

# FDA, European Drug Agencies Extend Cooperation

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U.S. and European drug regulators have announced “intensified” information sharing and dialogue aimed at increasing cooperation in drug approval and surveillance 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 ac-

tivities will address counterfeit medicines.

The original agreement, signed in September 2003, paved the way for quarterly information exchanges on new drug applications, regulatory guidance, and inspections of manufacturing plants, which 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 is-

suating 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. As part of the initial confidentiality arrangement a 1-year pilot project was initiated in 2005. The three agencies agreed to extend the pilot project, although the document released by the agencies did not say how long it would be extended. ■

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<p><b>THE ECS IMPACTS THE METABOLISM OF LIPIDS AND GLUCOSE<sup>1-3</sup></b></p>	<ul style="list-style-type: none"> <li>ECS overactivity may be associated with the development of cardiometabolic risk factors including:                             <ul style="list-style-type: none"> <li>— Low HDL cholesterol</li> <li>— High triglycerides</li> <li>— High waist circumference</li> <li>— Elevated fasting glucose</li> <li>— Insulin resistance</li> </ul> </li> </ul>
<p><b>THE ECS HELPS REGULATE PHYSIOLOGIC PROCESSES<sup>1-4</sup></b></p>	<ul style="list-style-type: none"> <li>The ECS consists of signaling molecules and their receptors, including the cannabinoid receptor CB<sub>1</sub><sup>2</sup></li> <li>Endocannabinoids bind to CB<sub>1</sub> receptors and trigger events that may have a negative impact on lipid levels and insulin sensitivity<sup>1</sup></li> <li>CB<sub>1</sub> receptors are located in sites such as muscle, the liver, the brain, and adipose tissue<sup>1,2,4-6</sup></li> </ul>
<p><b>RESEARCH CONTINUES TO INVESTIGATE THE ROLE OF CB<sub>1</sub> RECEPTORS IN MUSCLE*</b></p>	<ul style="list-style-type: none"> <li>Reduced glucose uptake has been observed in isolated skeletal muscle of genetically obese, insulin-resistant animals</li> </ul>
<p><b>ENDOCANNABINOIDS TARGET FATTY ACID PRODUCTION IN THE LIVER<sup>3</sup></b></p>	<ul style="list-style-type: none"> <li>May contribute to dyslipidemia and insulin resistance<sup>3,7</sup></li> </ul>
<p><b>PRESENT IN MULTIPLE AREAS OF THE BRAIN<sup>2</sup></b></p>	<ul style="list-style-type: none"> <li>Hypothalamus integrates signals from adipose tissue and other peripheral tissues<sup>8,9</sup></li> </ul>
<p><b>ADIPOSE TISSUE—MORE THAN SIMPLY A FAT STORAGE DEPOT</b></p>	<ul style="list-style-type: none"> <li>Produces factors active in the metabolism of lipids and glucose<sup>10</sup></li> <li>Low levels of adiponectin negatively affect glucose and free fatty acids<sup>1,10</sup></li> </ul>
<p><b>EXPLORING THE EFFECTS OF THE ECS</b></p>	<ul style="list-style-type: none"> <li>This newly discovered physiologic system provides new opportunities for understanding cardiometabolic risk</li> </ul>

\*Data from animal model only.

**References**

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