Transatlantic Drug Information Sharing to Increase

BY JONATHAN GARDNER

U.S. and European drug regulators have announced "intensified" information sharing and dialogue aimed at increasing cooperation in drug approval and surveillance activities in the world's two largest pharmaceutical markets. At a March review meeting in Brussels, representatives from the Food and Drug Administration, the European Medicines Agency, and the European Commission judged as a success the implementation of a confidentiality agreement that has enabled greater transatlantic information sharing and dialogue on pharmaceutical regulations protecting 753 million people in 26 countries.

The three agencies hope to strengthen joint activities on vaccines in preparation for potential pandemic flu outbreaks, as well as cancer, children's, and orphan drugs, and pharmacogenomics. Future activities will address counterfeit medicines.

The original agreement, signed in September 2003, paved the way for quarterly exchanges on information on new drug applications, regulatory guidance, and inspections of manufacturing plants that began in 2004. The agreement also authorized ad hoc exchanges of information on drug safety and public health, including advance notice of significant regulatory actions such as pulling drugs from the market. Such an exchange prevents other agencies from issuing contradictory advice when one agency takes significant regulatory action.

The ad hoc exchanges also have enabled "parallel" scientific guidance for drug applicants seeking the advice of the three agencies on how to proceed with research at such milestones as the conclusion of clinical trials. The first such parallel scientific meeting occurred in September 2003, and as part of the initial confidentiality arrangement a 1-year pilot project was initiated in 2005.

Use Unlisted Code 64999 for Pulsed Radiofrequency

SAN DIEGO — Reimbursement for pulsed radiofrequency, an experimental treatment for some types of chronic pain, now requires the use of unlisted procedure code 64999, as designated by the American Medical Association's Current Procedural Terminology (CPT).

"When seeking reimbursement for pulsed radiofrequency, it is incorrect to use codes for radiofrequency ablation, including 64626 and 64627, which are neurolytic codes," Dr. Eduardo M. Fraifeld, chairman of the Coding and Reimbursement Committee of the American Academy of Pain Medicine (AAPM), explained at the annual meeting of the AAPM.

In another pain-therapy CPT code overhaul, the AAPM's Coding and Reimbursement Committee eliminated the "Sevoflurane With or Without Analgesia (Conscious Sedation)" category (99141-42) and replaced it with "Moderate (Conscious) Sedation." The new category has three codes for drug administration by the same physician performing the diagnostic or therapeutic service (99143-45) and three codes requiring an additional independent observer to monitor the patient (99148-50). These two categories are then broken down into three subcategories, which include under age 5 first 30 minutes intraservice time, age 5 and older first 30 minutes intraservice time, and an add-on code for each additional 15 minutes intraservice time, Dr. Fraifeld said.

Other deletions this year include eight evaluation and management codes for "Follow-up Inpatient Consultations" (99261-3) and "Confirmatory Consultations" (99271-5).