Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

Wednesday 14th November 2012

University College London
Gower Street
London WC1E 6BT

Dear Professor Colquhoun

Our ref: FOI 12/416

Thank you for your communications of 18 October. For ease of reference, I have listed each of your questions with our corresponding response included immediately below:

Q.1 Is it correct that all of the items described there have full marketing authorisation?

R.1 Benylin Chesty Coughs Non-drowsy (PL 15513/0056), Benylin Tickly Coughs Non-Drowsy (PL 15513/0142), Covonia Herbal Mucus Cough Syrup (PL 00240/5209R), Cold and Flu Relief Tablets (PL 00014/5234R) and Adios Tablets (PL 17418/0005) have Marketing Authorisations.

Bach Rescue Remedy Spray (PLR 01175/8233) is the subject of a Product Licence of Right; this means that the product was on the UK market when the Medicines Act 1968 came into force in 1971. A PLR is not a full Marketing Authorisation. With the exception of certain categories of medicines, all such licences were reviewed in the 1980s to ensure that the products were safe, of suitable quality and have evidence of efficacy. The status of Bach Rescue Remedy Spray is currently under review. For your information, the relevant Marketing Authorisation reference number is included in brackets after each product name.

SevenSeas Jointcare be active and Bio-Oil are not medicinal products and do not hold Marketing Authorisations.

Q.2 A related point is that I see that Metatone and Minadex "tonics" also have MA. Can you please send me the assessments of efficacy for all of these medicines?

R.2 Metatone (PL 02855/0017), Covonia Herbal Mucus Cough Syrup, Cold and Flu Relief Tablets and Adios Tablets originally held Product Licences of Right. These products were on the market before the Medicines Act 1968 came into force in 1971. These licences were reviewed in the 1980s to ensure that the products were safe, of suitable quality and have evidence of efficacy. Because of the length of time that the products had been on the market they were considered to have well established use and original clinical data to today's standards was not necessarily available.

We are able to provide you with a copy of the Expert Report submitted to the MHRA as part of the 1988 review of the Product Licence of Right for Coltsfoot, Pine & Honey Balsam (as Covonia Herbal Mucus

Cough Syrup was then named). We have checked our records and we do not appear to hold the equivalent information for Metatone, Cold and Flu Relief Tablets and Adios Tablets. We have exhausted all the usual avenues in our search - including a check in our archived paper records - for this information and must conclude that it is no longer in our systems in a retrievable form.

The Expert Report for Covonia Herbal Mucus Cough Syrup contains references to published literature describing the therapeutic effects of the active ingredients of Covonia Herbal Mucus Cough Syrup. This Expert Report should be read with consideration of the following caveats:

1. Data relating to coltsfoot is no longer applicable as this active ingredient was removed from the formulation
2. Data relating to pumilio pine oil is no longer applicable as this active ingredient was removed from the formulation
3. Data relating to interactions and adverse reactions have been updated in line with current safety data.

Please also note that redactions have been made to this Expert Report in accordance with Section 40 of the FOI Act relating to personal information.

Benylin Tickly Coughs Non-Drowsy was granted a Marketing Authorisation on the basis that it is identical to Nirolex Dry Syrup (PL 00014/0550) which, in turn, was granted a Marketing Authorisation on the basis that it is identical to Glycerin and Blackcurrant Linctus (PL 00014/0307).

Minadex Tonic (PL 01932/0004) was granted a Marketing Authorisation on the basis that it is identical to Minadex Mixture (PL 00039/0216).

Efficacy data were not included in the applications for Benylin Tickly Coughs Non-Drowsy and Minadex Tonic as the MHRA accepted that these products were identical to the previously licensed cross-reference products Glycerin and Blackcurrant Linctus and Minadex Mixture, respectively. We have checked our records and we do not appear to hold the efficacy data for Benylin Chesty Coughs Non-drowsy, Glycerin and Blackcurrant Linctus or Minadex Mixture. We have exhausted all the usual avenues in our search - including a check in our archived paper records - for this information and must conclude that it is no longer on our systems in a retrievable form.

Q.3 Apropos of Metatone. I see that the "active ingredient" is listed as calcium glycerophosphate. I'm not aware that this compound has any effects, in particular the "tonic" effects claimed for it. Could you please send me whatever evidence you may possess?

R.3 As stated in R.2, we do not hold the assessments of the efficacy of Metatone. Nor do we hold any efficacy data submitted by the Marketing Authorisation Holder.

Q.4 I checked the SPC for Metatone
http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1346209570671.pdf
It lists under para 5.1 a number of well-known characteristics of the ingredients, but says nothing whatsoever about the clinical efficacy of the product.

I also checked the SPC for "Minadex Tonic", at
http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1349843491770.pdf
This says essentially nothing under 5.1
Minadex Tonic is formulated as a vitamin and mineral supplement and appetite restorative for children and adults. Detailed Pharmacology not applicable.

Again I see nothing about clinical efficacy. Yet both products have full marketing authorisation and are permitted to advertise themselves as "tonics". Since MA is supposed to provide a guarantee that the product is effective. Can you explain this discrepancy?

R.4 Bibliographic evidence relating to the components of the formulation would have been taken into account when the PLRs for Metatone and Minadex Mixture (the reference product for Minadex Tonic) were reviewed. This information was accepted in place of original efficacy data, in line with the expectations of medicines legislation for products of this type at that time.

Q.5 Can you tell me what criteria the MHRA uses when allowing a product to be advertised as a "tonic"?

R.5 The MHRA assesses proposed product names on a case by case basis. On the basis of the well established use of Minadex Tonic it was decided that the use of the word tonic in the product name was acceptable. For the same reason, it was accepted that Metatone could be referred to as a tonic in the Product Information Leaflet and product labels.

If you require any further information about this FOI request please contact me at FOIlicensing@mhra.gsi.gov.uk.

If you are unhappy with this response, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Area 4 T, Medicines and Healthcare products Regulatory Agency, quoting the above Freedom of Information reference number. After that, if you remain dissatisfied, you may ask the Information Commissioner at The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF, UK to make a decision on whether or not we have interpreted the FOIA correctly in withholding some information from you.

Yours sincerely

Freedom of Information Team
Licensing Division
MHRA

Email: FOIlicensing@mhra.gsi.gov.uk