FOR IMMEDIATE RELEASE
February 20, 2015
Richmond, Virginia 23235

Contact: Vicki Welch
TEL: 804-338-5778
E-MAIL: vickiwelch@hcpconline.com

HCPC Study Reveals Tablets May Have a Higher Risk of Physical Degradation During Normal Use When Packed in Conventional Pharmaceutical Packaging vs High Barrier Unit Dose Blisters

Richmond, VA – The Healthcare Compliance Packaging Council has released the results of its study investigating the potential degradation of three widely prescribed chronic condition prescription drugs during normal patient use when packaged in conventional pharmacy formats. The study results reveal the effect daily exposure to oxygen and moisture can have on non-coated Simvastatin, Lisinopril and Metformin tablets during in home use of multi-dose containers or through permeation of low barrier blister film typically used in Long Term Care settings. The results of the HCPC study support the longstanding theory that undue moisture and oxygen exposure increases the risk of physical degradation during normal use. More specifically, polypropylene vials, HDPE bottles or PVC blisters found in retail and institutional settings may increase the risk of higher physical degradation than high barrier packages such as PVC/Aclar® or PVC/PVdC blisters. The HCPC study also revealed that higher temperature conditions affected the physical properties of products studied, regardless of packaging format, calling into question the practice of mail-order delivery for some prescriptions.

The study was designed to compare how the length of a prescription and the associated increased environmental exposure, could impact the degradation of these chronic condition drugs. To accomplish this, all vials, bottles and blisters were tested using 30, 60, and 90 day fills. The study

focused on the physical degradation that occurs during the prescribed in-use period by assessing changes to the drug in moisture gain, tablet hardness, and disintegration time. It was found that degradation increased when the tablets were tested in higher humidity (25°C/90%RH), simulating bathroom conditions, versus those tested in 25°C/75%RH. In addition, when subjected to higher temperature conditions (40°C/75%RH) temperature sensitivity was observed in all drugs calling into question the practice of mail order prescription delivery especially during the summer months when some prescriptions can sit in hot trucks or mailboxes for hours or days. The degradation observed under these various conditions indicate that Simvastatin, Lisinopril and Metformin when dispensed in polypropylene amber vials, HDPE bottles or PVC blisters undergo physical changes through daily exposure to typical home environments. Whether these changes affect these drugs' specific efficacy or their absorption rates needs further investigation.

Walt Berghahn, HCPC Executive Director, states, "The unique outcomes seen with these three products indicates how little we know about the impact of patient at-home storage conditions on the quality of the $320 billion of drugs we dispense today. Regardless of the drug form, all medicines need to be protected through distribution and pharmacy until used by the patient. We welcome further research on in-use stability by other organizations concerned with patient safety, not only for the three drugs we studied, but for the thousands of pharmaceuticals used and trusted by patients. We feel additional research should be conducted to determine whether current packaging formats are effectively protecting the wide variety of drug products on the market, each with unique environmental sensitivities, as they relate to moisture and oxygen ingress and exposure during "in-use" conditions. Packages need to protect drug products during their entire life cycle. As shown in this study, unit dose packages using high barrier materials can accomplish that goal, if the temperature profile is

maintained. Once we move closer to protecting these products appropriately, we ensure that patients will receive effective products to treat their conditions.

The HCPC notes that the results of this study are not intended to challenge pharmaceutical manufacturers' stability criteria for primary bulk packages that are not intended to reach the patient, nor state that the products failed in anyway, but the HCPC data does indicate that current prescription packaging does not protect the physical characteristics of these three products during normal use. Through this study the HCPC wants to bring awareness to potential impact on drug products' efficacy due to the packaging format along with the environment in which they are kept. The study leads to the initial conclusion that U.S. patients taking their medications from non-barrier packaging may not get the designed clinical benefit of the drug due to potential product compromise as a result of daily exposure to the home environment. The HCPC believes the next step would be to broaden the scope of this study and include chemical assay tests on drugs exposed to these or similar study conditions in order to determine the potential impact on efficacy. Copies of the HCPC Prescription Packaging-In-Use Stability Study can be downloaded by visiting www.hcpconline.org.

About the HCPC

*Since 1990, the **Healthcare Compliance Packaging Council** offers its members a "voice" in pharmaceutical packaging issues and the opportunity to help promote the many benefits of patient compliance packaging. From suppliers of pharmaceutical packaging components, to machinery manufacturers, to contract packagers, to industry consultants and experts, our members share the mission of promoting broader adoption of compliance-prompting packaging to improve patient outcomes. HCPC has hosted an annual conference on improving patient adherence for over 20 years,*

RxAdherence, this year taking place in Florham Park, NJ on March 31st (see www.rxadherenceconference.com) and also sponsors the HCPC Compliance Package of the Year competition that recognizes innovative patient adherence packaging designs.

# # #

2711 Buford Road, #268 | Bon Air, VA 23235-2423 | 804-338-5778 | FAX: 888-812-HCPC (4272)