CPC COMBINATION PRODUCT COALITION

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VIA E-MAIL (ENTR-MD-RECAST@ec.europa.eu)

European Commission
Unit ENTR F/3, Cosmetics and Medical Devices
BREY 10/176
B-1049 Brussels
Belgium

Re: Recast of the Medical Devices Directives, 6. Borderline Cases, Item 15

Dear Sir or Madam:

The Combination Products Coalition ("CPC") commends the European Commission ("EC") for seeking public comments on the potential recast of the Medical Devices Directives ("MDD"). We are pleased that the Public Consultation also solicits comments on a potential process for addressing jurisdictional issues involving combination products and borderline cases. In this letter, the CPC offers comments on that portion of the Public Consultation – 6. Borderline Cases, Item 15.

By way of background, the CPC is a group of leading drug, biological product, and medical device companies with substantial experience and interest in the combination products area. Our membership is diverse – our members vary widely in terms of size, experience, and types of product portfolios. Because of our diverse, cross-industry membership, we believe the CPC brings a broad and unique perspective to issues affecting combination products. With that in mind, the CPC offers the following comments on Item 15 of the Public Consultation.

As an initial matter, we believe that two critical and sometimes opposing considerations impact the development of a jurisdictional decision-making process for combination products and borderline cases. One consideration is the need for certainty in regulatory decision-making, which companies and investors feel most acutely. The second consideration is the rapidly-changing and innovative nature of the medical product and medical device industries. Below we elaborate on these considerations and how they impact

an early decision-making process for products comprised of medicinal products and medical devices.

With respect to the first consideration, as the Public Consultation recognizes, medical device and other medical product innovators require certainty early in the development process. The regulatory pathways for medicinal products and medical devices are quite different and, consequently, differ substantially in the timing and the financial resources they require. Because of these differences, investors and companies must know early in the development process whether a given product is a medicinal product, medical device, or a combination of the two, in order to develop an appropriate business plan. In the absence of such certainty, the flow of capital into these sectors will be inhibited, and business growth will be stunted due to inadequate capital resources. Business projects may also be hindered or even fail if businesses cannot adequately predict the capital resources needed to complete a project.

Just as important, any written, static guidance on combination products or borderline cases is inherently limited in anticipating the ever-changing innovations in the medical product industry. For example, over time, the U.S. Food & Drug Administration ("FDA") has learned that the basic FDA internal agreements and other written guidance documents were inherently limited and unable to keep pace with technology. Ultimately, the FDA needed to adopt a process (the Request for Jurisdiction, or RFD, process) for resolving the ambiguous cases.[1] As another example, advances in nanotechnology and human tissue engineered products are likely to progress rapidly in the near term, and a written guidance document would be unlikely to anticipate all possible scenarios and products. Indeed, we believe that the MedDev 2.1/3 guidance is already out of date in many important respects.

In light of these considerations, the CPC agrees that there should be a process available by which companies may resolve the jurisdictional issues impacting their combination and borderline products. We also believe that such a process can be developed and implemented within the existing regulatory framework and Directives. That said, given the complexity of the European system and the EC's stated intention to reconsider the fundamental design of its medical device regulatory scheme, at this time we are unable to recommend a specific process. Rather, we would like to offer the following key criteria that any decision-making process should adopt:

- Composition. As the Public Consultation alludes, the composition of the group that decides the jurisdiction of a product should be jointly comprised of medicinal product and medical device experts. This composition will help balance and avoid bias with respect to jurisdictional evaluations and outcomes, as it's quite human to favor the regulatory scheme and products with which one is most familiar and comfortable. Therefore, to achieve the optimal regulatory pathway from the viewpoint of the patient, those engaged in the decision-making must have a balanced perspective.

[1] *See* 21 U.S.C. § 353(g); 21 C.F.R. Part 3; *see also* FDA, OCP website, at http://www.fda.gov/oc/combination/assignment.html (last accessed June 24, 2008).

- Transparency. For the process to work efficiently in the long term, companies and other members of the public must be able to see the results of the process at a level of detail that allows them to understand the reasoning of the decision-maker. This transparency will enable future companies to make more informed decisions about likely regulatory pathways for their products even before submitting a request. Ultimately, a high level of transparency will lead to efficiency, because over time companies may bypass the process if they can understand and apply prior decisions. One example of the type of transparency we describe is that employed by the FDA's Office of Combination Products ("OCP"), which makes significant use of its website to publish prior jurisdictional decisions with as much detail as possible.[2] Transparency also leads to a reassurance of fairness, in that companies can understand that their competitors are treated similarly.

- Reliability. Because these decisions will determine and influence important regulatory and business decisions, companies must be able to rely on the process outcomes. Thus, the decisions need to be binding on the regulators.

- Timeliness. Medical innovation moves quickly, and companies need to work efficiently. This process must therefore produce a decision within a predictable and reasonably short amount of time.

- Optional. As discussed above under transparency, as companies observe and understand the outcomes of the process, a decision on the jurisdiction of their products ultimately may not be necessary. Thus, this process needs to be optional, permitting companies to pursue marketing authorization directly, without first seeking a jurisdictional decision if they feel the jurisdictional issues are clear enough.

- Plurality. Companies doing business in the European Union understand the need for plurality among the many nations that are part of the EU. That plurality offers certain advantages (for example, flexibility), that centralization does not. In this respect, we believe that requiring a centralized decision point for jurisdictional decisions could lead to bureaucracy and delay, both of which would disadvantage patients. Further, and as mentioned above, we also believe that the jurisdictional process can be implemented within existing legal and regulatory frameworks, which have worked well to protect the patient while ensuring proper access to new technologies. For these reasons, we would not support creating a Committee on Medical Devices in the EMEA and charging it with the responsibility, in whole or in part, for making jurisdictional decisions with respect to combination products or borderline cases.

[2] *See* FDA, OCP website, at http://www.fda.gov/oc/combination/updates.html and http://www.fda.gov/oc/combination/determinations.html (last accessed June 24, 2008).

We hope that these comments are helpful as the EC begins to make important decisions about the recasting of the MDD. Please feel free to contact us with any questions or comments. You may reach me at (317) 514-5008 or via e-mail at bthompson@ebglaw.com.

Respectfully submitted,

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On behalf of the Combination Products Coalition