colin Pratt fined the above company a total of £11,500 (inclusive of costs).

Beijing Tong Ren Tang, a company selling Traditional Chinese Medicines, pleaded guilty to the sale of cream

containing a corticosteroid (clobetasol) which is a prescription only medicine. The cream was sold for the treatment of eczema.

The company was fined £3500 for an offence under 58(2) of the Medicines Act 1968 and £3000 for an offence in relation to schedule 3 of the Medicines for Human Use (Marketing Authorisations) Regulation 1994.

The Medicines and

Healthcare products Regulatory Agency was awarded costs of £5000.

This prosecution was brought following a seizure of creams by MCA Investigators at Beijing Tong Ren Tang 124 Shaftesbury Avenue, London.

If you would like to know more about the work of our Enforcement Group please telephone 020-7273 0025.



PUBLICATIONS

Recent MLX

- MLX 287 - European Union Directive 2001/20/EC on Good Clinical Practice in clinical trials - consultation on the UK's proposed implementing Regulations.

Copies of MLXs are available from the

MHRA Information Centre on 020-7273 0228/0352, Fax 020-7273 0353. They are also available on the MHRA website at www.mhra.gov.uk/inforesources/publications/mlxpub.htm.

EuroDirect

New guidelines

SINCE the last edition of *MAIL* (January/February 2003) the following documents have been adopted:

- 130/96 Note for guidance on chemistry of the new active substance (QWP).
- 2887/99 Common Technical Document for the registration of pharmaceuticals for human use (ICH).
- 49/01 Appendix to the note for guidance on the clinical investigation of medicinal products in the treatment of schizophrenia-Methodology of clinical trials concerning the development of depot preparations of approved medicinal products in schizophrenia (EWP).
- 2289/01 Points to consider on the development of live attenuated influenza vaccines (BWP).
- 3309/01 Note for guidance on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations (QWP).
- 420/02 Note for guidance on evaluation of stability data (ICH).
- 421/02 Note for guidance on stability data package for registration applications in climatic zones III and IV (ICH).
- 2599/02 Position paper on non-clinical safety studies to support clinical trials with a single microdose (SWP).
- 2879/02 CPMP position statement on Creutzfeldt-Jakob Disease (CJD) and plasma-derived and urine-derived medicinal products (BWP).
- 4679/02 Addendum to ICH E2C-Clinical safety

data management: Periodic safety update reports for marketed drugs (ICH).

- 4838/02 Concept paper on conduct of pharmacovigilance for medicines used by children (PhVWP).
- 252/03 Concept paper on the development of a CPMP points to consider on clinical investigation of medicinal products in neuropathic pain management (EWP).

- 415/03 Concept paper on the development of CPMP guidance on formulations of choice for the paediatric population (QWP).

The following document has been released for consultation:

- 419/03 Note for guidance on excipients, antioxidants and antimicrobial preservatives in the dossier for application for marketing authorisation of a medicinal product (QWP).

The following documents have corrections:

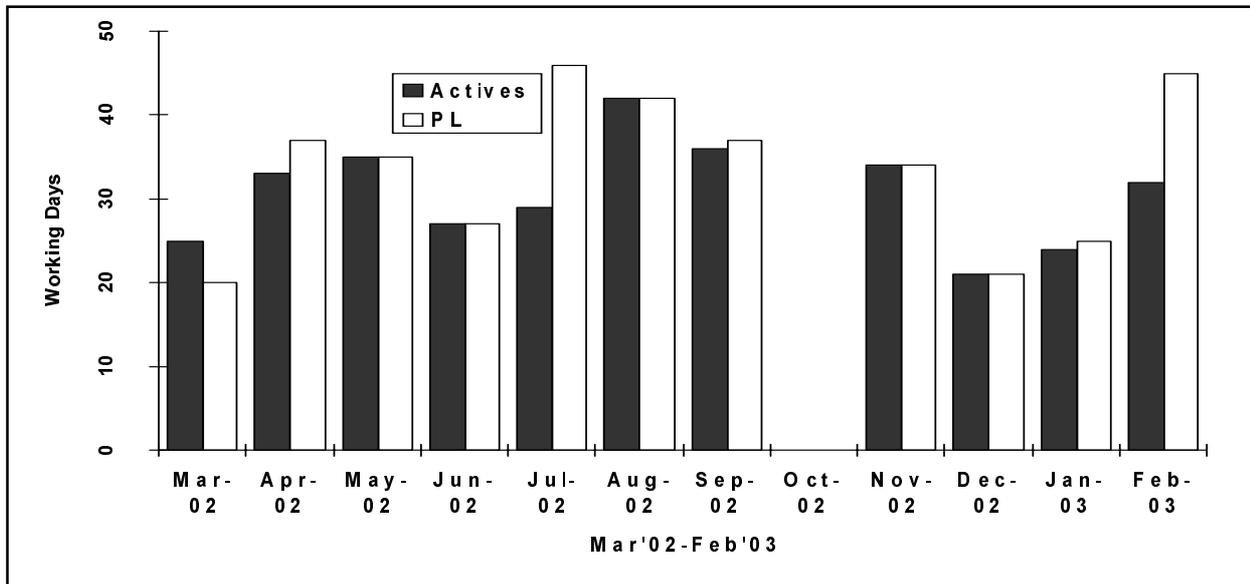
- 2736/99 Note for guidance on stability testing: stability testing of new drug substances and products (ICH).
- 2738/99 Note for guidance on impurities in new drug products (ICH).
- 122/02 Note for guidance on stability testing of existing active substances and related finished products (*rev. CPMP/SWP/556/96*) (QWP).

For further information about our EuroDirect Publications Service please contact Mrs Ronke Omotayo, Room 10-238, Market Towers, telephone 020-7273 0352.



New active substance applications - mean assessment times

New Active Substance Applications - Mean Assessment Times

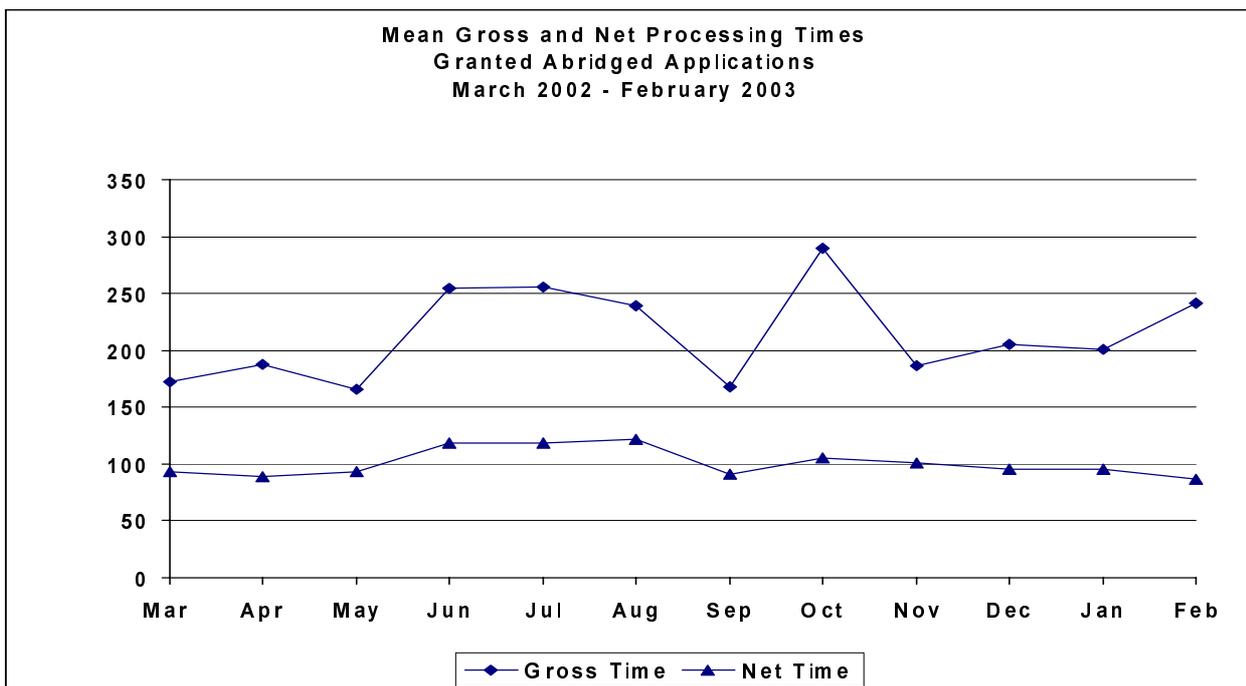


THE targets for the assessment of new active substances are based on the time from receipt of a valid application to the date on which the assessment report is completed for submission to the advisory committees.

The graph shows mean assessment time based on new active substance numbers and product licence numbers. Figures incorporate new active substance applications assessed by the NCE and Biological and Biotechnological Units. They include incoming NCE mutual recognition applications and the assessment of centralised applications (both parts A and B) when the United Kingdom is acting as either rapporteur or co-rapporteur.

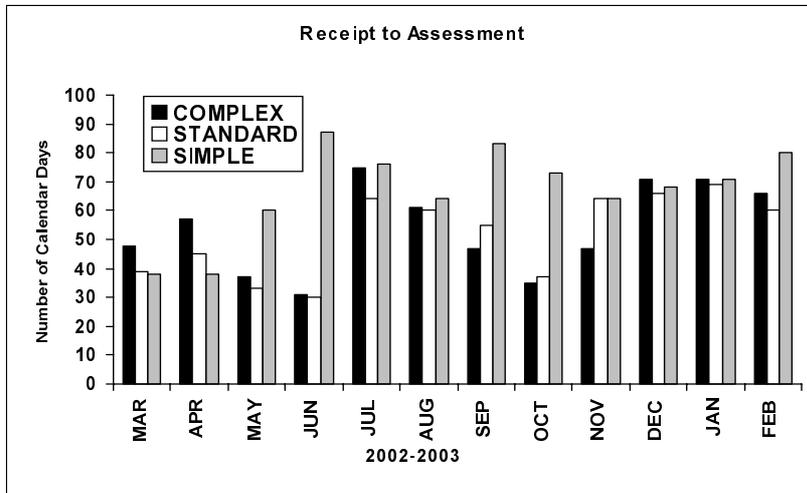
Abridged applications – net processing times

Mean Gross and Net Processing Times
Granted Abridged Applications
March 2002 - February 2003

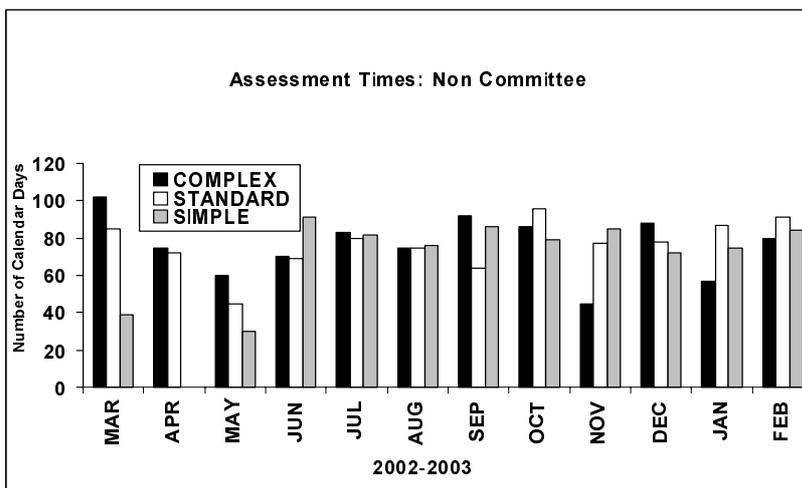


Abridged licensing - additional statistics

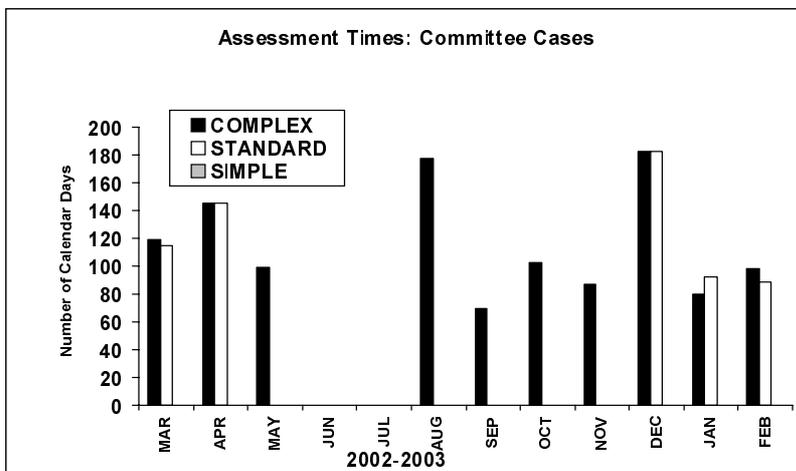
THE following graphs provide more detailed information on abridged applications to enable applicants to judge the length of time applications are taking. All abridged applications are included.



The receipt to assessment figure represents the mean number of calendar days that have elapsed from the date of receipt of an application to the date of the start of the assessment of the dossier.



The assessment times for non-committee cases figure represents the mean number of calendar days that have elapsed from the date of receipt of an application to the completion of the assessment report.

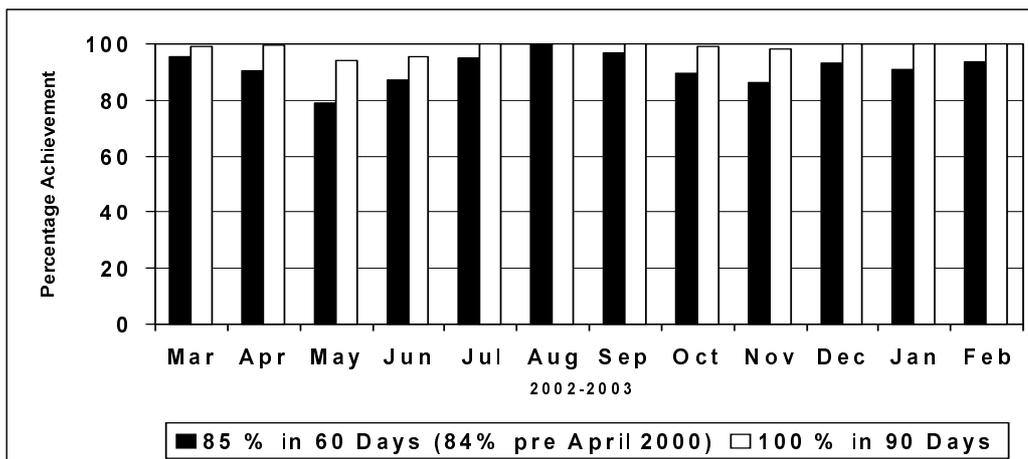
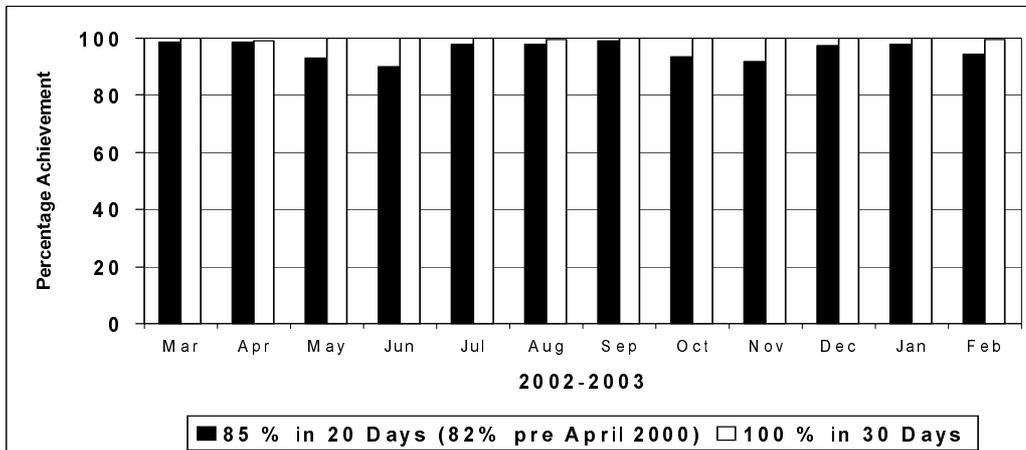


The assessment times for committee cases figure represents the same information as the previous figure but is for those applications scheduled to be seen by the Committee on Safety of Medicines.

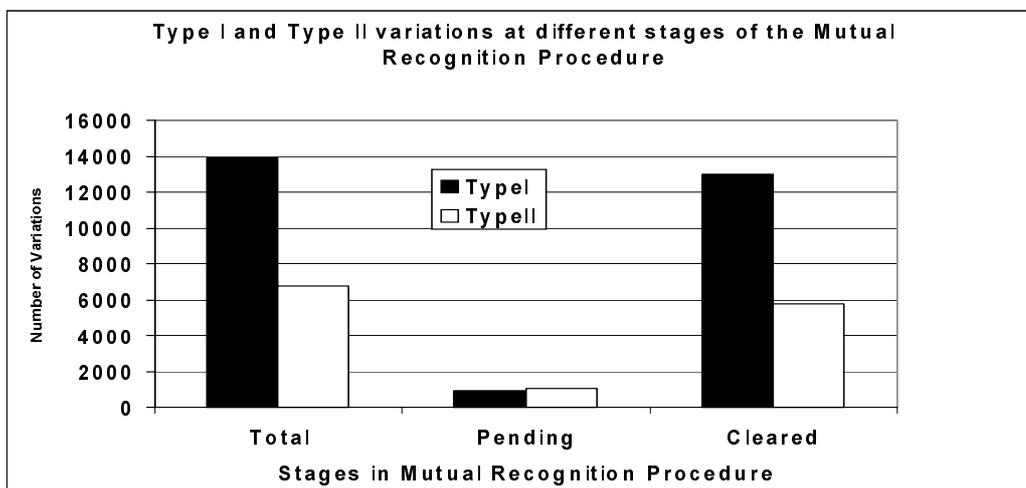
Variations - Performance

THE targets for processing variations are based on the time from the notified procedure start date (the “acknowledgement” letter) to the completion of assessment. For Type I variations, this is the time to the “notification with grounds” letter or “approval” letter. For Type II variations, this is the time to the “request for supplementary information” letter or “approval” letter.

Performance data reflect all national and Mutual Recognition variations where the UK is a concerned Member State.



Additionally, the following graph shows the number of Mutual Recognition variations, where the UK is a concerned Member State, at various stages of the procedure. It reflects the total number of variations received, the numbers waiting a procedure start date or in-process, and the number of procedures completed.



New manufacturer's and wholesale dealer's licences issued in January and February 2003

Licence	Licence Holder
AO 13082	Aeromedic Innovations Limited, Unit 1, Maple Grove Business Park, Lawrence Road, Hounslow, Middlesex, TW4 6DR
AO 18327	Edenwest Limited, House Of Edenwest, Stone Field Way, South Ruislip, Middlesex, HA1 0JW
AO 19097	Headflow Ltd, Colorama House, 23 Wadsworth Road, Greenford, Middlesex, UB6 7JS
MA 11412	Moorfields Eye Hospital NHS Trust, 34, Nile Street, London, N1 7LX
MA 20165	NYX Pharma Limited, Innovation House, 6 Seymour Court, Manor Park, Runcorn, Cheshire, WA7 1SY
WI 19065	Ecosse Pharmaceuticals Limited, 10 Stroud Road, Kelvin Industrial Estate, East Kilbride, Glasgow, G75 0YA
WI 19721	Dr Christopher Parry, Badcocks Farmhouse, Easthorpe Road, Colchester, Essex, CO5 9HA
WI 20166	Galen Limited, Seagoe International Estate, Craigavon, Armagh, BT63 5AU
WL 18923	Kelisdar Enterprises Limited, Swillington Pharmacy, Church Lane, Swillington, Leeds, West Yorkshire, LS26 8DY
WL 19441	European Nutri Pharm, The Dove Clinic, Northfields Farm, Hazely Road, Twyford, Nr Winchester, Hampshire, SO21 1QA
WL 19495	Brierfield Pharmacy Ltd, 10-12 Colne Road, Brierfield, Nelson, Lancashire, BB9 5PH
WL 19636	J.C. Pharmaceuticals Limited, United House, 23 Dorset Road, London, WIU 6EL
WL 19721	Dr Christopher Parry, Badcocks Farmhouse, Easthorpe Road, Colchester, Essex, CO5 9HA
WL 19730	Acorn Health Products, Health Centre, Oaktree Close, Benington, Hertfordshire, SG2 7QZ
WL 19731	Pulsion Medical UK Limited, Arundel Road, Uxbridge, Middlesex, UB8 2SA
WL 19863	Galen Consumer Ltd, 2 Glebe Road, Warlingham, Surrey, CR6 9NJ
WL 19915	Surgipharm Limited, Global Pharma, Flat 13, Magnolia Court, 39 Grange Road, Sutton, Surrey, SM2 6SY
WL 19940	Roughwood 2000 Limited, 81 Kennelwood Avenue, Kirkby, Merseyside, L33 6UE
WL 19975	Ashurst Generics Ltd, Oakfield House, 35 Perrymount Road, Haywards heath, West Sussex, RH16 3BW
WL 20088	Dispex Ltd, PO Box 9720, 257 Warwick Road, Olton, Solihull, West Midlands, B92 7HT
WL 20108	Dream Pharma Limited, 176 Horn Lane, Acton, London, W3 6PJ

For further information please contact Mr David Kwokori on 020-7273 0597.

**PROPOSED FEES PAYABLE FROM 1 APRIL 2003
LICENCE APPLICATIONS**

ANNEX A

	PROPOSED £
MARKETING AUTHORISATIONS	
MAJOR	
National Fee	79,630
MAJOR (Reduced in exceptional circumstances ¹ OR Orders under Section 104/105)	25,385
OUTGOING MUTUAL RECOGN Plus Regulatory assistance:	
- 1 ST WAVE	33,992
- 2 ND WAVE	22,328
INCOMING MUTUAL RECOGN	55,441
ABRIDGED COMPLEX	
National Fee	21,990
OUTGOING MUTUAL RECOGN Plus Regulatory Assistance:	
- 1 st WAVE	8,748
- 2 nd WAVE	5,832
INCOMING MUTUAL RECOGN	15,392
ABRIDGED STANDARD	
National Fee	8,063
OUTGOING MUTUAL RECOGN Plus Regulatory Assistance:	
- 1 st WAVE	3,499
- 2 nd WAVE	2,916
INCOMING MUTUAL RECOGN	5,640
ABRIDGED SIMPLE	2,199
OUTGOING MUTUAL RECOGN INFORMED CONSENT	2,094
OUTGOING MUTUAL RECOGN DUPLICATES for all of the above when undertaken at the same time as the lead application	
- 1 st WAVE	2,094
- 2 nd WAVE	2,094
PARALLEL IMPORT	1,465
CHANGE OF OWNERSHIP MANUFACTURERS' LICENCES*	362
(* Including manufacturers of Investigational Medicinal Products (IMP))	
STANDARD	2,415
NON ORTHODOX PRACTITIONERS (NOP)	140
CHANGE OF OWNERSHIP	265
WHOLESALE DEALERS' LICENCES	
STANDARD	949
REDUCED RATE ²	698
CHANGE OF OWNERSHIP	306
EXPORT CERTIFICATES	
PER SET (1 ORIGINAL + 2 COPIES)	52
PER SET (URGENT)	117
EXTRA COPIES (3rd COPY +)	26
APPLICATION	17,215
RENEWAL	2,199
VARIATION (STANDARD)	216
VARIATION (ADMINISTRATIVE)	110
CLINICAL TRIAL CERTIFICATES	

- Notes:** 1. To which Section G of Part IV of the Annex to Council Directive 75/318/EEC refers.
 2. Special reduced rate to apply for wholesale dealers handling GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover in licensed products.

PROPOSED FEES FOR HOMOEOPATHIC REGISTRATION SCHEME FROM 1 APRIL 2003

	PROPOSED	
	5 or fewer stocks	More than 5 Stocks
Standard	<i>656</i>	<i>859</i>
Reduced : Stock already assessed	<i>397</i>	<i>585</i>
Formulation already assessed	<i>397</i>	<i>585</i>
Both stock and formulation already assessed	<i>132</i>	<i>326</i>

PROPOSED FEES FOR DRUG/DEVICE COMBINATION PRODUCTS FROM 1 APRIL 2003

Device incorporating:	Proposed fee	Proposed Fee in respect of request by Notified Body to the MHRA to supply an additional assessment report
known medicinal substance from source previously used in medicinal products or in medical devices in respect of which MCA (now MHRA) has previously been consulted	<i>3,533</i>	<i>699</i>
known medicinal substance from new source	<i>8,234</i>	<i>1,955</i>
new active substance	<i>36,126</i>	<i>8,969</i>

NOTES

1. Where a device incorporates two or more medicinal substances the fee will relate to one of the substances only - the one which commands the highest fee.
2. The same fee will apply regardless of the strength or concentration of the medicinal substance. But only one fee will apply to multiple applications made at the same time for a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same medicinal substance at the same level.
3. The fee for an additional assessment report will apply when changes to the device require assessment under the terms of the Directive, and at any time after the initial assessment when further data is submitted to the MHRA for assessment.

PROPOSED FEES FROM 1 APRIL 2003 (Cont.)**LICENCE RENEWAL APPLICATIONS**

		PROPOSED £
MANUFACTURERS' LICENCES	NOP	125
OUTGOING MUTUAL RECOGNITION	FIRST RENEWAL OF A MAJOR APPLICATION ¹	7,327
	ALL OTHERS ²	598
RECLASSIFICATION	COMPLEX ³ - Additional for MA or PIL application with reclassification element	6,480
	- Reclassification variation application	6,480
	STANDARD ⁴ – Additional fee for MA or PIL application with reclassification element	3,240
	- Reclassification variation application	3,240
	Reclassification variation application (MA)(analogous product) ⁴	494
	Reclassification variation application (PIL) (analogous product)	140
ASSESSMENT OF LABELS AND LEAFLETS		
	SINGLE OR FIRST APPLICATION ⁵	350
	PARALLEL IMPORTS	270

Notes: : 1. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, Periodic Safety Update Report (PSUR), and renewal date, the full fee is charged for the first application, but a fee of £598 will be payable in respect of each of the other applications.

2. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, PSUR and renewal date, the full fee is charged for the first application, but a 50% "discount" applies to each other application.

3. A reclassification application is complex where it requires consideration by the Committee on Safety of Medicines is required; the 50% reduction (to £3,240) for standard applications applies where the Agency are of the view that no such consideration is required.

4. If multiple MA applications with reclassification elements are made at the same time and in relation to products with the same active ingredient, the full additional fee is charged for one application but only £494 (£458 currently) for each other application.

If multiple reclassification variations applications are made at the same time and in relation to products with the same active ingredient, the full fee is charged for the one application but in relation to each other application the fee is only £494 (£458 currently), in the case of other complex/standard applications, or £247 (£229 currently) in the case of other applications where there is analogous product already with the same legal status.

5. For all label and leaflet applications, a bulk "discount" applies where a number of simultaneous applications are made for identical changes covering a range of strengths of the same dosage form. The first application is charged at the full rate shown and second and subsequent applications are charged at 50%

PROPOSED FEES FROM 1 APRIL 2003 (Cont.)

**LICENCE VARIATION
APPLICATIONS¹**

		CURRENT	PROPOSED
		£	£
MARKETING			
AUTHORISATIONS			
<i>Type I</i>	RMS	310	334
<i>Type I</i>	NATIONAL/CMS	198	214
<i>Type II</i>	RMS	554	598
<i>Type II</i>	NATIONAL/CMS	458	494
<i>Type II Complex</i>	RMS	10,586	11,432
<i>Type II Complex</i>	NATIONAL/CMS	6,784	7326
<i>PL(PI)</i>	STANDARD	251	270
	ADMINISTRATIVE	130	140
	REDUCED MAJOR ²	270	292
			264
MANUFACTURERS'			
LICENCES			
	STANDARD	245	
	ADMINISTRATIVE	122	132
	NOP	122	132
WHOLESALE DEALERS'			
LICENCES			
	STANDARD	282	304
	ADMINISTRATIVE	122	132
HOMOEOPATHIC			
REGISTRATIONS³			
	NEW TECHNICAL	200	216
	OTHER	103	110

Notes:

1. For all variation applications a bulk "discount" applies where a number of simultaneous applications are made for identical variations. In general, the first of those applications is charged at the full rate shown above and second and subsequent applications are charged at 50%. But, where the first application is a Type II Complex, the second and subsequent applications are charged at the rate for Type II.

2. MA variations fees above apply to Reduced major applications except where they seek to extend the range of the drug's use outside of a limited use area – these attract a full Major Application Fee.

3. *For variations to homoeopathic registration certificates* a bulk "discount" applies where a number of simultaneous applications are made for identical variations. In general, the first of those applications is charged at the full rate shown above and second and subsequent applications up to 30 variations are charged at 50%. Subsequent simultaneous applications for identical variations are charged at 25% of the full rate shown.

PROPOSED FEES FROM 1 APRIL 2003 (Cont.)**INSPECTION FEES**

(including intermediate

biological sites) ¹**PROPOSED****£**

STERILE SITE	SUPERSITE	14,659
	MAJOR	8,061
	STANDARD	5,132
	MINOR	2,492
NON STERILE AND SITES USED FOR STERILISATION ONLY	SUPERSITE	8,796
	MAJOR	5,132
	STANDARD	4,249
	MINOR	2,291
ASSEMBLY ONLY	SUPERSITE	7,277
	MAJOR	3,677
	STANDARD	2,460
	MINOR	879
WHOLESALE DEALER	STANDARD	1,011
	REDUCED RATE ²	461
WHOLESALE DEALER (GSL)		461
WHOLESALE DEALERS IMPORTERS OF UNLICENSED MEDICINES	No of products imported in previous 12 months	
	0	1,011
	< 5	1,211
	5 – 20	2,011
	21 – 99	4,011
	100 - 499	9,011
	> 500	16,011
NOP ² SITE		166
NON-ROUTINE INSPECTIONS	UP TO 1 DAY'S DURATION ³	1,500
	2 – 3 DAYS	4,000
	3 DAYS +	7,500
PHARMACOVIGILANCE INSPECTIONS⁴	CATEGORY 1	3,500
	CATEGORY 2	5,000
	CATEGORY 3	10,000

NOTES

- Supersite = Manufacturing site where 250 or more employees (relevant persons) are involved. Major = between 60 and 250 employees. Standard = 10 or more but less than 60 employees. Minor = less than 10 employees.
- Special reduced rate to apply for wholesale dealers handling GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover in licensed products.
- The one-day fee will only be applied if the inspector spends more than two hours on site.
- Category 1 - MA holder has less than 5 MAs; Category 2 – MA holder has between 5 and 49 MAs; Category 3 – MA holder has 50 or more MAs.

PROPOSED PERIODIC FEES FROM 1 APRIL 2002 - PER LICENCE PER PERIOD

TYPE OF LICENCE		PROPOSED £
New Active Substance ¹		14,241
Derivatives with a different Route of Administration ¹ Or Complex Abridged ²		5,863
Other derivatives ¹		3,959

Legal Status/Sale Category	FEE TYPE - see note 3		PROPOSED £
POM	Standard fee		1,467
	Reduced rate fee		732
	'Maintenance' fee		238
P	Standard fee		642
	Reduced rate fee		321
	'Maintenance' fee		119
GSL	Standard fee		265
	Reduced rate fee		132
	'Maintenance' fee		58
NONE4	Standard fee		326
	Reduced rate fee		161
	'Maintenance' fee		68

		PROPOSED £
Herbal		72
Homoeopathic + Anthroposophic (per PLR)		NIL
Homoeopathic Registration		14
Manufacturer's Licence		293
Wholesale Dealer's Licence		180
Wholesale Dealer's Licence (reduced rate or GSL)		108

NOTES

1. Payable for first five complete fee periods following the year of grant. Includes Reduced Major Drugs with turnover greater than £200,000 - otherwise treat as POM.
2. Payable for first three complete fee periods following the year of grant.
3. The standard fee for 2003/2004 is payable when the turnover of the drug in the 2002/2003 year exceeded £35,000. If the turnover was £35,000 or less, the reduced fee is payable unless the maintenance fee is applicable. A maintenance fee is payable where the licence holder declares that he does not intend to manufacture or import the product during the licence fee period (1 April 2003 - 31 March 2004) and, either he has not manufactured or imported the product in the previous fee period, or, the turnover during that period (1 April 2002 - 31 March 2003) did not exceed £1,000.
4. To cover products licensed under Section 104 or 105 (of the Medicines Act 1968) Orders.

OTHER CHANGES FROM 1 APRIL 2003

1. New work areas

1.1 Non-routine inspections

1.1.1 In the past the MCA has charged fees for routine inspections of manufacturing sites. These inspections are carried out to confirm that the licence holder is complying with the conditions of his licence and to confirm continuous compliance with the requirements of good manufacturing practice (GMP). These inspections are carried out on a biannual cycle of inspection and the fees are based upon the size and complexity of the site.

1.1.2 These are occasions when it is necessary to conduct inspections, which are not part of this routine programme. Such non-routine inspections will not be full GMP compliance inspections but target more specific areas. They are normally of shorter duration than routine GMP inspections and should not therefore attract a full inspection fee. Examples of recent non-routine inspections were those related to TSE compliance. In these cases, no fees were charged to the industry but obviously much staff time was spent and not remunerated.

1.1.3 Non-routine inspections which the Inspection group undertake are:

- Pre inspection of new or newly developing sites as part of a licence variation or new licence application.
- Inspections of new or newly developing sites when they become operational.
- Task specific campaign inspections that are undertaken to evaluate a specific GMP requirement or area. These will usually be part of a national initiative to evaluate compliance by the ML holders with that requirement (e.g. TSE compliance inspections).

1.1.4 Non-routine inspections will normally be 1 – 2 days duration, but can last longer when re-inspection of critical deficiencies or low GMP sites is involved. It is proposed that a fee be charged for non-routine inspection which is calculated on the basis for time spent on site

- | | |
|---------------------|--------|
| a) one day*; | £1,500 |
| b) two – three days | £4,000 |
| c) < three days; | £7,500 |

**The one-day fee would only be applied if the inspector spent more than two hours on site.*

1.2 Pharmacovigilance inspections

1.2.1 Article 103 of Directive 2001/83/EC requires a Marketing Authorisation Holder to comply with all obligations relevant to pharmacovigilance requirements:

- report adverse reactions
- maintain detailed records of adverse reactions
- maintain systems for collecting and collating information of adverse reactions
- have a system for preparing reports for the licensing and answering requests from the Licensing Authority.

The CPMP has been requesting pharmacovigilance inspections by member states and serious non-compliances have been found and reported.

1.2.2 A programme of pharmacovigilance inspections including routine and triggered inspections is proposed to begin on April 1 2003. The fee structure will be based on the number of UK product licences held by the MA holder:

Category	No of MA's	Inspection Fee
1	<5	3,500
2	5 – 49	5,000
3	>50	10,000

1.3 Inspections of importers of unlicensed medicines

1.3.1 The Medicines (Standard Provisions for Licenses and Certificates) Amendment Regulation 1999 SI No 4 (SI 1999/4) introduced statutory and regulatory requirements for the importation of unlicensed medicines; in particular, licence holders are required to notify the MHRA in respect of each importation of such unlicensed medicines. The regulation of unlicensed imports places an additional burden on inspectors since they are required to perform additional audits of importer records of unlicensed imports. Furthermore a database of import notifications needs to be maintained up to date to inform this process. Currently one fee is charged for all inspections for wholesale dealers. For 2002 – 2003 this fee was £936, with a proposed increase to £1011 from 1st April 2003.

1.3.2 It is proposed to introduce a scale of fees for wholesale dealer inspections of importers of unlicensed medicines based on the number of different products imported in the twelve months proceeding the inspection. The fees for each level of the scale are set to reflect the increased work involved where more products are imported. This higher fee would be a single fee to cover both the wholesaler's unlicensed import activity and his other wholesale activities – it is not an additional fee. The new fees are summarised below:

No of Unlicensed Products Imported	Fee
0	<i>1,011</i>
<5	<i>1,211</i>
5 – 20	<i>2,011</i>
20 – 100	<i>4,011</i>
100 – 500	<i>9,011</i>
>500	<i>16,011</i>

2. Unremunerated work

2.1 Assessment of Labels and Leaflets (including PLPIs)

2.1.1 Under Title V of Directive 2001/83/EC, all medicines supplied to the public must be accompanied by approved labelling and a patient information leaflet. Article 61(3) provides that all proposed changes to the label or leaflet covered by the Directive, and not connected with the summary of product characteristics (SPC), must be submitted for review. We are introducing a flat rate fee of £350 for the assessment of these changes to labels and leaflets (£270 for Parallel Imports). For further details please see MAIL article "Assessment of Labels and Leaflets – NEW FEES FROM 1 APRIL 2003".

3. Fees for pre-application company meetings

3.1 New fees will be introduced on 1st July 2003 for pre-application company meetings where companies are seeking scientific advice. The cost of company meetings following an application being made to the Agency is met from the fees charged for applications. But we conduct a large number of company meetings which are not related to a specific lodged application and which often, do not end up with an application being made in the UK. We are introducing a fee that will be targeted at the right source – i.e. the companies, which receive these services.

3.2 The fees will range from £1,000 to £2,000 per meeting, depending on the issues under discussion and reflecting the number of Agency staff required to attend the meeting:

- where the advice provided is in connection with **either** quality development only **or** safety development only, the fee will be £1,000;
- where the advice provided is in connection with **either** quality and safety development only **or** clinical development only, the fee will be £1,330;
- where the advice provided is in connection with **either** quality and clinical development only **or** safety and clinical development only, the fee will be £1,670; and
- where the advice provided is in connection with quality, safety and clinical development, the fee will be £2,000.

3.3 It is also our intention that provision for fees for pre-variation application meetings will be made in the amending regulations dealing with the new variation categories, to be made later in 2003. The fee structure is expected to be similar to that for pre-MA application meetings.

3.4 Further more detailed guidance about how these meetings will work will be available shortly.

APPLICATION FOR CHANGES TO LABELS AND PATIENT INFORMATION LEAFLETS
(not accompanying a variation change)

(Please tick the appropriate category of the change)

Product name: _____ _____ _____ Active substance(s)/quantitative: _____ _____ _____ Pharmaceutical form: _____ _____ MA number: _____ Applicant's reference: _____ _____	Name and address of MA holder: _____ _____ _____ Contact: _____ _____ Telephone number: _____ Fax number: _____ E-mail address: _____
---	--

CHANGES PROPOSED TO *(Please tick all that apply)*

1 LABEL <input type="checkbox"/>	4 OWN BRAND LABEL <input type="checkbox"/>
2 LEAFLET <input type="checkbox"/>	5 OWN BRAND LEAFLET <input type="checkbox"/>
3 LABEL/LEAFLET <input type="checkbox"/>	6 OWN BRAND LABEL/LEAFLET <input type="checkbox"/>
(Please specify company)	

(Note change to different versions of the packaging components should be submitted on separate application forms).

RELATED APPLICATION(S) (Please specify including date of pending renewal/variation application(s)) _____ _____

BACKGROUND <i>(Please give brief background explanation for the proposed changes to your Label/Leaflet. Provide two copies of the current approved version with changes highlighted and attach two clean actual size mock-ups in full colour)</i>
--

I hereby make application for the above Label/Leaflet to be amended in accordance with the proposals given above and certify that the changes will not adversely affect the quality, efficacy or safe use of the product. I declare that amended duplicate actual size colour mock ups have been supplied and that the supporting information, where appropriate, meets the conditions or supports the proposed change. I declare that all changes have been identified and that there are no other changes in the amended documentation.

Fees paid (*If applicable*) Amount/Currency _____

Signatory _____ Status (Job title) _____

Print name _____ Date _____

L&L Application Form

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 London
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 Account no: **06781000**

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 Bank Address: 6 Coldharbour Lane
 Hayes
 Middlesex
 UB3 3EL
 Sort Code: **16 : 53 : 60**
 Account no: **6781**
 Reference: **MHRA**

For EURO currency payments from a Member State

Account name: Office of HM Paymaster General - Euro Receipts
 Account number: **08304793**
 Sort Code: **60 : 10 : 43**
 Swift Code: **NWBKGB2L**
 Reference: **6781 MHRA**

Branch Address: Natwest Bank
 6 Coldharbour Lane
 Hayes
 Middlesex UB3 3EL

For all other Overseas transfers

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 Account number: **25021001**
 Sort Code: **10 : 00 : 00**
 Swift Code: **BKENGB33**
 Reference: **6781 MHRA**

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 Government Counter
 Threadneedle Street
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MHRA ORGANISATIONAL STRUCTURE AND CONTACT POINTS

Complaints Procedure

THE policy of the Agency is to respond to all enquiries promptly and courteously. The MHRA currently has different complaints procedures for Medicines and Devices which are due to be merged shortly.

Medicines

For medicines we operate formal procedures for dealing with complaints about the Agency's administrative services (not licensing and enforcement decisions) and our aim is to respond to all written complaints within seven working days. The procedures ensure that all complaints are subject to a full and fair investigation, are handled confidentially, receive a full response and are examined for ways of improving our service provision in the future. If you remain dissatisfied with the way your enquiry was handled, having first contacted the head of the relevant unit or Division, you are invited to write to Mrs Sue Jones, Central Complaints Officer. If, following her reply, you remain dissatisfied you will have access to the Independent Complaints Advisor (ICA) who will also fully investigate your complaint.

Separate procedures cover complaints made under the Code of Practice on Access to Government Information (the Code). If we cannot give you the information you have asked for, or have to charge for that information,

we will explain the reasons why. If you are dissatisfied with our reply to your request, or the decision to impose a charge, you can, as a first step, request a formal internal review. A senior member of the Agency who was not involved in the original decision will undertake that review. If you remain dissatisfied, you can ask a Member of Parliament to refer your complaint to the Parliamentary Commissioner for Administration (the Ombudsman) who may decide to conduct his own investigation.

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Medicines and Healthcare products Regulatory Agency
Market Towers
1, Nine Elms Lane
London SW8 5NQ

Telephone: 020 7273 0000

Fax: 020 7273 0353

E-Mail: info@mhra.gsi.gov.uk

Devices

If you have a complaint concerning a device issue please contact the following person by letter, telephone, fax or e-mail:

Yinka Olushola
Room 1204
Hannibal House
Elephant and Castle
London SE1 6TQ
Telephone: 020 7972 8236
Fax: 020 7972 8108
E-Mail mail@medical-devices.gov.uk

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