• Pre-application scientific advice meetings for companies

• Reminders for marketing authorisation (MA) holders on child resistant packaging

• BANs to rINNs changes for existing marketing authorisations (MAs)
General Practice Research Database

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Welcome to MAIL 144. We have two leading issues this month; firstly, we have further information for companies wishing to arrange a meeting for scientific advice, and secondly, important reminders for marketing authorisation (MA) holders concerning child resistant packaging and changes of medicine names from BANs to rINNs. We also have a reminder to MA holders of the need to submit variations for changes in names of substances with declared active ingredients, by 1 December 2004. Also in this issue we have items on the linking of products in advertising, and new legislation concerning Good Manufacturing Practice (GMP).
Company meetings

Since 1 July 2003 formal procedures have been in place for companies to request pre-application scientific advice meetings with MHRA staff. This was extended in October 2003 to include pre-application scientific advice meetings for variations and in April 2004 to meetings requested by marketing authorisation (MA) holders to discuss pharmacovigilance, advertising, proposed changes to labelling or package leaflets or post-authorisation regulatory advice relating to a product range.

We are now providing additional information to companies to facilitate these procedures.

**Requesting a meeting**
To ensure that your initial request is dealt with promptly, it should be sent to the appropriate MHRA co-ordinator. For a pre-submission advice meeting with the Licensing Division the initial request should be directed to Mr Simon Day, Statistics Unit Manager (simon.day@mhra.gsi.gov.uk). This includes meeting requests concerning licensing of new line extensions (i.e. abridged applications) and outgoing Mutual Recognition (MR) Procedures of UK licensed products. For advice relating to variations or other Post-Licensing aspects (including pharmacovigilance, advertising, labelling/leaflets, rebranding or post-referral procedures) the initial request should be sent to Ms Anne Ambrose (anne.ambrose@mhra.gsi.gov.uk), Acting Unit Manager for European Variations in the Post Licensing Division. The request forms are provided on our website.

Where the meeting request concerns a post-licensing aspect of a biological product it will be dealt with by the MHRA Biologicals Unit in the Licensing Division and therefore the meeting request should be sent to Mr Day.

Where the meeting request concerns a paediatric specific application, it will be co-ordinated by the Post Licensing division and therefore the meeting request should be sent to Ms Ambrose. Please note that meetings on paediatric specific issues may not attract a fee.

To avoid possible cancellation of your meeting, a request should only be submitted if the MA holder is in full possession of the information required and is able to provide the briefing within the required timescale.

**Briefing documents**
Companies are asked to provide a draft of their questions when they request a meeting and the final briefing documents ten days prior to the meeting. This briefing should include the questions that the MA holder wishes to discuss with the MHRA. The question(s) posed to the MHRA by the company should be as precise and clear as possible.

To help assessors in pre-meeting preparation, the briefing documents should be kept reasonably short, clear and concise and should focus on the key issues. Copies should be provided of any key references (but not necessarily all references) quoted in the briefing document.

With respect to meetings concerning labels and leaflets, the artwork that will form the basis of the discussion should be provided to the Product Information Unit at least two weeks prior to the meeting.

Although briefings should be provided in advance of the meeting it should however be noted that meetings to discuss advertising can be arranged at very short notice and in these cases the briefings can be supplied one or two days in advance.

**After the meeting**
The company should take notes of the meeting and a copy of these should be received by MHRA within five working days of the meeting. These notes will be for information only; the final advice should be taken as written in the MHRA final advice letter (sent within 30 working days of the meeting), not the company’s notes.

Further information on company meetings can be found on the MHRA Internet site at: http://medicines.mhra.gov.uk/inforesources/infolapps/sciadvice/sciadvice.htm. or you can contact Ms Anne Ambrose on 020-7084 2186 or Mr Simon Day on 020-7084 2112, for meetings with Post Licensing Division or Licensing Division respectively. For further information on paediatric applications you may contact Dr Julia Dunne on 020-7084 2115.
New regulations, which affect the packaging of aspirin, paracetamol and iron containing medicines, came into force on 1 October 2003 (SI 2317/2003) with a two-year transitional period for products already on the market. New British Standards have been introduced for both reclosable (clic-loc type) and non-reclosable (blister and strip) packs. BSEN 28317 covers the testing protocols to be applied to reclosable containers. BS 8404 covers the testing protocols to be applied to non-reclosable containers.

To help prevent accidental poisonings in children we announced, on 1 August 2003, that all aspirin, paracetamol and iron products must be in child resistant packaging that meets the new British Standard on child resistance for medicines. Further information is available in consultation document MLX 291 which can be found on our website (www.mhra.gov.uk).

For MAs that were granted before 1 October 2003, MA holders should make the necessary changes to the packaging by variation in the usual manner. Companies will have until 1 October 2005 to submit their applications to demonstrate that the packaging complies with the relevant standards. Medicines that are to be packed in reclosable containers will have to demonstrate compliance with BSEN 28317 and medicines that are to be packaged in blister or strip packs will have to demonstrate compliance with BS8404. This may be by reliance on a full certification by an approved test house to BS8404 or by using DIN compliant packaging components with an additional elderly adult test.

After 1 October 2005 it will be illegal to place on the market any of the relevant products that do not comply with the relevant standards of child safety.

 Guidance to help MA holders comply with the new regulations and a list of compliant materials are displayed on our website (www.mhra.gov.uk). For further information please contact Jan MacDonald, Room 14-107, Market Towers. Telephone 020-7084 2267.

1 October 2005 deadline for compliance with regulations on child safety

MARKETING authorisation (MA) holders should be updating their licences with respect to child resistant packaging and changing British Approved Names (BANs) to Recommended International Non-proprietary Names (rINNs) where applicable. We would like to remind MA holders of the arrangements in place to facilitate these changes.

BANs to rINNs changes for existing marketing authorisations (MAs)

WE HAVE previously published instructions to marketing authorisation (MA) holders for products affected by the changeover from BANs to rINNs which came into effect in December 2003 (see MAIL 138, July/August 2003, and information on our website www.mhra.gov.uk). Please may we remind MA holders that changes in names of declared active ingredients should be effected by submission of variations by 1 December 2004. To avoid a heavy influx of applications at the beginning of December, we would like to encourage submissions to be made as soon as possible to allow smooth processing of all the necessary changes. Type IA notifications (category 3) should be submitted to Variations Processing, MHRA, Room 13-1 Market Towers, 1 Nine Elms Lane, London SW8 5NQ

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

Advertising

Advertising to the public: linked medicines

WE RECENTLY investigated several advertisements in which the products promoted were linked with other products with similar names also marketed by the company.

The MHRA does not encourage references to other products in advertising since this may cause confusion. Where a link between products is proposed, companies should take into consideration any potential risk to public health to ensure that messages conveyed to the audience support the safe use of the products concerned.

Companies are advised to carefully consider any differences between the products concerned and whether the implied link between the products in the advertisement has the potential to cause confusion that could lead to irrational or inappropriate use of the products in each target patient population that could be put at risk. This should include not only the specific words and images used but also the overall impression given by the advertisement as a whole.

When two products are being promoted in one advertisement but the indicated populations are different, it is good practice to make clear what the target group for each product is. This is particularly important where inappropriate use of the product that could be encouraged by the advertisement could pose a risk to public health. The messages conveyed to the audience should support the safe use of the products concerned.

Case reports for recent investigations on this advertising issue are available on our website at http://medicines.mhra.gov.uk/ourwork/advertpromed/complaints/complaints.htm. In each of the cases upheld, there were specific restrictions on who should use the product being advertised but, in the MHRA’s view, the link to a product with wider indications could have given the misleading impression that the products could be used interchangeably.

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

Manufacturing and wholesaling

Good Manufacturing Practice


Medicinal products must be manufactured in accordance with Good Manufacturing Practice (GMP). This applies both to medicinal products manufactured for use in clinical trials and those manufactured for the purpose of marketing. The principles and guidelines of GMP are set out in Commission Directive 2003/94/EC. Both UK manufacturing practice and inspection activity take these requirements into account as a matter of course, via the standard provisions relating to manufacturer’s licences.

The new Regulations make a minor amendment to the Standard Provisions by substituting the revised definition of GMP contained within the Directive to ensure that the principles and guidelines of GMP as set out in Commission Directive 2003/94/EC are complied with in the UK. The revised definition states: “good manufacturing practice means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use”.

Further details are available from Rob Dickman, telephone 020-7084 2442 or from our website, www.mhra.gov.uk.
Enforcement

Prosecutions

Regina v Bernard Long
On 3 June 2004 at Wigan Magistrates court, Bernard Long pleaded guilty to one offence under section 58 of the Medicines Act 1968 and three offences under section 52 of the Medicines Act 1968.

One of the offences concerned the illegal sale of a product called “Heat Seeker” which was found to contain ephedrine.

One aspect of the case involved the consumption of a product containing ephedrine by a professional rugby player who later tested positive for a banned substance.

Bernard Long was given a two-year conditional discharge and ordered to pay costs of £2600.

Regina v Dr Duo Gao (Chinese Herbal Medicine & Healthcare Ltd / Trading as Herbal King)
Dr Gao pleaded guilty on 8 March 2004 at Leeds Crown Court to four offences under section 52 of the Medicines Act 1968 and was sentenced on 10 March 2004.

The offences related to the offering or exposing for sale the following four medicinal products in shops based either in Leeds and/ or Eastbourne:

- Guan Xin Su He - found to contain the banned ingredient Aristolochia (aristolochic acids)
- Tian Wang Bu Xin wan - found to contain mercuric sulphide
- Fang Feng Tong Sheng wan - found to contain ephedrine
- She Dan - product label specifying presence of several medicinal ingredients (also containing snake bile)

In sentencing Dr Gao was fined a total of £2700 and ordered to pay £4000 costs.

Regina v Peter Kaul (Mens Health Matters)
On 14 January 2004, at Croydon Crown Court, Judge Tanzer sentenced Peter Kaul to six months’ imprisonment, suspended for two years, for conspiracy and for offences under section 52 and 58 of the Medicines Act 1968.

The offences relate to the illegal sale and supply of Viagra, a prescription only medicine (POM).

On 14 May at Croydon Crown Court a confiscation order for £170,000 and MHRA costs of £15,000 were awarded.

If you would like to know more about the work of our Enforcement Group please telephone 020-7084 2330/2168

PUBLICATIONS

EuroDirect

First opportunity to subscribe to EuroDirect 2004/2005

THIS issue of MAIL gives you the first opportunity to take out a subscription to EuroDirect for the year 1 December 2004 to 30 November 2005. Subscriptions received before 1 November 2004 will be available at the reduced price of £340. If you would like to subscribe please use the order form at Appendix 4.

What do I receive?
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Continued on page 6
Since the last edition of MAIL (May/June 2004) the following documents have been adopted:

- 345/03 Final position statement on chamomilla containing herbal medicinal products (HMPWP).
- 1470/04 Concept paper on the development of a CHMP note for guidance on the need for regulatory guidance in the evaluation of medicinal products for the secondary cardiovascular prevention (EWP).
- 225/02 Note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function (EWP).
- 2998/03 Note for guidance on the inclusion of appendices to clinical study reports in Marketing Authorisation applications (EWP).
- 1820/04 Concept paper on the development of a CHMP revised guideline on clinical evaluation of new vaccines (VEG).
- 2592/02 CHMP SWP conclusions and recommendations on the use of genetically modified animal models for carcinogenicity assessment (Rev. 1) (SWP).
- 10/04 Concept paper on the development of a CHMP guideline on detection of early signals for hepatotoxicity from non-clinical documentation (SWP).
- 1483/04 Concept paper on the development of a CHMP guideline for the non-clinical development of fixed-combinations of medicinal products (SWP).
- 3833/03 Discussion paper on contraindications in pregnancy concerning sections 4.3, 4.6 and 5.3 of the Summary of Product Characteristics (CHMP).
- 2599/02 Position paper on non-clinical safety studies to support clinical trials with a single microdose (SWP).

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- 2998/03 Note for guidance on the inclusion of appendices to clinical study reports in Marketing Authorisation applications (EWP).
- 1820/04 Concept paper on the development of a CHMP revised guideline on clinical evaluation of new vaccines (VEG).
Recent SIs


Statutory Instruments may be purchased from The Stationery Office, PO Box 29, Norwich NR3 1GN, telephone 0870-600 5522. They may also be accessed on the website at www.tso.co.uk.
**APPENDIX 1**

**New active substance applications - mean assessment times**

![Graph showing mean assessment times](image)

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**

![Graph showingMean Gross and Net Processing Times](image)

‘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 May and June 2004

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<td>MA 12762</td>
<td>Goldshield Pharmaceuticals Limited, NLA Tower, 12-16 Addiscombe Road, Surrey, CR0 0XT</td>
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<td>MA 20848</td>
<td>Thorpe Laboratories Limited, Golf Road Industrial Estate, Mablethorpe, Lincolnshire, LN12 1NB</td>
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<td>MA 21538</td>
<td>Gambro Northern Ireland Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim, BT40 2SH</td>
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<td>MS 20474</td>
<td>Medway NHS Trust, Department of Nuclear Medicine, Department of Nuclear Medicine, Maritime Hospital, Gillingham, Kent, ME5 7NY</td>
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<td>MS 21227</td>
<td>Biosurgical Research Unit, SMTL, Princess of Wales Hospital, Coity Road, Bridgend, Mid Glamorgan, CF31 1RQ</td>
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<td>Ceuta Healthcare Limited, Hill House, 41 Richmond Hill, Bournemouth, Dorset, BH2 6HS</td>
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<td>Medihealth (Northern) Limited, PO Box 2076, Lymstock House, Lymstock Way, Lostock, Bolton, Greater Manchester BL6 4SA</td>
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<td>African Society Limited, 87 Kent View Road, Basildon, Essex, SS16 4JP</td>
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<td>Dime Ltd, Unit 8 Winton Lea, Monument Way West, Woking, Surrey, GU21 5EN</td>
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<td>Dixons Pharmaceuticals Ltd, Unit 1A, Meteor Business Park, Meteor Centre, Mansfield Road, Derby, Derbyshire DE21 4ST</td>
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For further information please contact Mr David Kwokori on 020-7084 2597.
# MHRA PUBLICATION ORDER FORM

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<td>10-99 copies @ £7.50 per copy</td>
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Medicines and Healthcare products Regulatory Agency
Room 21-138, Market Towers,
1 Nine Elms Lane,
London SW8 5NQ
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Please send remittances for the attention of the Cashier OR fax to 020-7084 2528 OR e-mail to cashiers@mhra.gsi.gov.uk

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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

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Account name: Office of HM Paymaster General - Cash a/c
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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
### 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: 02-70842353  
**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  
London SE1 6TQ  
Telephone: 020-7972 8136  
Fax: 02-79728108  
**E-mail:** mail@medical-devices.gov.uk
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