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Newsletter

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Dear Readers,

This is the first issue of our new report about HCPC-Europe, our activities, events and topics that relate to pharmaceutical packaging and patient compliance. Since my appointment as HCPC-Europe's executive director at the beginning of July I have taken over the responsibility to inform you about what is going on and hence the change of design. Let me take this opportunity to thank the directors of the board for their confidence and Concilius for the excellent work they have

done and I would like to add, that Concilius will continue to support our endeavours in the future.

The objective of this News-Letter is to offer you information about administrative activities (in as much as they impact the issue of patient compliance) as well as about new studies and technical developments in this field. Since its foundation, HCPC-Europe has been working hard towards its goals, in particular to collect scientific data about packaging design and its impact on patient compliance.

The task of my function as Executive Director is to continue this work with the help of Health insurance companies, of Patient Organisations and with your help, to the benefit of all those who are in need of medication.

I sincerely thank you for your contribution to achieve our common goal

Tassilo Korab

- ***Alcan presents New CR Blister Pack***

22/07/2005 - Alcan has launched the Guardlid, a new child-resistant pharmaceutical packaging solution that has been designed specifically for use in the pharmaceutical and healthcare markets.

The Guardlid, a new aluminium-based medicine packaging provides improved child resistance characteristics, assisting pharmaceutical companies in their compliance with Child Resistance legislation. New regulations within the European Union have placed new standards on packaging in which some manufacturers have had to implement a radical overhaul of their production processes. For example, the new legislation in the UK - the Medicines (Child Safety) Regulations 2003 - came into effect last October and holds that child resistant packs should be accredited according to two standards - BS

8404 and ISO 8317.

Both standards use panels of children to test for child resistance and panels of adults to test for openability. The legislation initially affects products containing paracetamol, aspirin and iron (24mg or over). The material has been fully tested and approved to comply with European child-resistant standards (EN 14375). Several major customers have already assessed and approved the structure on their lines, and their new

packs will appear on store shelves in the near future.

- ***Ohio State University investigates the Impact of Packaging Design on Patient Compliance***

Changing Medication Packages May Help Patients Follow Prescriptions, Study Suggests

16 May 2005

Distributing prescription medications in specially designed blister packages rather than in bottles may increase the likelihood that medications will be taken properly, a new study suggests.

The study found that patients taking lisinopril - a medication used to treat chronic [high blood pressure](#) - were more likely to have their prescriptions refilled on time if the medication came in a blister package rather than as loose tablets in a bottle. In this case, the blister package clearly started the day on which to take each pill.

Moreover, diastolic blood pressure was reduced in nearly half of the patients who received the drug in a blister package,

compared to fewer than 20 percent of those participants who received bottles of medication. Diastolic pressure measures the pressure of the blood between heart beats, while the heart is resting. In a typical blood pressure reading of 120/80, the diastolic pressure is 80.

“This suggests that a better system of packaging for medications helped people take their medications properly, said Philip Schneider, the study's lead author and a clinical professor of pharmacy at Ohio State University.

He presented the findings on May 16 in Washington, D.C., at the American Heart Association's Sixth Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and [Stroke](#). Schneider conducted the study with Ohio State colleague Craig Pedersen, an associate professor of pharmacy, and with John Murphy, of the University of Arizona.

The researchers referred to the blister packs that were used in this study as “pill calendars.” Like traditional pill calendars - usually a plastic box with individual compartments that can hold pills to be taken each day of the week - these blister packs included the day that each dose was to be taken.

Blister packages are cards in which individual pills are put in small plastic bubbles, and then backed with foil. A person pushes on the bubble, forcing the pill through the foil to retrieve it. The card also has more room to print important information about the proper use of the medication.

Although putting medication in blister packs isn't a new idea - many short-term medications are distributed in such packages - most long-term medications are not packaged that way. (Birth control pills are one exception.) The study included 88 adults who were 65

and older. All of the participants had hypertension, indicated by a blood pressure reading of 140/90 or higher, and were treated with lisinopril (brand name Prinivil) during the study.

More than half (48) of the participants were randomly assigned to receive a 28-day supply of medication in the blister package, while the rest of the patients (40) received a traditional bottle of loose tablets. The study lasted nearly two years, and participants were enrolled for 12 months each. During their time in the study, the patients saw their physician once every six months and their pharmacist about once each month for refills.

The researchers gathered information from pharmacy records that showed how often participants refilled their prescriptions. The researchers also collected blood pressure readings and information about the onset of diseases associated with hypertension from the patients' medical records.

Results showed that 14 percent more participants who received their medication in a blister pack with the pill calendar format had their prescriptions refilled on time. Also, the researchers noted that 48 percent of the patients in this group had lower diastolic blood pressure after 12 months, compared to only 18 percent of the patients who received their medications in a bottle.

While a few patients complained that the blister packaging was too difficult to open, no other adverse events were noted.

“If people can tell whether or not they have taken their medication on a particular day, it improves the chance that they will take the medicine properly,” Schneider said. “It's often hard to put all of the information a patient may need on to one container.” About 50 million Americans have chronic hypertension, and most that do are 65 or older. If left untreated, the disease can cause a whole host of health problems,

including changes in the blood vessels in the back of the eye, heart attacks, kidney damage and [stroke](#).

“There often aren't any symptoms that signal [high blood pressure](#),” Schneider said. “And medications like lisinopril that are given to treat the disease can have unpleasant side effects such as a dry, hacking cough, so adherence to treatment regimens is often poor.”

The findings may also have important political ramifications.

“As the federal government develops policies for the new prescription drug benefit for older adults, there is a need to consider how these medications are distributed,” Schneider said. “Although blister packs are slightly more expensive than a bottle, people often forget to take their bottled medications, or get confused on how to take them properly. Offering long-term medications in this type of packaging could ultimately save millions of dollars.”

Financial support for this work came from the Centers for Medicare and Medicaid Services. Merck & Co., Inc. provided the lisinopril, while Cardinal Health provided the blister packages used in the study.

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- ***Pharmacy in Ingelheim investigates Acceptance of Pharmaceutical Packaging upon request of HCPC-Europe Chairman Dr. Thomas Dries***

Dr. Thomas Dries succeeded in winning the cooperation of the Pfalz-Apotheke, a pharmacy of Ingelheim/Germany to do research on the acceptance of pharmaceutical packaging. He designed and compiled a questionnaire which refers to design, understandability and readability of text and reactions to compliance enhancing features. The questionnaire is currently being distributed to a large number of patients and the responses will be assessed as from Sept. 9 2005. We are currently actively engaged in finding other pharmacies in other European countries to take part in the investigation.

It goes without saying, that HCPC-Europe will inform you about the result of this project as soon as it is available.

- ***Project Blista to continue?***

Dr. Thomas Dries, Honeywell, Chairman of the Board, HCPC-Europe, Tassilo Korab, Executive Director, HCPC-Europe met with Dr. Manfred Beuttenmüller, Roche, Delegate to DIN and Colin Scaife, C& E Partnership, Chairman Working Group CEN 14375 at Burg Schwarzenstein July 28/29 2005

The purpose of the meeting was to discuss the actual status of EN 14375, the respective legal situation in the UK as well as the status of Project Blista.

EN 14375, which was adopted in Sept. 2003, overrules all national standards, including BS 8404 and DIN 55559. Whereas, for the time being, there is no change to the situation in Germany, the new standard and regulation leave many questions unanswered in the UK. British legislation refers to Type Testing as used in Germany and accepted by the authority Bundesinstitut für Arzneimittel und Medizinprodukte BfArM. They published and update a list of types of packages (reclosables and non-reclosables) accepted as being child resistant according to the requirements of the existing standards, the so called “Fortschreibelliste”. There is, however, often a great deal of uncertainty with regards to the exact specification of packaging materials

approved. Since a number of countries have voted against the present standard as it was their intention to have toxicity included, and Germany has abstained from the vote linked with the application to change the opening criteria changed (from 8 units to four*), there is concern that pharmaceutical packages will have to undergo new child panel tests.

Project Blista aims to replace child panel testing by repeatable validated mechanical tests. The necessary equipment, developed by the FRAUNHOFER INSTITUT DRESDEN and PERA with the support of a number of small and medium size enterprises and financial sponsoring of some of the leading pharmaceutical companies in the world is ready for use. However, the forces applied to the packages, the sequence of movements and the respective validation process still require several months of work. An essential part of this work will be the statistical appraisal of the outcome of child panel test versus mechanical test results. There is the possibility to get funds from the E U for the completion of Project Blista, The necessary documentation to apply for such funds would have to be put together by PERA by the end of 2006 and would cost 100,000.—GB Sterling, of which PERA would bear half.

Mechanical tests could at least diminish the number of panel tests, lead to a higher reliability of the test results (since exactly repeatable) and last but not least to better cost efficiencies. Consequently, pharmaceutical packaging could be at the same time safer and still remain consumer friendly. HCPC-Europe therefore considers to support Project Blista and will put a formal vote on the subject on the agenda of the next general assembly.

- ***HCPC-Europe General Assembly in Ulm and Laupheim/Germany October 6 and 7 hosted by Uhlmann Pac-Systeme***

The second general assembly of our organisation is due to take place in Ulm and Laupheim/Germany next month. The first Assembly which took place in Bologna last year and which was

wonderfully organised and hosted by IMA set out the goals to which we have been working. This time we will have to assess our achievements, to set new targets and to make a number of decisions. This is why this assembly is strictly reserved to members of the organisation. Some of the decisions to be taken will be:

- Election of a new Director of the Board to replace Tassilo Korab, who left the board after his appointment to become executive director.
 - Support for the Project Blista
 - Cooperation with other organisations that work to the same objectives.
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- ***Conferences on Patient Compliance***

CBI's 2nd Annual Conference on **Patient compliance, Persistency and Disease Management**

Sept. 19 and 20 2005 Radisson SAS Hotel Amsterdam, The Netherlands

Thomas Dries will speak to the topic "*Enhanced Drug Packaging – A Powerful Tool to Achieve Patient Adherence and Brand Loyalty*".

Employees of member companies of HCPC Europe will be granted a 300 USD discount. Please contact Nkechi Enere at nkechi.enere@cbinet.com and refer to Thomas Dries (HCPC Europe).

www.cbinet.com