European Medicines Agency
Evaluation of Medicines for Human Use

London, 30 November 2006
Doc. Ref. EMEA/487680/2006

REPORT FROM THE JOINT EMEA (NRG)/EFPIA WORKSHOP ON INVENTED NAMES 11 SEPTEMBER 2006 (10H00 TO 13H00)

Chairman: Tony Humphreys
Head of Sector
Regulatory Affairs and Organisational Support

REPORT PREPARED BY EFPIA

Introduction

The Chairman welcomed participants and reminded them of the purpose of the Workshop: exchange information in order to improve predictability of invented Name Review Group (NRG) outcome and provide recommendations to Industry to improve overall efficiency of process. There followed a "tour de table" presentation.

Invented Name Approval Process

Trademarks (EFPIA)

- General introduction / Presentation by Ann ROBINS (AR) (see **Annex I**)

AR introduced EFPIA, its mission, its membership as well as some key figures showing the importance of the research-based pharmaceutical industry and its economic contribution to the European economy in terms of employment and trade surplus. Stefano Marino, Chairman of the EFPIA Trademarks ad hoc Group, thanked the EMEA for the invitation and expressed the hope that the parties will keep up their annual dialogue.

- Principles and timelines on Trademarks / Community Trademarks

and

- Trademark creation and development: process including validation / testing methodology and cost implications /Presentation by Joanne GREEN (JG) and Anja MANZ (AM) (see **Annex II**)

JG and AM presented the trademark creation process in a global environment. They stressed the function of a trademark, the development process of a global trademark, companies' objectives, facts figures and average timelines, trademark registration systems, name safety testing, expert review, major hurdles (market suitability, culture and linguistic suitability, registration at TM offices, safety and health concerns at EMEA and FDA, single trademark requirement at EU Commission), facts and figures and conclusions.

Q&A: The speakers answered questions on the trademark review for look-sound alike: it takes place internally within companies, not externally; on a hierarchy of name testing: company staff need to be trained for this but it is an option albeit expensive, as are external agencies as well – it is up to each company to decide if they can make the investment and how they will benchmark against the rejection

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu/

rate – it is considered "best practice"; on whether companies check linguistic similarities taking into account the Guideline: yes they do; a Member State representative indicated that they take look-alike analysis very seriously, in particular with medication error cases filed by doctors (one case was reported to EMEA so far, in addition to reports from literature and clinics);

- Global Trademarks and exceptions to the single trademark / Presentation by Dr Gordon WRIGHT (GW) (see **Annex III**)

Dr Wright introduced a forthcoming proposal from EFPIA for increased flexibility under the EU single trademark requirement for centrally approved products. He reminded participants of the history and objectives of the single trademark requirement - already an agenda item at the first Workshop in April 2001-, in particular the Commission Communication of July 1998 and the scope of "exceptional cases", the two derogations granted by the Commission (in the cases of "Refludan" and "Infergen"), the Dr Karl Thomae case (Court of First Instance decision of 02/12/2002) and the inclusion of the requirement into the pharmaceutical law (Regulation 726/2004). It is proposed to ask for minor variations of an invented name to be considered to be the same name (as are the different linguistic versions of INNs) and constitute a single name for the purpose of Regulation 726/2004 (Article 6). Minor variations could be proposed when facing EMEA objections based on a potential risk of confusion, thus to avoid any risk to public health. The proposed variation should maintain sufficient common elements with the proposed invented name to indicate that they are intimately related. Industry proposes that, under such conditions, minor variations could be accepted "de facto" by EMEA. The policy on derogations for different names would continue to follow the above mentioned Communication since both derogations continue to apply to products currently on the market. Derogations which should cover health and safety issues raised by the EMEA, issues of connotation and other reasons to be agreed by the Commission and they should be approved by the Commission before the CHMP opinion to avoid delay in access. GW made reference to a letter which EFPIA received from the Commission the day before the meetings, too late to consider before the meeting but making proposal timely indeed.

Q&A: TH asked how we would see the two derogations in light of the above: GW said we would see them as minor variations based on health and safety concern as they address the main cause for rejections and since the names were fairly close; there followed questions on the impact on parallel imported products: there would not be a problem since the issue is already dealt with for co-marketed products and with each derogation the Commission has imposed that the MAH undertakes not to use the different trademarks to partition the market. In addition, so far no safety issues have arisen from repackaging. Minor variations would constitute a pragmatic solution to a longstanding and frustrating problem. The representative from Portugal asked if the Communication still applied: GW replied that it does. Ultimately the reply would lie with the ECJ which would look at the purpose of the law, i.e. to allow access to the market while not risking public health. The Communication is coherent with these two purposes. EFPIA will shortly be replying to a recent letter from the Commission, which sets a narrower view.

Chairman's comment: the Commission is aware of the worsened rejection rate (up to 67%) and is sensitive to the complexity for industry. It is now minded to revisit the topic, so that it was timely to hear the EFPIA proposal.

!! Action: EFPIA to go back to the Commission and propose policy line to take in the future.

- Use of suffixes, prefixes and qualifiers with connotations in names (EFPIA) / Presentation by Hanne BROKOPP (HB) (see **Annex IV**)

The issue was not formally presented and was moved to item 4. under "Specific points for discussion".

- Invented names containing INNs and INN stems (EFPIA) / Presentation by Catherine BOUDOT (CB) and Ann ROBINS (AR) (see **Annex V**)

The issue was not formally presented and was moved to item 4. under "Specific points for discussion".

Guideline on acceptability of invented names for human use (EMEA)

- Presentation by Zaide FRIAS (ZF) (see **Annex VI**)

ZF presented the recent changes since the last meeting in Sept. '04, the aim of which is to improve efficiency of the process. The request form has been amended: it is now possible to submit up to 4 names at once (it is more efficient for the NRG to look at them at the same meeting). Applicants are asked to indicate whether an application concerns a multiple application because if so, it is necessary to see if the names resemble each other. The "outcome fax template" form was amended (slide 21) so that objections are relayed in a more consistent way.

!! Action point: If companies have questions on a fax containing the outcome, they should not hesitate to contact ZF.

- Criteria applied when reviewing the acceptability of proposed invented names

A consultation takes place with Member States, WHO and the EC. A check is made against authorised, applied for, suspended and revoked / withdrawn medicinal products according to relevant national legislation. The Member States checks proposed invented names against pending authorisations in their countries including those withdrawn since a number of years (national legislation varies: five years in the UK, two years in other MS). ZF pointed out that the rules applied at the national level are not harmonised and that the name of pending applications can not be disclosed to the companies when informing about objections raised.

!! Action point: ZF asked whether EFPIA was interested in a harmonisation project in this matter for products submitted through the Centralised procedure.

The IN should not convey misleading therapeutic or pharmaceutical connotations, nor be misleading with respect to product composition, nor be liable to cause confusion with the IN of an existing medicine in print, speech or handwriting. Recommendations: If IN is rejected, try to amend your proposed IN to take it away from the potentially confusing names, to help improve predictability. Include in your justification an assessment of potential for harm in case of mix-up.

!! Action point: Does EFPIA wish to develop with EMEA a concept about the methodology for the conduct of "Prescription and interpretation studies and surveys"? Recommendation: Companies are encouraged to report prescription errors / medication errors due to IN (slide 31).

- International Nonproprietary names (INNs) concerns in proposing invented names

It is recommended that the applicant / MA holder (1) undertakes to review similarities with existing INNs and INN stem inclusions prior to submitting their proposed invented names and (2) addresses any issues arising from the above in the notification form or provide a justification for deviation. See statistics.

- Other public health concerns in proposing invented names

ZF reminded participants of the other current criteria: names should consist of one word, the use of short qualification / abbreviations which do not have an established meaning in all Member States is unacceptable, name should not convey any promotional message with respect to the use of the product, name should not appear offensive or to have a bad connotation in any of the languages, use of capitals should reflect the proposed / approved trademark registration, IN for fixed combinations should be completely different (but what does this mean?) from the IN of individual active ingredients. See slide 44 for rest of the list.

- NRG origin, composition and review procedure

See under point 4. Specific points for discussion: Transparency.

US /FDA and EU / EMEA invented name approval process: similarities and differences – Industry viewpoint (EFPIA) /Presentation by Joêlle SAINT-HUGOT (JSH) (see **Annex VII**)

JSH presented FDA practices, in particular the advance approval of proprietary names, the FDA assessment process and teams involved (DMETS - use of POCA and prescription simulations),

FDA criteria, industry / FDA dialogue, reconsideration process and comparison between EMEA and FDA practices.

Q&A: the speaker was thanked for a very useful comparative information session; there followed an exchange of views on the methodology with respect to studies and surveys.

Specific points for discussion

- Transparency CHMP and NRG (EFPIA / EMEA)

New features: published information under CHMP: role, composition and membership of other associated groups including NRG as part of overall transparency policy; Pre-submission Guidance: Q/A on invented names made more practical; CHMP monthly report (slide 51).

Moved from above:

- Use of suffixes, prefixes and qualifiers with connotations in names

The issue was not formally presented and was moved to item 4. under "Specific points for discussion". During the exchange of views, industry representatives reminded participants of the rules contained in the Guideline with respect to the use of short qualifiers and the conveyance of so-called "promotional " messages (example "Plus"). Practical issues were raised. Clarification and guidance were sought on the interpretation and use of the Guideline. It was suggested that the possibility for local variations / derogations in the IN and their suffixes should be allowed. The subject matter was also on the agenda for the Interested Parties Meeting in the afternoon (see separate report).

- Invented names containing INNs and INN stems. See separate Interested Parties Meeting report.

Proposed future developments (EMEA / EFPIA) /Presentation by Zaide FRIAS (see **Annex VI**)

Revision of the Guideline on acceptability of invented names for human use (EMEA)

This topic was mainly introduced at the Interested Parties Meeting in the afternoon. ZF listed the reasons for the next revision of the IN Guideline: update in line with the new Community legislation including the single trademark requirement, update taking into account practice and experience gathered within the NRG since revision 4 and increased transparency measures.

Accession of Bulgaria and Romania – Timeline NRG preparatory activities (EMEA)

In April 2006, countries were asked to nominate NRG contact point and observers to NRG who were sent listings of INs for review by 5 October 2006 (see slides 55- 58).

!! Action: S.Marino asked if EFPIA could have informal meetings with a subgroup of the NRG in addition to the annual Workshop, once or twice / year. The chairman welcomed the proposal provided that EFPIA suggests topics for discussion.

Conclusions

EMEA thanked all participants to the Workshop for their contribution. The chairman thanked the Group for its input. The action points will be recorded in the minutes. The EMEA will be happy to have sub-groups set up in cooperation with industry to continue the work as effectively as possible. All parties look forward to pursuing the excellent collaboration.