Mail

The MHRA updating service for medicines

- Guidance to companies on producing a corrective statement
- New administrative procedure for renewal submissions
- Reminder to MA holders on BANs to rINNs changes
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WELCOME to MAIL 146. As our main article this month we have guidance to companies on producing a corrective statement when advertising is found to be in breach of the regulations. We also have news of a new administrative procedure for renewal submissions, and a further reminder to marketing authorisation (MA) holders who have yet to submit applications concerning changes from BANs to rINNs. Also in this issue we have news of a forthcoming change in the information we publish as a result of advertising complaints investigations. Finally, I would like to wish all our readers a very happy Christmas and New Year.

ED SCULLY
The Editor, MAIL, 10th floor, Market Towers.
Telephone 020-7084 2345.

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.

ISSN 1360-8738 © Crown Copyright 2004
Leading issues

Advertising: corrective statements

We report the outcome of all complaints on our website. However, the website report may not be sufficient to correct any misconceptions which may have led to inappropriate prescribing or use of the product and potential risk to public health. In this situation we may request a corrective statement to be issued. We have statutory powers to compel the publication of a corrective statement where advertising has been found to be in breach of the Regulations, although most companies agree voluntarily to issue the correction.

This article provides guidance on producing a corrective statement to promote greater clarity. While most corrective statements would fit within this format there may be circumstances where it would not be appropriate to use it and in such cases we would consider an alternative format.

Corrective statement
• Opening statement: This should clearly indicate that this is a corrective statement issued at the request of the MHRA and the product concerned. Example wording: “The MHRA have asked … to provide a corrective statement regarding the promotion of …”
• Description of the case: This should include when and where the original advertisement was used and what type of advertisement/promotional material it was and whether it has been withdrawn or not.
• Statement on the breach: This should outline how the advertisement was in breach of the Advertising Regulations without repeating the original wording and give a description of the correct facts including a summary of the MHRA view.
• An expression of regret and apology.
• Contact information: Details of the company contact should readers have any further questions about these matters or about the product.

The tone and content of the corrective statement should convey the message that this is an informative publication, without giving the impression of promoting the product again, while keeping mentions of the product name to a minimum. The corrective statement should be targeted to the audience who saw the original advertisement, e.g. via a journal, mailing, or Dear Doctor Letter and should be proportionate in size to the original material.

Advice on advertising issues is available from Beryl Keeley, Product Information and Advertising Unit Manager, on 020-7084 2765.

MAIL subscriptions for 2005: reminder

The subscription for MAIL for the coming year, 1 January 2005 to 31 December 2005 has been held at £50.00. The subscription covers six issues and the subscription form is on the back of this issue. We also provide an e-mail alerting service for when MAIL appears on the MHRA website and the subscription is £10.00 per year. The MHRA website is at www.mhra.gov.uk.
Leading issues

Renewals administrative process

IN JULY 2003, we introduced a new administrative procedure for renewal submissions which has improved the efficiency with which we are able to process these applications. Having further reviewed our procedures, we have decided that it is not necessary to issue draft Summary of Product Characteristics (SPC) and licence details for those applications where the Marketing Authorisation (MA) has not been updated by variation since the previous renewal. In these cases, the MA holders will not receive draft SPC and licence details for applications but will be sent instead the final renewed licence documents directly after assessment has been completed. The opportunity will be retained to have the licence amended following determination if the MA Holder considers that it contains information that is incorrect or is not in accordance with the application.

This change will further streamline our renewals process. The guidance on renewals that is available on the MHRA website has been updated to incorporate this revision (http://medicines.mhra.gov.uk/ourwork/licensingmeds/maintaining/renewals.htm).

Further information on administrative aspects of national renewals procedures may be obtained from Pratibha Madan on 020-7084 2338.

BANs to rINNs: further reminders to MA holders

MARKETING authorisation (MA) holders should have already updated their licences by changing BANs to rINNs where applicable to active ingredients by 1 December 2004. We would like to thank MA holders for their cooperation in achieving the change from BANs to rINNs and encourage any outstanding submissions to be made as soon as possible. Such applications should continue to be made using the Type IA notification procedure (category 3) as previously instructed (see MAIL 138 July/August 2003 and information on the MHRA website www.mhra.gov.uk).

These variations should be submitted to the Variations Processing Team, MHRA, Room 13-1 Market Towers, at the usual address.

Where the change from BAN to rINN affects a substance named in the product particulars other than the active ingredient (e.g. in the interactions section of the Summary of Product Characteristics (SPC), then the name should be updated alongside other regulatory activity at the first available opportunity. Such changes should be made by 1 December 2005. The change in name may be effected, for example, at the same time as a variation, renewal or review of product information and should be described in a covering letter to the MHRA. It should be noted that some salts and esters are affected by the changes and may be used in substance names appearing in the product literature.

Furthermore, the names of some excipients are also different and Section 6.1 of the SPC should be updated where appropriate. There will be no additional charge for these changes made alongside other regulatory action before 1 December 2005, and separate Type IA notifications are not required. However, if the revisions are not achieved by that date, then applicants should submit a Type IA category 3 notification to effect the change.

For further information on the change from BANs to rINNs for existing MAs, please e-mail: sarah.branch@mhra.gsi.gov.uk.
Advertising

Naming of competitor company in outcome reports of complaints investigated

AS PART of an initiative on transparency for advertising investigations, which came into effect on 1 December 2003, we have been publishing outcome reports of the complaints we investigate on our website. Currently the identity of complainants is not disclosed.

With effect from 1 January 2005, the MHRA will name complainants in outcome reports where complaints originate from a competitor company. However, for those complaints received from any other sources, including healthcare professionals and private individuals, the identity of the complainant will continue to remain confidential. This proposed change will coincide with the coming into force of the Freedom of Information Act.

The Agency considers that naming of competitor complainants is fair to both parties and promotes openness in an important area but will not be a disincentive for genuine and legitimate complaints.

Advice on advertising issues is available from Beryl Keeley, Product Information and Advertising Unit Manager, on 020-7084 2765.

General Issues

Invitation to apply for membership of the Veterinary Residues Committee

THE VETERINARY Medicines Directorate and the Food Standards Agency are inviting nominations/applications for membership of the Veterinary Residues Committee (VRC) for terms of office from early 2005 to 31 December 2006. We will welcome in particular applications from members of currently under-represented groups including women, people with minority ethnic backgrounds and disabled people. All public appointments are based on the principle of merit. These appointments are not for full-time employment.

The VRC requires three new members:
- two who have an understanding of food safety issues from a consumer perspective. Ties to consumer organisations would be useful but are not essential, and
- one who has a detailed knowledge and several years’ experience of working in the retail industry, who knows about the implications of veterinary residues for the retail food industry, and has an understanding of the storage and distribution methods employed in the retail sector.

Applicants must be strong team players, with effective communication, negotiation, judgement and influencing skills combined with strong analytical and problem solving skills. As members they must be able to weigh issues outside their own specialist areas and to appreciate the impact that their decisions may have on public health. They must also be able to work in a committee structure and to arrive at sound, balanced and timely decisions.

For more information or an application form contact Colin Bennett, VRC Appointments’ Secretary, Veterinary Medicines Directorate, Woodham Lane, New Haw, Surrey KT15 3LS. Tel: 01932 338490, fax 01932 336618, email: c.bennett@vmd.defra.gsi.gov.uk or visit the VRC website at www.vet-residues-committee.gov.uk.

The closing date for all nominations is 7 January 2005. Nominations should be sent to COLIN BENNETT at the above address and marked for his attention. Completed application forms must be received by 4 February 2005.
General Issues

Suspicious callers alert

IN OCTOBER we alerted industry associations about a suspicious caller purporting to work for the MHRA who had made a call to a company seeking information. The company was suspicious and rang the MHRA to check whether the person named worked for the Agency. He did not and had used a false name. This has now happened on several occasions with the caller(s) using different names; the most recent case was a female caller.

We recommend that if you have any suspicion at all about a caller purporting to be from the MHRA do not give them any information, take their details and contact the MHRA Information Centre on 020-7084 2000 or e-mail: karen.salawu@mhra.gsi.gov.uk.

New e-mail addresses

PLEASE note we have set up two new e-mail addresses, one for National licensing enquiries and the other for the Biologicals Unit of the Licensing Division.

National licensing enquiries:
MAAqueries.chemicals@mhra.gsi.gov.uk

Biologicals Unit:
MAAqueries.biologicals@mhra.gsi.gov.uk

British Pharmacopoeia

British Pharmacopoeia 2004 and British Pharmacopoeia Veterinary 2004

ADDENDA to the British Pharmacopoeia 2004 and British Pharmacopoeia (Veterinary) 2004 will be available in January 2005 and will be published in electronic format only including an eBook. This electronic publication incorporates all the monographs of the 5th Edition of the European Pharmacopoeia and includes British Approved Names 2002 and its Supplements. The eBook allows the British Pharmacopoeia to be accessed via a personal digital assistant, “smart” phone or compatible device.

For technical matters concerning these publications please contact members of the BP Secretariat.

For all enquiries concerning purchase of publications and information regarding network licences including the BP eBook, please contact The Stationery Office, P O Box 29, Norwich NR3 1GN telephone 0870 243 0123, fax 0870 243 0129, textphone 0870 240 3701.

European Pharmacopoeia

The European Directorate for the Quality of Medicines (EDQM) will hold its first training course on the European Pharmacopoeia at the Royal Pharmaceutical Society of Great Britain, London, on 17 February 2005. This one-day programme will offer a greater understanding of the work and procedures of the European Pharmacopoeia, including international harmonisation of monographs, use and interpretation of the Ph Eur and regulatory
**EuroDirect**

**New guidelines**

SINCE the last edition of MAIL (September/October 2004) the following documents have been adopted:

- 328/98 Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure (CPMP).
- 5136/03 Guideline on the investigation of manufacturing processes for plasma-derived medicinal products with regard to VCJD risk (BWP).
- 3735/02 Core SPC for human prothrombin complex products (BPWG).
- 2455/02 Guideline on the clinical development of medicinal products for the treatment of allergic rhino-conjunctivitis (EWP).
- 104288/2004 Recommendation on the need for revision of (CHMP) note for guidance on clinical trials with haemopoietic growth factors for the prophylaxis of infection following melospressive or myeloablative therapy (CPMP/EWP/555/95) (EWP).
- 115735/2004 Note for guidance on the Electronic Data Interchange (EDI) of Individual Case Safety Reports (ICSRS) and medicinal products Reports (MPRS) in pharmacovigilance during the pre- and post- authorisation phase in the European Economic Area (EEA) (EMEA).

The following documents were released for consultation:

- 64/04 Concept paper on the need to revise the guideline on production and quality control of monoclonal antibodies (BWP).
- 5579/04 Guideline on procedural aspects regarding a CHMP scientific opinion in the context of cooperation with the World Health Organisation (WHO) for the evaluation of medicinal products intended exclusively for markets outside the community (EMEA).
- 278/02 Core SPC for human plasma derived von Willebrand factor (BPWG).

The following documents were also released:

- 24143/04 Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework (EMEA).
- 5180/03 Guideline on assessing the risk for virus transmission – new chapter 6 of the note for guidance on plasma-derived medicinal products (CPMP/BWP/269/95) (BWP).
Publications

Continued from page 6

- MLX 313 - Proposal for amendments to medicines legislation to allow supply of water for injection by people employed in Needle Exchange Schemes.


- MLX 316 - Review of the Code of Practice on interests to apply to the chairman and members of the Advisory Bodies laid down in the Medicines Act 1968.

MLX documents are available from the MHRA Information Centre on 020-7084 2352 and from the MHRA website at www.mhra.gov.uk.

Recent MLXs

- MLX 313 - Proposal for amendments to medicines legislation to allow supply of water for injection by people employed in Needle Exchange Schemes.


Conferences and seminars

MHRA conferences and seminars Forthcoming Programme 2005

THE MHRA will be hosting a series of events over the coming months on a variety of areas. For further information on the event below please send an email to: conferences@mhra.gsi.gov.uk or call 020-7084 2393, or see our website www.mhra.gov.uk.

- Clinical Trials: 6 Months On
  15-17 February 2005
  Venue to beConfirmed

To receive more information or to register for an event please contact Melanie Taylor at the Medicines and Healthcare products Regulatory Agency (MHRA) on:

T 020-7084 2393
F 020-7084 2676
E melanie.taylor@mhra.gsi.gov.uk or conferences@mhra.gsi.gov.uk
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 NCE and Biological 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

‘Gross’ processing time covers the entire period from receipt to grant, including weekends. ‘Net’ processing time refers to the number of working days the application has been worked on. This does not include time that has elapsed due to ‘clock-off’ events.
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, other than Type IA notifications, are based on the time from the advised procedure start date (the ‘acknowledgement letter’) to the completion of assessment. For Type I variations (received before 1 October 2003) or Type IB notifications (received on or after 1 October 2003), this is the time to the ‘Notification with Ground’s or ‘Approval’ letter. For Type II variations, this is the time to the ‘Request for Supplementary Information’ letter or ‘Approval’ letter. For Type IA notifications, the targets are based on the time from receipt to completion of the validation process. This is the time to the ‘acknowledgement’ or ‘non-acceptance letter.’

Performance data reflect all national and Mutual Recognition variations where the UK is Reference or Concerned Member State.

Performance for extended timescale (120 days) and expedited timescale (30 days). Type II variation procedures will be reported in future months when appropriate.
**New manufacturer’s and wholesale dealer’s licences issued in September to November 2004**

<table>
<thead>
<tr>
<th>Licence</th>
<th>Licence Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>AO 21030</td>
<td>Q Pak, 11 Halifax Way, Welwyn Garden City, Hertfordshire, AL7 2QH</td>
</tr>
<tr>
<td>MA 12014</td>
<td>Custom Powders Limited, Gateway, Crewe, Cheshire, CW1 6YT</td>
</tr>
<tr>
<td>MA 21248</td>
<td>Medlock Medical Ltd, Tubiton House, Medlock Street, Oldham, Lancashire, OL1 3HS</td>
</tr>
<tr>
<td>MA 21753</td>
<td>JohnsonDiversey (UK) Ltd, Weston Favell Centre, Northampton, Northamptonshire, NN3 8PD</td>
</tr>
<tr>
<td>MS 2635</td>
<td>TD Packaging Limited, Unit C, Stirling Road, South Marston Park, Swindon, Wiltshire, SN3 4TQ</td>
</tr>
<tr>
<td>MS 3070</td>
<td>Ipsen Biopharm Limited, Ash Road, Wrexham Industrial Estate, Wrexham, Clwyd, LL13 9UF</td>
</tr>
<tr>
<td>MS 19559</td>
<td>NuPharm Laboratories Limited, 2 Newtech Square, Deeside Industrial Park, Deeside, Flintshire, CH5 2NT</td>
</tr>
<tr>
<td>MS 20009</td>
<td>Wythenshawe Hospital, Pharmacy Aseptic Services, Southmoor Road, Wythenshaw, Manchester, Greater Manchester, M23 9LT</td>
</tr>
<tr>
<td>WI 19348</td>
<td>LPC Medical (UK) Limited, 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ</td>
</tr>
<tr>
<td>WI 20715</td>
<td>Nidus Medical Limited, 2 Stable Court, Beechwoods, Elmete Lane, Roundhay, Leeds, West Yorkshire, LS8 2LQ</td>
</tr>
<tr>
<td>WI 21702</td>
<td>PMB Pallet Express Limited, Wesley Street, Langley Mill, Nottinghamshire, NG16 4AL</td>
</tr>
<tr>
<td>WL 10341</td>
<td>Dr Falk Pharma UK Limited, Unit K Bourne End Business Park, Cores End Road, Bourne End, Bucks, SL8 5AS</td>
</tr>
<tr>
<td>WL 11234</td>
<td>Hospital Services Ltd, 2, Wildflower Way, Adelaide Industrial Estate, Belfast, BT12 6TA</td>
</tr>
<tr>
<td>WL 18166</td>
<td>Leeds Teaching Hospitals NHS Trust, Leeds Pharmaceutical Store, Mayfair House, Shannon Street, Leeds, West Yorkshire, LS9 8SS</td>
</tr>
<tr>
<td>WL 20869</td>
<td>J &amp; T Distribution Limited, Tilton Road, Burbage, Hinckley, Leicestershire, LE10 2SE</td>
</tr>
</tbody>
</table>

For further information please contact Mr David Kwokori on 020-7084 2597.
# MHRA PUBLICATION ORDER FORM

**Good Laboratory Practice**  
The GLP Pocket-Book

Price per copy at 0% VAT* (includes first class mail/airmail within EC. For locations outside the EC please add £2.00):

- 1-9 copies @ £10.00 per copy
- 10-99 copies @ £7.50 per copy
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To avoid delays in processing your order, please can you enter your cheque number in the box below.

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Medicines and Healthcare products Regulatory Agency  
Room 21-138, Market Towers,  
1 Nine Elms Lane,  
London SW8 5NQ  
United Kingdom

VAT No. GBGD 150
**EuroDirect Annual Subscription and Individual Copies Order Form**

### Annual EuroDirect Subscription - 1 December 2004 - 30 November 2005

Name of Subscriber to be used for mailing purposes: .......................................................... ..........................................................

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Room 21-138, Market Towers,
1 Nine Elms Lane,
London SW8 5NQ
United Kingdom
**APPENDIX 5**

<table>
<thead>
<tr>
<th>MHRA PUBLICATION ORDER FORM</th>
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<tbody>
<tr>
<td><strong>Annual Reports for 2003</strong></td>
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<tr>
<td><strong>Medicines Act 1968 Advisory Bodies</strong></td>
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Payment can be made by cheque and MUST be in £STERLING and drawn on a UK bank or by bank transfer (see appendix 7).

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London SW8 5NQ
United Kingdom

**VAT No. GBGD 150**
MHRA PUBLICATION ORDER FORM

Manufacturer’s Licences and Wholesale Dealer’s Licences Registers

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<thead>
<tr>
<th>Manufacturer’s Licences Register</th>
<th>Wholesale Dealer’s Licences Register</th>
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<td>Price per copy £5.00 VAT at 0%* (includes first class mail/airmail within EC. For locations outside the EC please add £2.00 for each).</td>
<td>Price per copy £10.00 VAT at 0%* (includes first class mail/airmail within EC. For locations outside the EC please add £2.00 for each).</td>
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Cheque Number: 15

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Medicines and Healthcare products
Regulatory Agency
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1 Nine Elms Lane,
London SW8 5NQ
United Kingdom

VAT No. GBGD 150
Bank Details for Payment by Bank Transfer
Please send remittances for the attention of the Cashier OR fax to 020-7084 2528 OR e-mail to cashiers@mhra.gsi.gov.uk

BACS Payments:
Bank Name: Bank Of England
Bank Address: Government Counter
Threadneedle Street
London
EC2R 8AH
Sort Code: 10 : 14 : 99
Account no: 06781000

Sterling CHAPS Payments from a UK Account:
Bank Name: Natwest Bank
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: 55001008304793
Sort Code: 60 : 10 : 43
Swift Code: NWBKGB2L
Reference: 6781 MHRA
IBAN: GB43NWBK60720608304793
Branch Address: Natwest Bank
6 Coldharbour Lane
Hayes
Middlesex UB3 3EL

For all other Overseas transfers:
Account name: Office of HM Paymaster General - Cash a/c
Account number: 25021001
Sort Code: 10 : 00 : 00
Swift Code: BKENGB33
Reference: 6781 MHRA
IBAN: GB57BKEN10000025021001
Bank Address: Bank of England
Government Counter
Threadneedle Street
London
EC2R 8AH

Finance Department
Medicines and Healthcare products
Regulatory Agency
Room 21-138, Market Towers,
1 Nine Elms Lane,
London SW8 5NQ
United Kingdom
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.

Postal Address:

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

Telephone: 020-7084 2000
Fax: 020-70842353
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
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