Workshop 1: Studying Service and Pharmaceutical Care Delivery
Co-chairs: Cecilia Bernsten and Suzete Costa

Outcome: Draft Research Protocol

Title:
Safety and effectiveness issues of switches to non prescription. The orlistat case

Background (based on literature search)
The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended for the first time that the status for supply of a centrally authorised medicine in the European Union be switched from prescription-only to non-prescription. This will enable patients to buy the medicine over-the-counter.

The medicine concerned is orlistat, an anti-obesity medicine. The switch was part of an extension of the marketing authorisation, when the marketing authorisation holder applied for a lower dose capsule (60 mg) with a new classification as a non-prescription medicine. Orlistat (60 mg) is used in conjunction with dieting for the treatment of overweight patients who have a body mass index (BMI) of 28 or above.

[Additional information required on epidemiology of obesity (Obesity Organisations), use data and patterns of use of orlistat, OTC prescription sale data]

[literature searches on knowledge, attitude and beliefs regarding OTC medication use; misuse and abuse; sales increases on prescription meds that have gone OTC]

This specific marketing authorisation is unique and important, since it is the first product centrally authorized in EU to be switched from prescription only to non-prescription and it is a door open for future switches of complex substances in which pharmacists' intervention plays a major role.

Thus, this first switch represents a unique opportunity for community pharmacists in Europe to make best use of their expertise in medicines and demonstrate the added value in the safe and adequate provision of this particular substance – more complex than traditional non-prescription medicines.

[Need to explain complexity concept]

Research question
What are the patient safety and effectiveness issues in the case of switching complex medicines, such as orlistat, to non-prescription status?

Aim (s)
To determine what the differences are in patient safety and effectiveness of treatment with orlistat purchase in pharmacies applying a standard operating procedure (SOP) vs. pharmacies with no SOP vs. other outlets

Objectives 1, 2, 3 …..

To determine differences of safety and treatment with orlistat purchase in pharmacies applying a standard operating procedure (SOP) vs. pharmacies with no SOP vs. other outlets, with regards to:

- demographic and clinical data;
- BMI / waist circumference;
- regular preferred point of purchase for non-prescription medicines;
- reason for purchase;
- length of time of previous use of product;
- attempted other interventions for obesity;
- knowledge on product (indications, direction of use, side-effects);

To determine effectiveness and safety issues at follow-up:

- BMI / waist circumference;
- regular preferred point of purchase for non-prescription medicines;
- use of product;
- attempted other interventions for obesity;
- knowledge on product (indications, direction of use, side-effects)
- experience of side effects or adverse effects

	Our choice	Problems?	Solutions
Study design	Controlled trial	Outside interferences	Take into account when do limitations of the study
Subjects/settings	-Everyone buying olistat for own use -Pharmacy/outlets	- Getting permission from outlets to made interviews - Getting enough subjects/recruit	- Look at use/sales patterns - Determine best period (month) for data collection
Data collection methods	- Structured questionnaire interviews (baseline at point-of-purchase and follow-up telephone questionnaire)	- Follow up collaboration - Follow up might be an issue and drop out problem Patient Recall	Take into account in the analysis Follow up ASAP
Analysis of findings	Analysis by SPSS	- Missing data - Sample size	- Code the missing information - Suggestions of the results
Researchers	Research team and Students	Motivation	Training course
Time frame	- Data collection - Protocol Development and Ethics: March 2009 – August 2009 - Recruitment and Permissions: September to December 2009 - Training: Jan-Feb 2010 - Start March/April/May 2010 - Follow-up telephone questionnaire: May-June 2010 - Data Entry and Analysis: June – Aug 2010 - Report Writing: Sept – Dec 2010 - Pilot study Oct. 2009!	Timeframe based on high usage of orlistat and quick results seen with orlistat	Time frame will need to be adjusted if this is not so.
Cost	- Researchers - Training of researchers - Training of Pharmacists - Questionnaire printing - Telephone calls - Data enterers - Statistician	Too expensive	Could be a pilot on a smaller scale
Approvals needed	- Ethics - Data Protection Agency - Pharmacists - Supermarkets - Patients		

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