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BRIDGING REPORT

For Promazine Hydrochloride 50mg/5ml Oral Syrup Leaflet

Marketing Authorisation Holder:	Rosemont Pharmaceuticals Ltd. Yorkdale Industrial Park Braithwaite Street Leeds LS11 9XE
Daughter Leaflet: (Product leaflet proposed for bridging)	Promazine Hydrochloride 50mg/5ml Oral Syrup
Parent Leaflet: (Product leaflet that has been user tested)	Chlorpromazine Hydrochloride 25mg/5ml Oral Syrup
User Test Result:	[redacted]

Issued by [redacted]

Date of Statement: **3rd December 2007**

Principal Investigator: [redacted]

Written by:

[redacted]

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BRIDGING REPORT

For Promazine Hydrochloride 50mg/5ml Oral Syrup Leaflet

The validity of limiting the number of User Tests across Patient Information Leaflets (PILs)

1 Background to Bridging

EU and UK national guidance on user testing does not require all Patient Information Leaflets (PILs) to have individual User Tests. Where sufficient user testing has already been performed on products identified as being similar or related, the results of such testing can be applied across related leaflets in order to limit further testing whilst still adhering to the principles set out in Council Directive 2004/27/EC, Article 59 (3).

EU and UK guidance on bridging permits the use of successful User Tests carried out for one or more leaflets (parent leaflets) as justification for not testing similar leaflets (daughter leaflets). Daughter leaflets should be of sufficiently similar content, design, layout and writing style as the parent leaflet.

2 Proposal for bridging

It is proposed that a User Test is not required on the leaflet for Promazine Hydrochloride 50mg/5ml Oral Syrup, hereafter referred to as Promazine 50mg or the daughter leaflet.

[redacted] have previously conducted and documented a User Test on behalf of Rosemont Pharmaceuticals Ltd. for the leaflet that is presented with the related product Chlorpromazine Hydrochloride 25mg/5ml Oral Syrup, hereafter referred to as Chlorpromazine 25mg or the parent leaflet.

The rationale for this bridging proposal and the assessment of the relevance of the User Test data is detailed below.

3 Bridging Assessment by [redacted]

3.1 Rationale for bridging

[redacted] reviewed the product portfolio for Rosemont Pharmaceuticals Ltd and performed a bridging analysis to determine which leaflets would require a User Test (parent leaflets) and which leaflets would be bridged (daughter leaflets). The outcome of this analysis was approved by the UK regulatory authority in 2006.

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For the leaflet which is the subject of this bridging proposal, it was determined that a User Test for the related leaflet Chlorpromazine 25mg would provide sufficient data to permit bridging. The User Test of the parent leaflet has now been performed and the methods employed that led to this positive result are detailed in report 1007/Rose/27. In the opinion of [redacted] the leaflet successfully passed a User Test and complied with Council Directive 2004/27/EC, Article 59 (3).

Bridging is acceptable in this case because the daughter leaflet and the parent leaflet are medicines in the same therapeutic class where the key messages for the safe and effective use of the daughter product were covered in the User Test of the parent leaflet.

3.2 Analysis of content and layout

3.2.1 Key messages

For the daughter leaflet, the most critical information for safe and effective use is considered to be as follows:

- Advice against taking this medicine if you are pregnant or breast-feeding
- To understand the requirement for heart and blood tests if you have a family history of heart problems
- Advice against drinking alcohol whilst taking this medicine
- To understand that you should not drive or use machines if this medicine makes you feel drowsy
- Not to take a double dose to make up for a forgotten dose
- To understand that the doctor will gradually lower the dose when stopping this medicine
- Identifying the warning signs of a disorder caused by this type of medicine.

These correspond to the critical information in the parent leaflet.

3.2.2 Content

There are no significant differences between the content of the parent and daughter leaflet because they are medicines in the same therapeutic class. In addition, the same writing style has been used in both leaflets.

It is the opinion of [redacted] that the content of the Promazine 50mg/5ml Syrup leaflet being bridged is similar to the Chlorpromazine 25mg leaflet that has been successfully user tested.

3.2.3 Format

The overall layout, design and writing style of the leaflet being bridged is similar to the tested leaflet. This includes the same headings, paragraph and sentence structure and other layout features. The dimensions of the leaflet are the same: 210mm x 300mm. The only difference is that the text in the columns has been split in different places. However, the location of these breaks has been carefully chosen to optimise readability.

4 Conclusion

It is the opinion of [redacted] that the Chlorpromazine 25mg leaflet sufficiently covers all content and format aspects of the Promazine 50mg/5ml Syrup leaflet being bridged and that the

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overall content and format of the two leaflets is sufficiently similar to permit bridging. Therefore a separate User Test is not required.

All leaflets referenced in this report have been developed through direct user testing or by applying learnings from related and successfully user tested leaflets (bridging). It is the opinion of [redacted] therefore, that all leaflets mentioned in this report have been shown to be legible, clear and easy to use in line with the requirements of Council Directive 2004/27/EC, Article 59 (3).

----------End of report----------

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