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*Newsletter*

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Dear Readers!

Over the last few months the number of members to HCPC-Europe has significantly increased. The idea of improving patient compliance by better design of pharmaceutical packaging is gaining momentum.

And as often, when a number of people with different background get together to think about resolving a problem looking at it from different angles new ideas spark off and innovations are born.

I believe I don't exaggerate when I say that at our general assembly in Ulm and Laupheim there was more expertise in pharmaceutical packaging united in one room than you can find anywhere else in the world.

This knowledge, combined with the experience of the patient organisations and the understanding of the requirements of packaging processes in pharmaceutical environment are the solid ground on which novel packaging with regards to both design and function will be developed. The focus of our endeavours will always be on those who need medication – on the patients. Improved patient compliance will lead to better quality of life and to a better use of the funds of our health care systems - to the benefit of all of us.

Tassilo Korab  
Executive Director

- ***HCPC-Europe General Assembly in Ulm and Laupheim/Germany October 6 and 7 hosted by Uhlmann Pac-Systeme. The Minutes of the Meeting***

HCPC Europe's 2<sup>nd</sup> General Assembly was generously hosted by Uhlmann-Pac Systeme (Laupheim Germany). Siegfried Drost General Manager and Oliver Naucke (Head of Marketing) greeted the members and opened the meeting as hosts.

Thomas Dries chairman of HCPC-Europe started the first day dedicated to the review of 2004/2005. He highlighted the core of the organization's mission and goals, which focus on assisting patients in their daily life through packaging solutions improving adherence, persistence and safety in drug-therapies. He gave a brief update on HCPC Europe's achievements: The board's first goal was to inform, get feedback and backing from stakeholders outside HCPC Europe. Therefore board members met with EU-level representatives of Pharma companies and various associations including pharma and pharmacies. The good news is: HCPC Europe gained full backing and therefore plans to enhance the dialogue with pharma company representatives and other stakeholders such as patient associations, health insurances, physicians, nurses etc. As an ongoing task board members actively participated as speakers on more than 10 international conferences focussing on packaging and/or compliance related topics. As another important step HCPC Europe sponsored two Voice of the Patient (VOP) initiatives with the goal to assess patient satisfaction levels with drug packaging. The first initiative was a study focussing on elderly patients, carried out by the University of Vienna, the second was a patient questionnaire of 222 pharmacy customers, who refilled a prescription. Another milestone was the appointment of Tassilo Korab as HCPC Europe's Executive Director in July 2005. As a consequence, Mr. Korab withdrew from the Board of Directors. A successor was due to be elected at the meeting's 2<sup>nd</sup> day, which was dedicated to the organizations future course.

John Bath, Vice Chairman outlined the benefits of membership to HCPC-Europe. (See attachment). He emphasized on the facts that poor compliance impact patients lives and ultimately costs money. Acting proactively to improve compliance means acting responsibly and can at the same time create innovative business opportunities.

Dieter Laube, Treasurer, gave a report about the financial status, which was unanimously approved. The next year's budget is due to be finalized at the next board meeting, which will take place November 30<sup>th</sup>, 2005.

Tassilo Korab, Executive Director gave a membership update (membership list on web site) and outlined the ongoing activities to acquire new members amongst those stake holder groups that are not yet or insufficiently represented. He then reported about the study that Prof. Schoberberger, University of Vienna, Austria, Institute of Public Health and carried out upon request of HCPC-Europe. (see web site).

Thomas Dries presented the summary of the Voice of the Patient initiative, carried out by the (Pfalz Apotheke Ingelheim/Germany) and gave an overview of a statistical analysis of packaging solutions used in the German market.

On the assembly's second day five working groups discussed the following topics:

- Full market analysis of European drug packaging solutions focussing on compliance and CR features ( including the topic Voice of the Patient initiatives)
- Stakeholder analysis with special emphasis on patient organisations
- Quantitative analysis of benefits of patient compliance with emphasis on compliance packaging – a socio economic full cost model employing EU-based data and scenarios.
- Draft of a CR-standard for blister packaging focussing on physical testing
- Preparation of the agenda for a compliance symposium dedicated to the packaging aspects.

The objective of these work shops was to develop HCPC-Europe-Projects and to come to an agreement which of them should have priority in the organizations action plan.

The HCPC-Europe members agreed on the following ranking:

### Actions HCPC

| <u>Actions</u>  | <u>Votes</u> |
|---|--------------|
| 1. Compliance Symposium                               | 16           |
| 2. Build European Stakeholder Database                | 11           |
| 3. Study with Physicians Compliance vs. Regular Packs | 10           |
| 4. Gather / Research the Big Numbers                  | 9            |
| 5. Broaden German Compliance Study                    | 8            |
| 6. Compliance Pack Quality Label                      | 6            |
| 7. Broaden Patient Satisfaction Study (VOP)           | 5            |
| 8. Bottle vs. Blister Compliance Study                | 5            |
| 9. Facilitate Mechanical Testing Standard (CR)        | 2            |
| 10. HCPC Fund Project BLISTA (mechanical CR testing)  | 0            |

On the occasion of their next gathering the board of directors will allocate funds to projects 1 to 5 and set a time frame for their turn around.

Beyond the above defined project a number of new ideas and easy to realise projects were identified:

- Put packaging legislation updates on web site
- Put links to member companies on web site
- Create a pictorial "Packaging Compliance Leaflet"
- Create a short generic presentation about HCPC-Europe as handout for non-members
- Create a 'Membership Certificate of HCPC-Europe' to be placed in member companies' lobbies.

Dr. Willem Kort and Jos Geboers from the Netherlands presented a new model of a RFID based system to enhance and measure patient compliance.

Oliver Naucke was elected as successor of Tassilo Korab in the board via an anonymous poll, In the past years Oliver worked with strong commitment in the interest of HCPC-Europe by setting up HCPC Europe's website accepted the election.

The assembly ended with a plant tour of the Uhlmann factory in Laupheim.

- ***Electronic compliance packaging enhances drug efficacy***

According to an article by Anna Marie Mohan, Senior Editor THE PACKAGING Digest, August 2005

Abstract:

New pharmaceutical packaging for prescription-drug and clinical-trial patients uses electronics to monitor and record drug compliance, which is becoming increasingly critical as the U.S. faces nearly \$100 billion in annual healthcare costs related to noncompliance.

One of the most important elements of a prescription drug's ability to provide the anticipated therapeutic benefit is time. Increasingly, drugs are being formulated with greater specificity and for a "stepped-care" approach, whereby medications are prescribed in escalating strengths or chemical combinations, depending upon a patient's resistance to initial treatments. In this environment, the patient's compliance with the recommended dosing regimen (i.e., their ability to consistently take the prescribed dosage at the proper time) is essential for the patient's safety, as well as for maximum drug effectiveness. Within the clinical-trial setting, compliance is equally critical, as the efficacy of new drugs is reliant upon accurate data.

Unfortunately, study after study report systematic noncompliance, especially among those patients taking multiple medications. According to information compiled by Zug, Switzerland-based **AARDEX(R) Ltd.** ([www.aardex.ch](http://www.aardex.ch)), a supplier of compliance packaging for the pharmaceutical market, only one-sixth of patients execute a drug regimen with strict punctuality. At the lowest rung of the compliance ladder, approximately 17 percent of patients "take few or no doses, while maintaining the appearance of satisfactory, if not perfect, compliance."

Feedback on compliance has relied primarily on the patient's recollections, especially in clinical trials where they are asked to record their drug usage in a diary.

Other ways that compliance is documented in clinical trials is through drug reconciliation, where clinicians count the drugs left in the actual package and try to reconcile that number with the diary, and by taking blood, which, while it may indicate the amount of an active ingredient in a patient's system, will not show the regularity with which the patient has been taking the drug.

Over the last several years, as smart packaging technologies have become more accessible, a number of companies have developed new solutions that incorporate electronics to address noncompliance. In addition to providing the patient with visual or audio cues to encourage greater compliance, these packages also enable more accurate data collection for use in clinical trials, as well as by physicians to help counsel patients on improved compliance.

While the electronic packaging solutions presently on the market for compliance may differ in format—mainly bottles and blister-packs—they all incorporate three essential components: an electronic chip to gather and store information; a reader to transfer that information to a PC; and software to compile the data.

### ***The MEMS cap from AARDEX***



The company with perhaps the most experience in electronic-compliance monitoring solutions mentioned in this article, AARDEX Ltd. was formed in 1995 when the European division of U.S.-based Apex® was acquired by key staff. In 1999, the company acquired Apex, which was responsible for the company's development of electronic monitoring solutions in the 1980s.

AARDEX' electronic monitoring solution, the Medication Event Monitoring System (or MEMS(R)) bottle cap was introduced in 1987. Available in standard diameters of 38, 42 and 45 mm for use with pharmaceutical bottles with a threaded neck finish of 38/400, 42/400 and 45/400 respectively, the MEMS cap incorporates a microelectronic circuit that registers and stores data on when the closure is opened, and when it is closed.

Among the pharmaceutical companies cited by AARDEX as having used the MEMS cap are Abbott, Pfizer, Sanofi-Aventis and Bristol-Myers Squibb.

### ***BOM's Helping Hand, IDAS II***



#### **Bang & Olufsen Medicom a/s**

([www.medicom.bang-olufsen.com](http://www.medicom.bang-olufsen.com)), a wholly owned subsidiary of Bang & Olufsen a/s based in Struer, Denmark, was established in 1989 to develop compliance devices and services for use in clinical trials and as an integrated part of marketed drug concepts, relates Christian Husegaard, head of sales and marketing for BOM. Its solutions include The Helping Hand(TM) electronic blister-card and dispenser (**B**) and the IDAS II (Intelligent Drug Administration System) compliance monitor for clinical trials.

The Helping Hand, also known as the IDAS I, was launched in January 2004 and is designed to remind patients to take their medication, helping them to achieve a high level of compliance through the use of the very simple, intuitive and well-known format of a blister-card. Tablets are housed in a nonmedical, easy-to-access dispenser that uses an electronic chip and a mechanical switch to manage algorithms such as reminders, registration, feedback, resetting, power-down, shut-down, etc. The solution uses visual (LED) and acoustic reminders, and shows the patient's dose-intake pattern for the previous week, or two weeks, via a patented traffic-light color-code system.

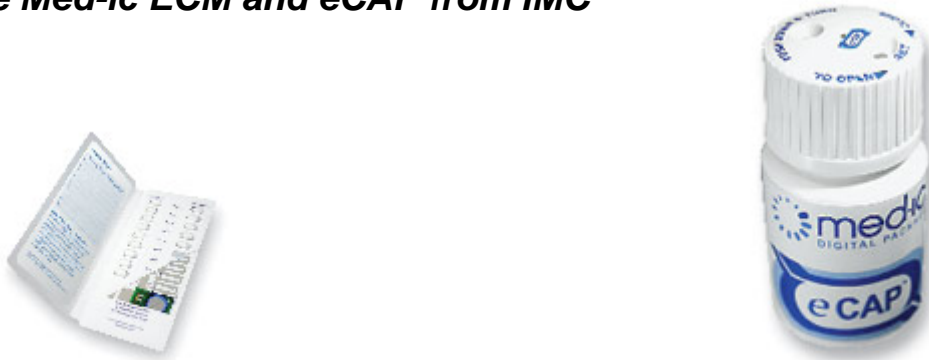
The device works with blister-strips printed with lines of conductive ink. The lines are placed over the thin foil that covers the wells containing the tablet or capsule, while the blister-strip is held in a monitor equipped with contact points for the conductive lines. A microprocessor sends an electric current through the conductive lines at regular intervals. When the patient takes a tablet/capsule from the pack, the foil and conductive line are broken. This is registered in the microprocessor as an event.

This information is stored in the monitor's memory until it is loaded onto a PC or a server via a USB cable. Uploaded data, which is compatible with AARDEX' PowerView software, is presented in a graphic format with relevant tables for use by prescribing physicians and investigators. The device is also being further developed and prepared for wireless data transfer.

Like The Helping Hand, the IDAS II also has acoustic and visual indicators to remind the patient to take their medication, while its LCD screen shows the time since last dose, actual time and a battery indicator.

BOM says that the IDAS II has also been used for the company's internal purposes, in order to obtain more knowledge about compliance and persistence for use in developing technical solutions such as The Helping Hand, for high-volume, commercial applications. Relates Husegaard, "A recent study on patients with hypertension demonstrated an average compliance of 94 percent over a four-month period using our devices.

### ***The Med-ic ECM and eCAP from IMC***



Established by Dr. Allan Wilson and business partner Michael Peterson just three years ago, Ottawa, ON-based Information Mediary Corp. ([www.informationmediary.com](http://www.informationmediary.com)) has created packaging solutions that use custom-designed Class 3 EPC (electronic product code) RFID (radio-frequency identification) tags, RFID readers and printed electronics to monitor patient compliance. Its flagship products are the Med-ic(R) ECM (electronic compliance monitor) device (C), which couples electronics with a standard blister-pack, and the eCAP(TM) (D), which IMC says is "the world's first and only RFID smart cap."

"RFID is a hot topic in pharmaceuticals and logistics," explains Peterson. "Although Med-ic merely utilizes RFID to transfer data and keep track of packages, it is an excellent way to combine both compliance monitoring and track-and-trace applications into one simple solution."

Med-ic was first previewed in March 2002 at the Interphex tradeshow. At the following year's event, IMC made a commercial announcement on the product, and since then, Peterson tells PD, various parties have been conducting validations, tests and trials for the future integration of Med-ic into their projects.

The Med-ic ECM device works much like BOM's IDAS II. The blister-pack uses proprietary patterns of conductive ink attached to an RFID tag to monitor and store information on the removal of a tablet or capsule from the pack. Unlike the BOM system, however, Med-ic uses a standard, wallet-style paperboard blister-card with the smart label applied to the pack, and is engineered for large-scale, industrial production.

Med-ic ECM package technology consists of a generic tag and a printed smart label that is custom-designed for each package configuration. As of July 2004, IMC has brought all packaging design and production activities in-house, where it manufactures the self-adhesive smart labels for application by the pharmaceutical customer to their blister-pack.

A special download protocol speeds data transmission from the ECM-equipped device to the desktop, allowing, for example, 40 events from a Med-ic blister-pack to be downloaded in less than one-tenth of a second. Proprietary GUI (Graphical User Interface) software provides the user with an intuitive display and an overview of the patient's compliance history.

Introduced in the spring of 2004, IMC's eCAP bottle cap records each opening of a standard, 33-mm, child-resistant (CR) pharmacy vial or a 38-mm medication bottle and includes a programmable reminder feature. Compatible with the same reader and software solution used with Med-ic ECM, the eCAP consists of an RFID tag embedded into a RemindCap(R) bottle cap from **Remind Cap Ltd.** ([www.remindcap.com](http://www.remindcap.com)), with the cap, plastic liners and bottles supplied by **Owens-Illinois Prescription Products** ([www.us.o-i.com](http://www.us.o-i.com)).

The eCAP is currently being used in commercial applications by the University of Texas SW and by Weill Medical College at Cornell University. According to Peterson, the Med-ic ECM blister-pack is being tested by several university study groups and has been included in the protocol of various clinical studies. In addition, IMC has also signed a partnership agreement with contract research organization ABR Pharma of France. Together, Peterson says, the companies plan to make an announcement in the near future regarding a "sizable, three-year study, representing one of the first large-scale commercial rollouts of Med-ic electronic-adherence blisters—indeed the largest electronic-adherence-monitored study ever conducted."

### ***MeadWestvaco's Cerepak***

Brought to market in the spring of 2004 for clinical-trial applications, the Cerepak(TM) (E) smart blister-pack from MeadWestvaco Healthcare Packaging uses technology similar to competitive electronic blister-packs, but goes a step further, incorporating the ability to capture patient QOL (quality of life) information via a reusable, electronic questionnaire. "That's very unusual," says Thomas Grinnan, VP Business Development for MeadWestvaco. "Typically, you can only gather that information during a doctor's visit. To be able to capture that data in real-time is very attractive to the clinical industry."



MeadWestvaco's Cerepak is the result of an agreement with Swedish technology development company **Cypak AB** ([www.cypak.com](http://www.cypak.com)), which engineered the concept of Intelligent Pharmaceutical Packaging (IPP), combined with MeadWestvaco's standard pharmaceutical heat-seal blister-cards, such as its CR Dosepak(R) compliance packaging. MeadWestvaco

forged a licensing agreement with Cypak in early 2004 that gives the company exclusive rights to produce and market IPP technology in the Americas, as well as a nonexclusive right in the rest of the world.

The Cerepak solution includes four components: the data capture device, or the package; the reader; the software; and the analytical tools to create reports. Of these, Cypak's technology resides in the electronic module, or chip, that is embedded in the blister-pack, the way in which conductive inks are used in the package, and the interface that enables information to be uploaded from the package to a PC.

The Cerepak blister-pack containing the heat-seal card is printed with a conductive trace, or ink pattern, and the electronic chip is adhered to the card.

The Cerepak's electronic chip provides firmware and memory to store the data collected from its 32 inputs, where lines of ink are connected to the chip. Each input represents one blister cavity—or a place where a pill or a dose resides—or one answer in the package's QOL questionnaire. The chip also has a speaker and can be designed to activate an LED light to provide patient reminders.

As with other electronic compliance systems, Cerepak uses a mousepad-like reader that connects to a Windows-based PC via a USB port. The contactless reader, made in Europe under contract by Cypak, uploads information to AARDEX' PanelView software or to its password-protected website, the former of which Grinnan says is preferred for clinical trial work, and the latter, for academic purposes.

And lastly, the Cerepak solution provides the customer with analytical tools in the form of a complete analysis of the compiled data by AARDEX. "Many times with this technology, it's the data that is important, not the package," says Grinnan. "If the data is not used effectively, the industry will not adopt the technology, no matter how sexy or interesting it might be. The data needs to be compelling. It needs to help make trials less-expensive and more effective and to make drug development much more medically sound."

Although MeadWestvaco is under nondisclosure agreements with all of its Cerepak customers, Grinnan confirms that trials of the package have occurred in both the U.S. and Europe. "The package provides a tremendous amount of data that simply was not available before," he remarks. "There's been a lot more interest in reducing liability with the package than we originally foresaw. I think pharmaceutical companies see it as a way of being smarter in the way they are designing drugs."

Though it has been marketed first and foremost for the clinical-trial industry, the Cerepak blister-pack can also be used as an effective tool for some commercial applications, as well. These include chronic disease states and health conditions with asymptomatic indications, like high blood pressure or diabetes. Grinnan says that the Cerepak should be in commercial application by mid-2006.

**Read the full article at:**

<http://www.packagingdigest.com/articles/200508/26.php>

**or find more information at:**

- **AARDEX® Ltd.**, 41 41 768 01 01. [www.aardex.ch](http://www.aardex.ch)
- **Bang & Olufsen Medicom a/s**, 45 96 84 58 00. [www.medicom.bang-olufsen.com](http://www.medicom.bang-olufsen.com)
- **Cypak AB**, 46 8 545 008 35. [www.cypak.com](http://www.cypak.com)
- **Indtec S.A.**, 41 27 329 08 34.
- **Information Mediary Corp.**, 613/745-8400. [www.informationmediary.com](http://www.informationmediary.com)
- **Intelligent Devices, Inc.**, 613/745-8400. [www.ecmdevices.com](http://www.ecmdevices.com)
- **MeadWestvaco Healthcare Packaging**, 800/864-2685.  
[www.meadwestvaco.com/healthcare.nsf](http://www.meadwestvaco.com/healthcare.nsf)
- **Owens-Illinois Prescription Products, Inc.**, 800/321-3391. [www.us.o-i.com](http://www.us.o-i.com)
- **Remind Cap Ltd.**, 419/247-8529. [www.remindcap.com](http://www.remindcap.com)
- **XINK Laboratories Ltd.**, 613/745-8400. [www.xink.biz](http://www.xink.biz)

- *Conferences about Patient Compliances*



- Quick Links -

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**November 14 to 15, 2005 • Crowne Plaza Philadelphia Hotel - Philadelphia, PA**

### Conference Overview

The issue of Patient Compliance is of utmost importance to the pharmaceutical industry as non- and partially-compliant patients account for billions of dollars of unrealized revenue and over 125,000 deaths each year. The revenue lost from this problem has been approximated at \$30 billion annually, and the total societal loss is estimated at \$100 billion a year – from hospitalization, complications, disease progression, premature disability and death.

URL <http://www.srinstitute.com/CS349>

**2nd Annual**  
**Patient Compliance, Adherence and**  
**Education Conference, USA**  
**29-30 November, 2005**  
**The Rittenhouse Hotel, Philadelphia, USA**

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