Poster Presentation: International Congress on Phthiraptera, Buenos Aires,16-20 October 2006
(text for handout)

RAISING THE STANDARD OF THE LABELLING AND INSTRUCTION LEAFLETS OF TREATMENTS FOR HEAD LICE IN THE UK

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Introduction

In the UK, the National Health Service seeks to promote self-care for minor ailments such as head lice, with health providers in a supporting role. This raises an issue of rights and responsibilities.

Parents are held responsible for the detection and treatment of their children's head lice. This responsibility lasts many years because children are at constant risk of infestation, from the time they start socialising with other children, until their mid-teens. Consequently, the right of parents to be protected by the regulatory authorities from poorly-performing treatment products assumes greater importance. The delivery of successful self-care depends on the enforcement of minimum standards.

PARENT RIGHTS – to be met by Regulatory, Health and Education Authorities

- **Enforcement of minimum product standards**
- **Provision of informed choice**
- **Delivery of instruction in reliable detection of low level infestation**
- **Organisation of co-ordinated community-wide detection/treatment**

PARENT RESPONSIBILITIES

- **Acknowledgement that some unavoidable effort is required to manage head infestation successfully**
- **Routine, informed vigilance when children begin socialising**
- **Informed participation in co-ordinated community action**
- **Readiness to participate in case studies for post marketing product vigilance**

The current reality is that, across the UK, distress and anger prevail among parents whose expectations of a solution are raised by promises on product labelling and then dashed. Examples are "a single application…will kill head lice and their eggs" (e.g. 0.5% phenothrin, Full Marks® Liquid; 0.5% malathion, Derbac® M), and "for the fast effective treatment of head lice and their eggs" (1% permethrin, Lyclear® Crème Rinse). These products

were licensed between 15 and 35 years ago. They contain neuro-toxic insecticides to which a population of head lice inevitably becomes resistant with repeated use. Why manufacturers are not required to modify their claims according to the results of regular clinical evaluations is not clear, because of a lack of transparency in the standards applied by the regulatory authorities.

All formulated products used to poison or disable lice and eggs, or to attack louse cement should be subject to medicine licensing, where their potential toxicity is assessed. In the European Union, many formulated products are currently trading as combing aids in association with fine-tooth combs, which are registered medical devices. Nonetheless, the formula carries the instruction to leave on the head for a set period of time prior to beginning combing. This suggests to the user that the formula is chemically harmful to lice and/or their eggs. Some such products may be toxic to lice, and therefore the implications for humans should be considered. Moreover, these products cannot logically be defined merely as combing aids.

Evidence currently available shows that NO FORMULATION on the market KILLS LOUSE EGGS WITH CERTAINTY, whether the active ingredients are synthetic insecticides (neuro-toxic or silicone) or plant derived alternatives (which may also be neuro-toxic). In the interest of the public health and fairness to product users, this information should appear on the carton of formulated products. The instruction leaflet should routinely state that the probable duration of the egg stage is 7 to 10 days. Advice should be included explaining the need to make a thorough check for lice before medication, to prove an infestation is active, and at 5 and 12 days afterwards, to check its efficacy. Neuro-toxic preparations should carry a warning against applications, of any combination, more often than once a week for 3 consecutive weeks, the maximum dose that the regulatory authorities consider is safe.

USER-FRIENDLY PRODUCT EVALUATION

ALL STUDIES
All study entrants should not have been treated with medication for head lice in the previous two weeks

Verification of infestation by removing at least one living louse from study entrant

In field studies, outcome assessment using a proven effective detection comb and method e.g. 1998 Bug Buster comb and the Bug Busting wet combing method

Testing pediculicidal properties of formulated products
Formulated product, applied in field studies without fine-tooth combing, then assessed at 5 days post treatment
If any fine-tooth combing is part of the treatment protocol, it is not possible to assess the pediculicidal properties of formulated product on its own.

Testing ovicidal properties of formulated products
Formulated product, applied in field studies, eggs on hairs harvested and comparison of the hatching rate of treated and untreated eggs during incubation of 14 days, simulating conditions on the head

PRE-LICENSING

Appropriate human toxicity assessment

At least one **randomized controlled clinical trial** where parents follow the product instructions, outcome assessed 5 and 14 days post treatment, **to obtain a marketing licence**

POST MARKETING VIGILANCE
Post marketing vigilance based on community case studies, outcome assessed 5 and 14 days post treatment, results placed in the public domain

USER-FRIENDLY PRODUCT LABELLING AND INSTRUCTION LEAFLETS

Carton and Product Label

For all products realistic statements should appear on

- quantity supplied e.g. “Enough for one application to shoulder length hair”
- application requirement e.g. “X minutes/hours application time”
- repeat dosing required e.g. “X number of applications required to complete treatment”

Neuro-toxic products should carry a warning against applications, of any combination, more often than once a week for 3 consecutive weeks

For products containing insecticides to which lice become resistant, the date of the last clinical evaluation should be displayed with the percentage success rate.

Instruction Leaflet

For all products

- advice on making a thorough check for lice before medication, to prove an infestation is active
- an accurate statement on the incubation period of head louse eggs
- practical tips on product use e.g. preventing stains, slip hazard and any difficulties in washing off the head
- advice on making a thorough check for lice 5 and 12 days after treatment. Some lice, hatching straight after an application that does not kill eggs, can become full-grown by day 6. At day 12, lice that hatched between days 5/6 and 12, can be found.

Classification of fine-tooth combs into either *louse combs* or *nit combs* at the time of registration as medical devices

A comb that is valid as a nit comb is not suitable for louse detection and removal.
The classification should be printed on the fine-tooth comb packaging and an explanation, directing the removal of lice from a head before attempting nit removal included in the instructions (see COMBS AND COMBING FOR

EFFECTIVE DETECTION AND ERADICATION OF HEAD LICE AND NITS, poster presentation, ICP3 – abstract overleaf).

Community Hygiene Concern, a health charity established in 1988 to assist parents and professionals to overcome the problem of head lice, call for an open debate of these issues which places the regulatory framework in the public domain. In this context, we welcome the work of the 3rd International Congress on Phthiraptera towards the establishment of objective criteria for the evaluation of product trials.

Competing interests: Community Hygiene Concern is a charity, part-funded by sales of the Bug Buster® Kit on a not-for-profit basis.

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COMBS AND COMBING FOR EFFECTIVE DETECTION AND ERADICATION OF HEAD LICE AND NITS

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Use of a reliable method to diagnose head lice and to check the efficacy of any treatment is crucial to control. We define the developmental stages of head infestation as:
lice, 3 nymphal stages and full-grown louse; eggs, live or dead; nits, empty eggshells.

The weakness of traditional screening, known as visual inspection, is that lice are not readily seen. This is because, in dry hair, lice move rapidly away from disturbance. The diagnosis tends to rely on finding "nits". Empty eggshells and scalp secretions wrapped round the hair shaft ("hair muffs") can be confused with eggs. Ideally, a microscope should be used to ascertain if a "nit" is an egg, and, if so, whether it is viable or not.

The importance, firstly, of finding a louse to prove that an infestation is active, and, secondly, of community education on wet methods of detection, was highlighted by Ibarra in 1988. It was found that wet lice stay still and that ordinary hairwashing conveniently produces thoroughly wet lice. They can be revealed by passing a fine-tooth plastic comb through the wet hair. Working under the auspices of the health charity, Community Hygiene Concern, Fry perfected the method described by Ibarra. Successively, shampooed hair is prepared with a generous amount of ordinary hair conditioner, combed through with a wide-tooth comb, the entire head is fine-tooth combed, the conditioner is rinsed off and fine-tooth combing is repeated in the wet hair. This produced the full Bug Busting® wet combing method for detection. With Ibarra and Wickenden, Fry developed a pilot Bug Buster® Kit in 1995. This could be used to diagnose active infestation initially. Subsequently, it could be used systematically to eradicate an infestation in 4 sessions spaced evenly over 2 weeks. Methodical removal of hatched lice alone breaks the life-cycle. No medicated product or egg removal is required. Only empty eggshells, true nits, are left on the head. Experimentation continued to improve the accuracy of the Bug Buster comb. In 1998 these investigations led to the current model of the Bug Buster comb and the Nit Buster. The exact balance between the slim handle and the deep bevel on the edge of the teeth, facilitates gentle insertion into the hair at the roots. The Nit Buster comfortably combs out nits, with the cement sheath intact, after the conditioner used during Bug Busting has made the hair silky. Normally, nit removal is an optional cosmetic procedure performed after louse removal is complete.

Families should be routinely instructed in the most reliable detection method and reusable mechanical methods of control of proven effectiveness. If Bug Busting wet combing is identified as the gold standard detection method, the relative sensitivity of other fine-combing methods such as the Belgian variation (wetting the hair thoroughly rather than washing it) application of conditioner to dry hair, or merely combing dry hair, should be measured against it.

We hope that ICP3 delegates will be able to consider the evidence at a video/DVD show featuring the various methods.

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