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HPCUS

Council on Pharmacy
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Please reply to: jborneman@hylands.com

May 4, 2003

To: Members of Council on Pharmacy
HPCUS Board of Directors

From: J.P.Borneman

Re: **COP Meeting May 4, 2003 REPORT**

The HPCUS Council on Pharmacy met at the Harbor Court Hotel, Baltimore, Maryland on May 4, 2003, convening immediately after the HPCUS Annual Meeting.

Attendees:

Jacky Abecassis	Clark Baker	J.P. Borneman	Eric Foxman
Sabine Hockenjos-Zogg	Marianne Heger	Peter Hinderberger	Didier Maillot
Thierry Montfort	Yvan Bourgault	Andy Bormeth	Mark Phillips
Michael Quinn	Wilfried Stock	Leandra Even	Anita Zieba
Denise Blume	Joyce Frye	Ronald Boyer	Mark Land
Todd Hoover			

Guests:
Petra Augustein-Caporale (HPCUS)
Margot Murphy-Moore (HPCUS)
Thierry Boiron (Boiron)
A. Balzer (Heel)
M. Lau x(QT 5)
L. Makowa (QT 5)
H. Wilner (QT 5)
F. Cecere (QT 5)
T. Owens (QT 5)
S. Bosse (Ropes and Grey)
D. Rosen (McDermott, Will and Emery)

1. Identification of substances that should be monographed

A list of substances that could be potentially be monographed (attached) was discussed. As Michael Quinn is the primary author of the list, he will make a first pass evaluation according to economic significance of the drugs and advise the chairman of up to 5 substances recommended for monographing. COP will evaluate this short list and make a recommendation to the Board.

2. Toxicology Guidelines for New Monographs

The following changes to General Pharmacy were approved by acclamation with no nays or abstentions:

Page 22 of General Pharmacy "Official Monograph review Procedure for the Homoeopathic Pharmacopoeia of the United States" the following language should be added as #2, with the rest of the section being appropriately re-numbered:

"Homeopathic medicines are prescribed according to the individual symptom picture, specific symptoms or keynotes and/or specific therapeutic indications. The potency used depends on the specific indication or clinical application of the homeopathic medication.

In order to guarantee the safety of new homeopathic medications (i.e. those that have not been in homeopathic clinical use for a long time) in humans, data on genotoxicity, acute and chronic toxicity, reproductive toxicity and carcinogenicity according to the current International Conference on Harmonization (ICH) -Guidelines are required for each new substance to be monographed in the HPUS. The toxic and carcinogenic potential of each substance will be assessed case by case. The type and number of studies which have to be conducted depend on the toxic and carcinogenic potential (e.g. results of standard battery for genotoxicity) of the substance and the intended application of the homeopathic medication (e.g. potency, long-term use)."

An FDA review of ICH Guidelines as well as specific ICH Guidelines for Genotoxicity and Carcinogenicity were distributed at the meeting. Committee members should familiarize themselves with these documents. They can be obtained electronically from the chairman on request.

3. Hypericum warning for mother tincture

The COP is concerned about the necessity for a warning for Hypericum perf. 3X and lower. The following warning in use in France:

"Warning: risk of interaction with other medicinal products. Combining this preparation with other medicinal products may render the other medicinal products less effective; suddenly stopping taking this preparation may increase the toxicity of the other medicinal products. Ask your doctor or pharmacist for advice".

Wilfried Stock agreed to circulate the warning and appropriate potencies used in Germany. COP will evaluate toxicity data and make a decision at its next meeting.

4. Change of OTC potency for the Nicotinum monograph from 6x to 5x

A sponsored request (see letter attached) was made of COP to change the lowest OTC potency for internal use for Nicotinum, HPUS from 6X to 5X.

A presentation of data was made in advance and live to the committee by David Rosen and Marcus Laux on behalf of the sponsor.

COP deliberated for quite a long period of time on the data presented and noted that much of the data concerned accidental ingestion of cigarette by children. Noting that there is a difference between nicotine and the complex cigarette, the group agreed to evaluate what data were available on ingestion of pure nicotine.

Data were provided by the sponsor and corroborated in Goodman and Gilman that the lethal dose for an adult is approximately 60 mg/70 kg. Using body weights of 10kg and 25kg and a dose volume of 30ml, the COP calculated the following:

Lethal Dose mg/kg	Body Weight kg	Dose reqd mg	equivalent potency (g/cc) in 30 ml	equivalent potency (x)	Safety Factor 100
0.8571	10	8.571	2.8571E-04	4X	6X
0.8571	25	21.429	7.1429E-04	4X	6X

Noting that the safety factor was 100 from a lethal dose and not from a NOAEL (No Observed Adverse Event Level) data point. After further discussion, the COP voted as follows:

Question: Should the request be granted and the OTC potency changed from 6X to 5X:

Yea: (1) Eric Foxman (Mr. Foxman disclosed that he is a consultant to the sponsor but declined recusal)

No: (15): Abecassis, Montfort, Maillot, Land. Hoover, Boyer,Frye, Quinn, Blume, Zieba, Bormeth, Heger, Bourgault, Stock, Phillips

Abstain: (5): Hinderberger, Hockenjos-Zogg, Baker, Even (Dr. Even disclosed a former relationship with the sponsor), Borneman (as chairman)

COP recommends to the Board that no change be made. Should the sponsor have other relevant data, COP welcomes receiving and evaluating it.

5. S&C Requested action on Ephedra Vulg.

S&C submits the following for the COP meeting in May 2003:

Ephedra vulgare

Allopathic 0.5% ephedrine at 2-3 gtt q 4h is OTC. This contains 0.5mg perdose. 30 ml of the MT could contain 75.0 mg of ephedrine which is well above the 0.5 mg per dose OTC above. S&C suggests OTC 3X, HPN-Tinc.

Action: Forward to COP suggestion of Ephedra OTC 3X, HPN Tinc.

COP agrees with the request and suggests this change be made.

6. Clarification of 'finish' potencies

Member Wilfried Stock has asked the COP to consider the following:

"I like to put a question and a request to put this issue concerning the "declarational" potency and the "calculatory" potency in a homeopathic complex remedy on the agenda of COP or PRC in Baltimore.
E.g. if the OTC-list of HPCUS says Belladonna 3X, is it conform, if a homeopathic complex remedy contains this ingredient as 10 g 2X in 100 g of the mixture?
In most of the European countries this is acknowledged. In case of the HPUS I don't find such a reference. Do you think HPCUS could give such an additional recommendation in the HPRS-Abstracts 2003 page 70 under OTC? For the toxicological relevant concentration would be equivalent 3X $\hat{=}$ 10 % of 2X.

In order to avoid confusion with officials I recommend to introduce such a reference especially for complex preparations in the HPRS Abstract."

COP discussed the matter and feels that General Pharmacy deals with this issue on page 68 Section 4.

7. Other Business

Eric brought to the attention of COP that a number of salts might require a change in class or alcohol strength. He will submit a list toCOP prior to the next meeting.

8. Conflict of Interest

Conflict of interest statements were collected by the chairman.

9. Database

Data bas corrections were collected and made by the chairman. Please review the updated list and suggest any corrections.

10. Next Meeting Dates:

The COP will reconvene:

By teleconference: 11/19/04 at 8:00 am PST, 11:00 am EST

Respectfully submitted,

John P. Borneman
Council on Pharmacy Chairman