

Mail

The MHRA updating service
for medicines

No. 163 September/October 2007

MHRA one day seminar:

Hot topics in advertising and information about medicines

21 November 2007

Radisson Edwardian Marlborough, London

Ever wanted to know what the do's and don'ts are for advertising your pharmaceutical products?

By attending this event you will have the opportunity to hear directly from the MHRA's

Advertising Standards Unit as well as interact with other advertising professionals.

In November 2007, we plan to launch the second Annual Report for the Advertising Standards Unit. To mark this event we will be hosting a one day seminar on advertising and information about medicines. This will provide insight into current advertising hot topics from action on complaints about medicines advertising and from prior vetting of promotional material. It will also provide an opportunity to get to grips with recent European developments in the area of information to patients.

Aims of seminar

Key topics to be addressed at this seminar are:

- Advertising Standards Unit Annual Report
- Current themes and concerns in advertising - cases to learn from
- Advertising and information - the impact of recent European developments

Who should attend

This event is aimed at Medical, Regulatory Affairs and other staff who review advertising and patient support materials for medicinal products.

Venue

Radisson Edwardian Marlborough

9-13 Bloomsbury Street

London WC1B 3QD

<http://www.radissonedwardian.com/> (external link)

Early bird special offer - register on or before 24 October 2007

An early bird booking fee of £550.00 + VAT.

Seminar fee

The standard fee for this event is £625.00 + VAT.

Registration closes on 12 November 2007.

How do I register?

Online www.mhra.gov.uk/mhra/conferences/register.htm

Fax or Post

Please Fax to 020 7084 3522 or post to MHRA Conference and Education Team, Market Towers - 16th Floor, 1 Nine Elms Lane, Vauxhall SW8 5NQ.

Need more information?

If you have any queries with registering or require further information please do not hesitate to contact our Conference & Education Team on Tel: 020 7084 2903 alternatively e-mail mhraconferences@mhra.gsi.gov.uk.

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No. 163

September/October 2007

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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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Patient Information Leaflets: compliance with new legal requirements**9 months to go - are you prepared?**

UK LEGISLATION effected in 2005 (The Medicines (Marketing Authorisations etc) Amendment Regulations 2005 number 3224 [SI 2005/3224]) means that all medicines on the UK market must have a patient information leaflet which complies with the new legal requirements in articles 59(1) and 59(3) of Council Directive 2001/83/EC by **1 July 2008**. Failure to do so will constitute an offence.

You should be in position to submit applications to update your marketing authorisation (MA) by the end of December 2007 to enable you to have enough time to update the MA in time for the July deadline. Remember – if you change the order of the information in the leaflet in line with article 59(1), at the same time you have to demonstrate compliance with article 59(3) [see below for more information]. Applications which fail to meet the full requirements of article 59 at the time of submission will incur delays.

The purpose of this new legislation is primarily to improve the quality of the information provided with all medicines. All leaflets will need to comply with these new requirements and we have published guidance on quality information, user testing and bridging studies and a series of FAQs to help you meet the requirements of article 59(3). The links to these documents are below.

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=12398&noSaveAs=0&Rendition=WEB

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=28093&noSaveAs=0&Rendition=WEB

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=28305&noSaveAs=0&Rendition=WEB

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=2324&noSaveAs=0&Rendition=WEB

<http://www.mhra.gov.uk/home/>

[idcplg?IdcService=GET_FILE&dDocName=con2024001&RevisionSelectionMethod=Latest](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=con2024001&RevisionSelectionMethod=Latest)

<http://www.mhra.gov.uk/home/>

[idcplg?IdcService=GET_FILE&dDocName=con2030572&RevisionSelectionMethod=Latest](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=con2030572&RevisionSelectionMethod=Latest)

If you hold MAs but do not currently market these medicines we will not ask you to update the MA at this time. Please let us know in writing which products are not currently on the market and provide an assurance that should you decide to market these in the future you will submit the necessary data to update the MA prior to placing the product back on the market. Please complete a notification form (external information update form):

[<http://www.mhra.gov.uk/home/>

[idcplg?IdcService=GET_FILE&dDocName=CON2023798&RevisionSelectionMethod=Latest](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2023798&RevisionSelectionMethod=Latest)]

and send your communication electronically to Area 6 to update to the MA.

Every marketing authorisation will need data in module m-1-3-4 of the eCTD which demonstrates compliance with article 59(3) of the directive. Some MAs will include a full user test report for that leaflet. However, not all leaflets will need to be the subject of a user test. If you are relying on a user test carried out on a leaflet for a similar product you will need to provide a bridging report. Most products will require a fulsome report as set out in the guidance documents above. However, where a leaflet for a different strength of product, for example, is being submitted, the supporting data necessary will be much less. Related applications which are submitted together will benefit from the bulk fee arrangements and will be handled by the same assessor.

For further information please contact Jan MacDonald on 020 7084 2267 or via email at patient.information@mhra.gsi.gov.uk

Update on PSUR applications

Key messages:

- **PSUR submission through the Sentinel portal**
- **Some practical aspects of the EU PSUR synchronisation scheme**
- **Frequently asked questions on MHRA website**

We have previously updated marketing authorisation (MA) holders regarding the submission of MR/DCP and national Renewals and Periodic Safety Update Reports (PSURs) according to the EU PSUR synchronisation scheme (*MAIL 152* and *MAIL 159*). In this article we provide some clarification of a few areas for which we receive the most queries.

PSUR Submissions

PSURs may be submitted via the Sentinel portal (size permitting) and these submissions should be made using the general submissions form available on the portal.

PSUR submissions should be made according to the advice in *Special MAIL 5* and the associated frequently asked questions (FAQs):

(http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2024282&ssTargetNodeId=380).

These documents are updated as required and MA holders are reminded they should check regularly for updates. Submissions for PSURs and renewals should be named as stated in *Special MAIL 5*, please see the FAQs for clarification. The relevant sections of the FAQs are currently on pages 11 and 20 of that document.

PSURs submitted under the EU PSUR synchronisation scheme

Requirement to notify the MHRA of your intention to follow the harmonised data lock points

In our previous communications we have stated that a notification was required to inform the MHRA of the new submission date for PSURs submitted under the scheme. Following a review of this under the Better Regulation of Medicines Initiative (BROMI) vigilance work stream we have noted that this is an unnecessary requirement. Therefore a statement in the cover letter accompanying the submission will be accepted as notification.

Submission of PSURs - cover letter

If a PSUR is submitted under the PSUR synchronisation scheme (for further details of this scheme please see *MAIL 159*) as stated above this needs to be mentioned in the cover letter. A PSUR submitted under the PSUR synchronisation scheme should be submitted for all of your MAs with that active at the same time and not just those requiring a PSUR at that time; therefore please list all the relevant MAs in your cover letter.

Submission of PSURs - timing

A PSUR, or several PSURs accompanied by a Summary Bridging Report, should be prepared which should be submitted to all member states where you have an MA. This should be submitted within 60 days of the agreed Data Lock Point (DLP). It is the responsibility of the MA holder to ensure that there are no time gaps in the data sent to individual National Competent Authorities.

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With the first harmonised PSUR there is likely to be some overlap of data which is acceptable. For generic products when the agreed DLP falls after the next PSUR/renewal is due the MA holder should submit the PSUR/renewal as required and then submit either an addendum report or line listings as appropriate to bring the product in line with the agreed DLP.

Frequently Asked Questions on MHRA Website

Our website has been updated with a set of FAQs in relation to the EU PSUR synchronisation scheme as well as in relation to the PSUR submissions in general. We hope you will find these useful and welcome any feedback. If there are any further questions you would like included please send these to the Therapeutic Reviews Group mailbox Therapeuticreviewsgroup@mhra.gsi.gov.uk and we will update the FAQs on a regular basis.

Advice on PSUR or Renewal submissions is available from Anne Ambrose, email: anne.ambrose@mhra.gsi.gov.uk and Emma Cornforth, email: emma.cornforth@mhra.gsi.gov.uk.

Pharmacovigilance Service Desk: providing a service to marketing authorisation (MA) holders

We recently introduced a new Pharmacovigilance Service Desk at the MHRA.

The aim of the Service Desk is to be the first port-of-call for marketing authorisation (MA) holders and their representatives, enquiring about any pharmacovigilance related matters and any associated regulatory activity.

We aim to provide an answer to all enquiries within 7 working days of receipt. If we are unable to respond directly we will refer to other relevant areas of the Agency. In such cases, we may need to revise the response timeframe and will keep you informed.

The Pharmacovigilance Service Desk will be manned between the hours of 09:00 and 17:00, Monday - Friday and can be contacted by telephone or preferably by e-mail at pharmacovigilanceservice@mhra.gsi.gov.uk.

MA holders A-L: 020 7084 2550
MA holders M-S: 020 7084 2318
MA holders T-Z: 020 7084 3730

The service desk aims to be a "one-stop shop" for MA holder enquiries relating to Pharmacovigilance. For submitting suspected adverse drug reaction reports, we ask that you continue to follow previously issued guidelines.

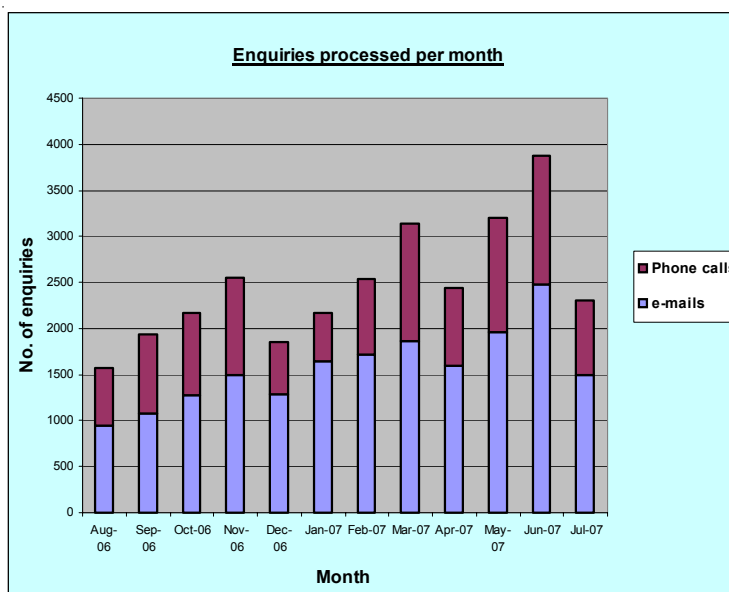
Should there be any questions about this new service, please contact Zamshed Harun, Service Desk Coordinator, on 020 7084 2242 or by e-mail at zamshed.harun@mhra.gsi.gov.uk. Alternatively, the Service Desk Team Leader, Lance Smithson on 020 7084 2764 or by e-mail at lance.smithson@mhra.gsi.gov.uk.

Alert: Impersonation of MHRA staff

We have again been alerted that there have been calls made to companies recently from people purporting to be members of MHRA staff, but who do not work for the Agency. We know that companies are generally alert to this type of activity but please remind your staff to be vigilant. If you do not recognise the name of the caller, please do not hesitate to take their number and call our Central Enquiry Point on 020 7084 2000 to check whether the caller is genuine before you give them any information.

Regulatory Information Service: 30,000 enquiries received in first twelve months of operation.

The Regulatory Information Service (RIS) began operating at the end of July 2006 and during their first twelve months received this large volume of enquiries from licence holders and their representatives:



The RIS was a product of the MHRA's business realignment project. It was created principally to meet the need to focus submission related enquiries and achieve a standardised and effective method by which industry stakeholders communicate with the Agency. It was increasingly becoming a disruption for the assessment teams as they were being asked to provide answers to questions about general regulatory issues and the progress of applications. These types of queries are now being handled by the RIS and, as projects initiated to improve the quality of product licence data available through Sentinel have been completed, the speed of responses has also improved.

Additionally, the RIS acts as a point of contact for a wide range of issues related to the interpretation of regulations, and the associated processes and procedures. These enquiries make up a large portion of the work and when the team are not able to provide an immediate response they are able to turn quickly to the most appropriate area of the agency, saving time for both the enquirer and the Agency. Enquiries are categorised by complexity and clear processes are in place which map out the key interactions required to obtain answers within target timeframes.

The Regulatory Information Advisors (RIAs) are able to deal directly with approximately 95% of all types of enquiries, while more specialised questions are diverted to assessors through Service Co-ordinators. This relationship between RIS staff and the Service Co-ordinators is an important link in the process of delivering to companies and meeting performance targets.

The RIS can be contacted by phone on 020 7084 3400 between the hours of 8.30 a.m. and 5.30 p.m. every working day the Agency is open, or at any time by sending a e-mail to the appropriate mailbox. These can be seen on the RIS webpage at:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=979

Pharmacopoeial news

British Pharmacopoeia 2008 ***British Pharmacopoeia (Veterinary) 2008***

The *British Pharmacopoeia* (BP) 2008 and *British Pharmacopoeia (Veterinary)* 2008 have recently been published. The two publications are presented together as a package comprising the following sections:

Volumes I and II	Medicinal substances
Volume III	Formulated preparations, blood-related products, immunological products, radiopharmaceutical preparations, surgical materials and homoeopathic preparations
Volume IV	Infrared reference spectra, appendices, supplementary chapters and index
Volume V	<i>British Pharmacopoeia (Veterinary)</i> 2008

The effective date for the *British Pharmacopoeia* 2008 and *British Pharmacopoeia (Veterinary)* 2008 is 1 January 2008.

A list of monographs included in the *British Pharmacopoeia* and *British Pharmacopoeia (Veterinary)* for the first time is given at the end of each Introduction to the two publications. It includes collectively 52 new texts of national origin. Six new infrared spectra have been added alphabetically to the previous collection. The new and revised monographs from Supplements 5.6 to 5.8 of the 5th edition of the *European Pharmacopoeia* are included in this edition of the *British Pharmacopoeia* or the *British Pharmacopoeia (Veterinary)*, as appropriate. The user of the *British Pharmacopoeia* thereby benefits by finding within these compendia all current United Kingdom pharmacopoeial standards for medicines for human and veterinary use.

In order to assist users of the Pharmacopoeia, the Introductions also list those national monographs which have been technically amended by means of this edition and indicate the section or sections of each monograph that have been revised.

The new edition of the *BP* 2008 continues the development of monographs for Traditional Herbal Medicines, initiated in the *BP* 2007, with the publication of seven new monographs for herbal materials and processed herbal materials used in Traditional Chinese Medicines. A new initiative to support the simplified registration scheme for homoeopathic preparations by the UK Licensing Authority has been introduced in the new edition with the publication of five new monographs for homoeopathic stocks and mother tinctures. The *BP* 2008 has also begun to improve the control of the quality of unlicensed medicines by providing standards for extensively used unlicensed formulations together with further legal and ethical guidance on the preparation and supply of these products.

A new supplementary chapter for Pharmacopoeial Quantitative Analysis, intended as a useful guide to the analyst and to complement existing appendices and general methods, has been introduced in this edition. Examples of colour change intervals for common indicators are also included in this chapter and, for the first time, the change interval charts are printed in colour.

Electronic Products

Purchasers of the *BP* 2008 will have single user access to the *BP* on-line via the publisher's dedicated portal, www.pharmacopoeia.co.uk. The online format is easy to network, allowing access for a specified number of users or across an entire organisation site.

Following registration using the ID code supplied with the hard copy, purchasers will be granted a single user licence to access *BP* on-line and will have the option to receive the CD-ROM that contains the *British Pharmacopoeia* 2008 and the *British Pharmacopoeia (Veterinary)*.

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For the first time, the *BP 2008* is available in an e-book format to purchasers. The contents of the *British Pharmacopoeia* can be downloaded to a portable PDA or laptop.

British Approved Names 2007 Supplement No.1

The first supplement (*Supplement No. 1*) to the *British Approved Names 2007* has recently been published. The supplement contains six new names together with editorial amendments to previous entries and a customer feedback form. The effective date is 1 January 2008. The Supplement is available from The Stationery Office (ISBN 978-0-11-322788-4).

Draft Monographs for the *British Pharmacopoeia*

Draft new and revised monographs for the preparations listed below have been prepared and it is intended that they will be included in the *British Pharmacopoeia* at a future date. We invite any manufacturer who has an interest in these monographs to request a copy of the draft(s) and to submit comments for consideration by the relevant Expert Advisory Group by **30 November 2007**.

New	Revised
Acitretin Capsules Bezafibrate Tablets, Prolonged-release Bupivacaine Heavy Injection Clarithromycin Tablets Prolonged-release Clarithromycin Tablets Chlorhexidine Gluconate Gel Desmopressin Tablets Desogestrel Tablets Gastro-resistant Erythromycin Capsules Erythropoietin Injection Felodipine Tablets, Prolonged-release Goserelin Implants Human Glucagon Injection Mesalazine Tablets Mupirocin Cream Mupirocin Nasal Ointment Nicotine Resinate Medicated Chewing Gum Ondansetron Injection Ondansetron Tablets Oxybutynin Oral solution Paracetamol, Codeine Phosphate and Caffeine Capsules Paracetamol, Codeine Phosphate and Caffeine Tablets Processed Sage Root for use in THMP Pseudoephedrine Oral Solution Sage Root for use in THM Tamsulosin Capsules, Prolonged-release Zidovudine and Lamivudine Tablets Zidovudine Capsules Zopiclone Tablets	Bisacodyl Tablets, Gastro-resistant Desmopressin Injection Desmopressin Intranasal Solution Mercaptopurine Tablets Progesterone Injection Sodium Federedetate Oral Solution

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Test for Pyrogens

The British Pharmacopoeia Commission has decided that, where possible, the remaining monographs in the *British Pharmacopoeia* that include the test for Pyrogens should be replaced with the test for Bacterial endotoxins. The monographs under review are listed below; comment from manufacturers is sought on the applicability of the test for Bacterial endotoxins to these monographs. Any changes will be implemented in the *British Pharmacopoeia* 2009 or the *British Pharmacopoeia (Veterinary)* 2009 as appropriate unless information is received that the test is not applicable to specific monographs.

British Pharmacopoeia	British Pharmacopoeia (Veterinary)
Menotrophin	Apramycin Injection
Acetylcysteine Injection	Oxytetracycline Injection
Benzylpenicillin Injection	Sodium Calcium Edetate
Chloramphenicol Sodium Succinate Injection	
Fructose Intravenous Infusion	
Inulin Injection	
Meglumine Amidotrizoate Injection	
Meglumine Iodipamide Injection	
Menotrophin Injection	
Sodium Amidotrizoate Injection	
Sodium Bicarbonate Intravenous Infusion	
Sodium Calcium Edetate Intravenous Infusion	
Tranexamic Acid Injection	
Trisodium Edetate Intravenous Infusion	

Manufacturers are invited to submit analytical procedures, validation data and proposals for limits for bacterial endotoxins for consideration by the relevant advisors to the British Pharmacopoeia Commission by **30 November 2007**. Further guidance on the data package required by the BPC Secretariat can be found in *Supplementary Chapter I C* of the *British Pharmacopoeia* 2007 (Volume IV, pages A494 to A498). Where it is considered the test for Bacterial endotoxins is not appropriate to a monograph, information is sought concerning the reason why the test is not applicable.

For copies of new and revised draft monographs, please contact Lorraine Phillips on 020 7084 2561 or fax on 020 7084 2566.

For further information, please contact the following members of staff supporting the monograph initiation programme.

Nesta Thomas 020 7084 2430 nesta.thomas@mhra.gsi.gov.uk
Stephen Young 020 7084 2790 stephen.young@mhra.gsi.gov.uk

For information on British Approved Names, please contact Patience Holland (020 7084 2560) or Adrian Evans (020 7084 2565).

For further information on the British Pharmacopoeia, please contact Matilda Vallender (020 7084 2562) or Fiona Swanson (020 7084 2567).

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For technical matters concerning the British Pharmacopoeia and the British Pharmacopoeia (Veterinary), please contact members of the BP Secretariat as shown below using the telephone number 020 7084 – with the extensions provided.

Monographs

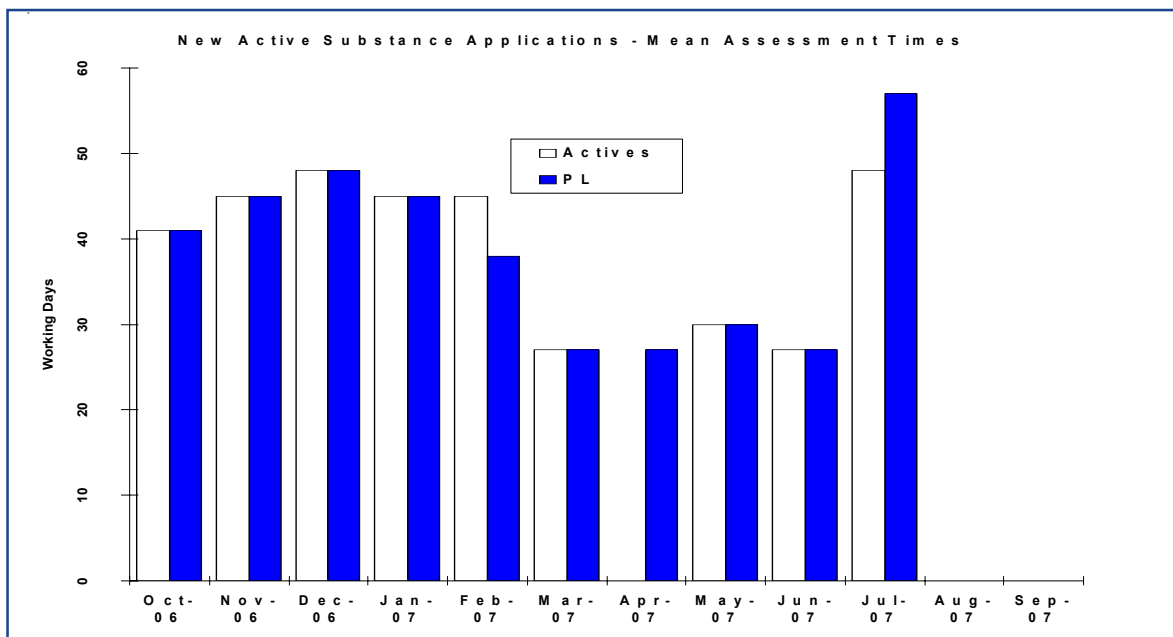
General enquiries	Ms L Phillips	2561
Antibiotics	Dr F J Swanson	2567
Analytical methods (general)	Mr R Turner	2563
European Pharmacopoeia(general matters) ¹	Mrs M Vallender	2562
	Mrs M Barrett	2555
	Dr R A Pask-Hughes	2558
	Mr A Bentley	2185
General monographs	Mrs M Vallender	2562
Herbal medicines	Dr P Holland	2560
	Dr R A Pask-Hughes	2558
	Ms N Thomas	2430
Inorganic chemicals	Mr A Evans	2565
Microbiological aspects	Dr R A Pask-Hughes	2558
	Mr A Bentley	2185
New monographs(general matters) ¹	Mr S Young	2790
	Ms N Thomas	2430
Nomenclature	Dr P Holland	2560
	Mr A Evans	2565
	Ms N Thomas	2430
Organic Chemicals	Dr P Holland	2560
	Mr R Turner	2563
	Mrs M Barrett	2555
	Mr A Evans	2565
Pharmaceutical aspects	Dr M G Lee	2568
	M A Bentley	2185
	Ms N Thomas	2430
Radioactive materials	Mrs M Barrett	2555
Reagents	Mr R Turner	2563
	Mr A Evans	2565
Surgical materials	Mrs M Vallender	2562
BPCRS	Mr S Young	2790

¹ For specific matters see under relevant subject entry

For all enquiries concerning purchase of publications and information regarding network licences, please contact The Stationery Office, P O Box 29, Norwich NR3 1GN telephone 0870 600 5522, fax 0870 600 5533, textphone 0870 240 3701.

APPENDIX 1

New active substance applications - mean assessment times

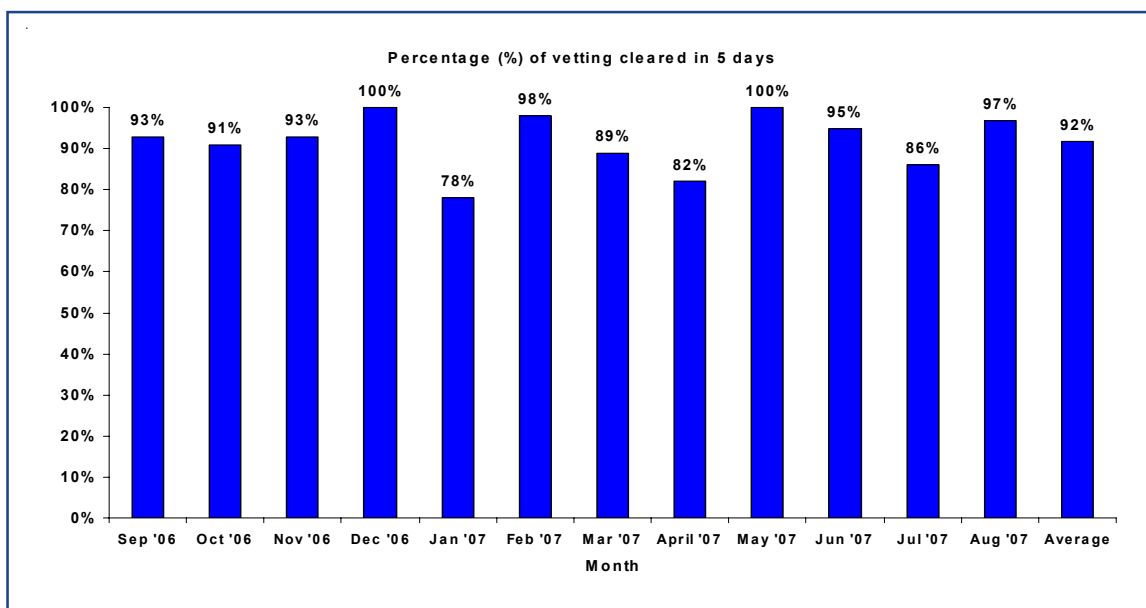


The graph shows mean assessment time based on new active substance numbers and product licence numbers. Figures incorporate new active substance applications assessed by all assessment units. They include incoming NAS mutual recognition applications and the assessment of centralised applications (both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

Other licensing time-based performance measures

These are now published and updated monthly on the MHRA website under the section on 'Information for licence applicants'.

Vetting of advertising prior to issue - percentage cleared in days



The graph shows for each month the percentage of advertising pieces submitted for vetting where the MHRA provided a response to the company within the target response time of 5 working days.

APPENDIX 1

Abridged licensing - additional statistics

Statistics on new application performance up to July 2005 were published in MAIL 151. Information on new applications performance since that date is currently unavailable but will be published on the MHRA website (www.mhra.gov.uk) when available.

Variations - performance

Statistics on variations performance up to July 2005 were published in MAIL 151. Information on variations performance since that date is currently unavailable but will be published on the MHRA website (www.mhra.gov.uk) when available.

New manufacturer's and wholesale dealer's licences issued in July and August 2007

Licence	Licence Holder
WL 29828	FRONTIER HEALTHCARE LIMITED, UNIT 7 PARKEND, HARLOW BUSINESS PARK, HARLOW, ESSEX, CM19 5QF
M/A 20492	CD PHARMA LIMITED, UNIT 3, MANOR POINT, MANOR WAY, BOREHAMWOOD, HERTFORDSHIRE, WD6 1EE
MS 1511	DEPARTMENT OF HEALTH, WELLINGTON HOUSE, 133-135 WATERLOO ROAD, LONDON, SE1 8UG
WL 30194	ZONATE LIMITED, 65 LONGLANDS WAY, CAMBERLEY, SURREY, GU15 1RH
WL 31379	IDEA MEDICAL LIMITED, UNIT 45, CAPITAL BUSINESS CENTRE, 22 CARLTON ROAD, SOUTH CROYDON, SURREY, CR2 0BS
WL 31404	FIRST CHOICE PHARMA LIMITED, 76A FORE STREET, EDMONTON, LONDON, N18 2SL
WDL 31611	SAVAGE AND WHITTEN WHOLESAL LIMITED, SHEPHERDS WAY, CARNBANE INDUSTRIAL ESTATE, NEWRY, CO DOWN, BT35 6EE
WL 31422	PHARMA 2U LIMITED, UNIT 8, DERBY ROAD INDUSTRIAL ESTATE, HOUNSLOW, MIDDLESEX, TW3 3HG
M/A 22443	ERIGAL LIMITED, KEELE UNIVERSITY SCIENCE PARK, KEELE, STAFFORDSHIRE, ST5 5BX
WDA 20492	CD PHARMA LIMITED, UNIT 3, MANOR POINT, MANOR WAY, BOREHAMWOOD, HERTFORDSHIRE, WD6 1EE
WDA 29828	FRONTIER HEALTHCARE LIMITED, UNIT 7 PARKEND, HARLOW BUSINESS PARK, HARLOW, ESSEX, CM19 5QF
WDA 31139	KANCO LIMITED, SCOTLAND LODGE, CHOLDERTON, SALISBURY, WILTSHIRE, SP4 0EJ
AO 20504	CROSS HEALTHCARE LIMITED, UNIT 2A, BANDEATH INDUSTRIAL ESTATE, THROSK, STIRLING, STIRLINGSHIRE, FK7 7NP
WL 6979	W P MOORE & COMPANY (BELFAST) LIMITED, 45/47 RAVENHILL ROAD, BELFAST, BT6 8DQ
WDL 31408	MORRIS AND SON (LEEDS) LIMITED, UNIT 4, NEWMARKET LANE, CROSS GREEN INDUSTRIAL ESTATE, LEEDS, LS9 0SH
WL 16719	UNIVERSITY HOSPITAL BIRMINGHAM NHS FOUNDATION TRUST, BIRMINGHAM WOMEN'S HOSPITAL, METCHLEY PARK ROAD, BIRMINGHAM, B15 2TG
WL 28426	POULTRY HEALTH SERVICES LIMITED, POULTRY HEALTH CENTRE, MAIN SITE LANE, DALTON, THIRSK, NORTH YORKSHIRE, YO7 3JA
WL 30472	PHARMAGONA LIMITED, 20 RUSHFIELD DRIVE, LONGSIGHT, MANCHESTER, M13 0RF
WL 31337	MIC GLOBAL (UK) LIMITED, 279 CLAPHAM ROAD, STOCKWELL, LONDON, SW9 9DN
WL 29412	HIKMA LIMITED, 13 HANOVER SQUARE, LONDON, W1S 1HW
WL 17379	DCS EUROPE LIMITED, TIMOTHY'S BRIDGE ROAD, STRATFORD-UPON-AVON, WARWICKSHIRE, CV37 9YL
WL 31533	COUNTRY MEDICAL SERVICES LIMITED, DEREHAM ROAD, MATTISHALL, DEREHAM, NR20 3QA
WDA 30492	U.K. POND PRODUCTS LIMITED, UNITS 18/19, RIVERSIDE, POWER STATION ROAD, RUGELEY, STAFFORDSHIRE, WS15 2YR
WL 31657	TRICOLOR GROUP HOLDINGS LIMITED, HEATH LODGE, COLCHESTER MAIN ROAD, ALRESFORD, COLCHESTER, ESSEX, CO7 8DB
WL 21012	CAPRILLO LIMITED, 81 COLLINGWOOD DRIVE, GREAT BARR, BIRMINGHAM, WEST MIDLANDS, B43 7JW
WL 31213	MEDI SPEC LIMITED, SUITE 7D, BRITANNIA HOUSE, LEAGRAVE ROAD, LUTON, LU3 1RJ
WDA 2198	FRANK WRIGHT LIMITED, BLENHEIM HOUSE, BLENHEIM ROAD, ASHBOURNE, DERBYSHIRE, DE6 1HA
WL 31138	8 PHARMA LIMITED, UNIT 8, PREMIER BUSINESS PARK, DENCORA WAY, LUTON, BEDFORDSHIRE, LU3 3HP
WL 31489	WYMONDHAM MEDICAL (WYMMED) LIMITED, NORWICH ROAD, 192 NEW COSTESSEY, NORWICH, NORFOLK, NR5 0EX
WL 31649	RED BAND CHEMICAL COMPANY LIMITED, 19, SMITH'S PLACE, EDINBURGH, EH6 8NU
WL 25057	CLEAR PHARMACY, 157-173 RODEN STREET, BELFAST, BT12 5QA

For further information please contact Mr David Kwokori on 020 7084 2597.

Licence	Licence Holder
MANA 3422	CROSS VETPHARM GROUP UK LIMITED, UNIT 2, BRYN CEFNI INDUSTRIAL PARK, LLANGFNI, ANGLESEY, LL77 7XA
MS 21758	THAME LABORATORIES LIMITED, UNIT 4, RIDGEWAY, DRAKES DRIVE, CRENDON INDUSTRIAL PARK, LONG CRENDON, AYLESBURY, BUCKINGHAMSHIRE, HP18 9BF
WDA 57	PFIZER LIMITED, RAMSGATE ROAD, SANDWICH, KENT, CT13 9NJ
WL 30813	GOLDFIELD VENTURES LIMITED, 75 SALISBURY ROAD, HOUNSLOW, MIDDLESEX, TW4 7NW
WL 31287	GLAMARY LIMITED, 101 WALMESLEY ROAD, ECCLESTON, ST HELENS, MERSEYSIDE, WA10 5JW
MANA 21734	VETAPHARMA LIMITED, SHERBURN ENTERPRISE PARK, SHERBURN-IN-ELMET, LEEDS, WEST YORKSHIRE, LS25 6NB
MANA 4261	AGRIMIN LIMITED, THE FLAREPATH, ELSHAM WOLD INDUSTRIAL ESTATE, BRIGG, SOUTH HUMBERSIDE, DN20 0SP
WDL 31199	IMPERIAL MEDICS LIMITED, 63 ROBIN HOOD LANE, LONDON, SW15 3PX
WL 31214	IXWORTH SURGERY, PEDDARS CLOSE, IXWORTH, BURY ST EDMUNDS, SUFFOLK, IP31 2HD
WL 31497	MAPS HEALTHCARE LIMITED, THE OLD CHAPEL, 69 PRIMROSE HILL, KINGS LANGLEY, HERTFORDSHIRE, WD4 8HX
WL 31518	NEWBRIDGE PHARMA LIMITED, MR A COLLIER, 31 RUMSAM GARDENS, BARNSTAPLE, DEVON, EX32 9EY
MANA 29895	HYPERDRUG PHARMACEUTICALS LIMITED, STATION INDUSTRIAL ESTATE, MIDDLETON IN TEESDALE, BARNARD CASTLE, CO DURHAM, DL12 0NG
WDL 29785	BIOURGE LIMITED, OFFICE 61, CARIOSCA BUSINESS PARK, 2 HELLIDON CLOSE, ARDWICK, MANCHESTER, M12 4AH
WL 31610	U L MEDICINES LIMITED, UNIT 9, PARK HOUSE, 15-19 GREENHILL CRESCENT, WATFORD BUSINESS PARK, WATFORD, HERTFORDSHIRE, WD18 8PH
WL 31437	SOLITAIRE PHARMA LIMITED, 1559 LONDON ROAD, LONDON, SW16 4AD
WDA 19611	NICHE GENERICS LIMITED, 1 THE CAM CENTRE, WILBURY WAY, HITCHIN, HERTFORDSHIRE, SG4 0TW
WDA 16782	BR PHARMA INTERNATIONAL LIMITED, UNIT 3, MANOR POINT, MANOR WAY, BOREHAMWOOD, HERTFORDSHIRE, WD6 1EE
WL 31748	BOWMED IBISQUS LIMITED, 113 PROMENADE, CHELTENHAM, GLOUCESTERSHIRE, GL50 1NW
WL 31619	PHARMACY LINK LIMITED, 4, WINTONLEA, MONUMENT WAY WEST, WOKING, SURREY, GU21 5EN
WDL 31768	SIEMENS MEDICAL SOLUTIONS, ASH GROVE, WILDFLOWER WAY, BELFAST, BT12 6TA

For further information please contact Mr David Kwokori on 020 7084 2597.

Complaints procedure

The policy of the Agency is to respond to all enquiries promptly and courteously.

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 Freedom of Information Act. 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.

Postal Address:

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