July 2, 2010 — A watch list of 13 drugs based on potential signs of serious risks or new safety information collected by the Adverse Event Reporting System (AERS) of the US Food and Drug Administration (FDA) during the first quarter of 2010 has been released.

The FDA is studying all of the drugs to determine the need for any regulatory action.

A drug's appearance on the watch list does not mean the agency has determined that the drug poses the health risk in question. Physicians should not stop prescribing the drug, and patients should not stop taking it, according to the FDA.

The FDA is evaluating 2 antibiotics — azithromycin (Zithromax; Pfizer) and clarithromycin (Biaxin; Abbott) — to find out whether they are associated with liver failure. Suspicions about azithromycin and liver failure are not new. The label for the antibiotic states that adverse events discovered after the drug entered the marketplace — and for which a causal relationship may not be established — include "abnormal liver function including hepatitis and cholestatic jaundice, as well as rare cases of hepatic necrosis and hepatic failure, some of which have resulted in death." During clinical trials, cholestatic jaundice was a rarely reported adverse effect.

Three other medications on the watch list are in the cardiovascular camp. The anticoagulant prasugrel (Effient; Eli Lilly), is being watched on account of thrombotic thrombocytopenic purpura — a rare and life-threatening disorder. Another drug, dronedarone (Multaq; Sanofi-Aventis), as come under surveillance because of reports of congestive heart failure. The third cardiovascular drug on the watch list is ranolazine (Ranexa; Gilead), prescribed for patients with angina. Here, the FDA is investigating reports of torsades de pointes — a ventricular tachycardia that can lead to sudden death. Two medications prescribed for narcolepsy — modafinil (Provigil; Cephalon) and sodium oxybacte (Xyrem; Jazz Pharmaceuticals) — are under study for a possible association with convulsions. Perhaps the most well-known product on the watch list is the blend of estrogens marketed as Premarin (Wyeth), used to treat symptoms of menopause. It landed on the list based on reports of angioedema.
Vitamins B6, B12 May Protect Against Depression in Older Adults

High total intakes of vitamins B6 and B12 are associated with a lower risk for depressive symptoms over time in community-residing older adults, according to the results of a cohort study reported online June 2 in the American Journal of Clinical Nutrition. After adjustment for age, sex, race, education, income, and use of antidepressant medications, higher total vitamin intakes including supplements were associated with a lower risk for incident depression during follow-up for up to 12 years. Odds of depressive symptoms were 2% lower per year for each additional 10 mg of vitamin B6 and an additional 10 µg of vitamin B12. Further adjustment for smoking, alcohol intake, widowhood, caregiver status, cognitive function, physical disability, and medical conditions did not abolish these associations. Food intakes of these vitamins or folate were not associated with depressive symptoms.

Source:
Am J Clin Nutr. Published online June 2, 2010.
The US Food and Drug Administration (FDA) has approved the first rapid blood test for antibodies to the hepatitis C virus (Or Quick HCV Rapid Antibody Test; OraSure Technologies, Inc) in patients aged 15 years and older who are at risk for HCV or have signs/symptoms of hepatitis.

According to information on the company website, the portable device uses a test strip that detects all HCV genotypes in about 20 to 40 minutes from samples of oral fluid, fingerstick/venipuncture whole blood, or collected serum/plasma. Test accuracy is greater than 99% with whole blood and serum/plasma samples but is somewhat less accurate with oral samples.

Once the sample is collected, the device is inserted into the buffer, and results are read on the device face as nonreactive (1 line) or reactive (2 lines). Mixing with the buffer solution is required for all samples not obtained orally.

"The OraQuick HCV test efficiently identifies previously undiagnosed HCV infected individuals who are at risk," said Eugene R. Schiff, MD, from the University of Miami School of Medicine, Florida, in a company news release. "We at the University of Miami found this test to be user-friendly, practical and an important tool for rapid HCV antibody detection."

HCV is transmitted via exposure to infected blood and also from mother to child. Although most individuals have few symptoms after initial infection, the virus persists in the liver to of cases. Chronic HCV affects about 3.2 mil-

Lion Americans, causing 12,000 deaths annually, and is a leading cause of liver transplants in the United States.

"Approval of Or Quick means that more patients can be notified of their HCV infection faster so that they can consult with their physicians for appropriate health measures," said Jeffrey Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, in an agency news release. "Getting faster treatment is an important public health step to control this dangerous disease."

The FDA notes that the point-of-care test is not approved for HCV screening purposes in the general population.

The rapid HCV antibody test previously was granted the CE mark by the European Commission, allowing its use in the European Union.

Source:-
1-Medscape.
Only half of the women with early-stage breast cancer who were prescribed tamoxifen and/or aromatase inhibitors completed the full course of treatment, putting themselves at increased risk for breast cancer recurrence.

One reason for the high rate of discontinuation might be toxicity, the researchers suggest. They cite a study of 622 postmenopausal women, which found a 30% discontinuation rate for aromatase inhibitors, in which 84% of those who discontinued said they did so because of adverse effects.

A recent British study found noncompliance with imatinib (Gleevec) in the treatment of chronic myeloid leukemia in 25% of patients, putting those patients at risk for poorer outcomes. Those researchers expressed surprise at this rate of no adherence among cancer patients, although it is similar to that seen with other chronic diseases. "You would think that cancer patients would be more motivated to keep taking their drug, so the finding is rather counterintuitive," said Nick Barber, PhD, professor of practice and policy at the School of Pharmacy, London.

Dr. Hershman and colleagues echo this sentiment, and say it is surprising that non-adherence appears to be almost as significant a problem in oncology, with potentially life-saving medications, as it is in other diseases.

Source;
1-J Clin Oncol. Published online July 28, 2010.