Health Enterprises

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May 3, 2013

Mr. David Weiner, Deputy Assistant U.S. Trade Representative for Europe
Office of the United States Trade Representative for Europe
600 17th Street, N.W.,
Washington, DC 20508

Comments in Response to Request for Public Comment:
"Transatlantic Trade & Investment Partnership"

Docket Number: USTR-2013-0019

Dear Mr. David Weiner,

Find below a specific example for regulatory cohesion in the TTIP which will benefit both U.S. and E.U. companies.

Our company, Health Enterprises, is a SME currently selling our ranges of consumer health products in the E.U. In general, our products are considered to be "Class I Medical Devices (non sterile, non measuring)" – the safest category for Medical Devices (for example, a low cost "Finger Splint" – the kind that you would buy in the 1st Aid aisle of a CVS Pharmacy for a few dollars) – and they are registered with the FDA (in their Medical Device database @ www.fda.gov) under our "Owner Operator Number: 9022512", for your reference.

U.S. and E.U. regulators have a similar degree of consumer safety (the purpose of regulating Medical Devices is "safety") in mind when regulating Medical Devices, and the philosophy should be "if a Medical Device is legally sold in the U.S., then it should also be legally sold in the E.U." (and vice versa). Let us start with "Class I Medical Devices (non sterile, non measuring)" – the safest category for Medical Devices – as a "test case" to get this process started.

Background information:

1) Regulatory agencies involved are the FDA in the U.S., and various Ministries of Health in the E.U. Note that the way it is supposed to work is that if you have a medical device legally registered with a Ministry of Health in an E.U. member country, then the medical device is legally sold throughout the E.U. However, in practice different E.U. member countries often require re-registration.

2) Pertinent directives are the FDA Medical Device Directives here in the U.S., and European Medical Devices Directive 93/42/EEC.

3) For "Class I Medical Devices (non sterile, non measuring)", the laws are similar and require that companies pay a nominal fee and self-register the product in a central database (FDA Medical Device database here in the U.S., and the database for the Ministry of Health in a given E.U. member state). So, as a U.S. company we register our products with the FDA. To sell in the E.U., we also need to register our products with a Ministry of Health (possibly more than one!) for an E.U. member state. To do this, we need to first appoint a "European Authorized Representative" or EAR (a legal corporate entity with a physical office in the E.U.). This can take a number of forms, but in our case we contracted the work of an EAR to whom we pay a few

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thousand dollars per year + hourly fees (which is at the low end of the price spectrum for these services). We then have to pay our EAR an hourly fee to register our products with the Ministry of Health, and pay the Ministry of Health a fee per item and annual fee to maintain the database.

4) "Class I Medical Devices (non sterile, non measuring)" are considered generally safe. Allow companies in the U.S. and E.U. to register their products with the Ministry of Health for their home country. These are public databases that anyone can access to track a product and confirm that it is registered – the purpose of these databases is traceability; knowing which products are on the market and which companies produce them, so that in the event of a problem with a product, the manufacturer can be easily found and contacted. Instead of requiring double registration (both in the U.S. and the E.U.) where the costs involved add no value to a manufacturer, require that companies maintain sufficient product liability coverage (perhaps US$2,000,000) to cover any product issues. Again, we are talking about simple products, like a low cost "Finger Splint" – the kind that you would buy in the 1st Aid aisle of a CVS Pharmacy for a few dollars.

5) Medical Device directives in the U.S. and E.U. need to be harmonized, and currently have many issues, aside from double registration, and including different standards used in certifying products. Best is to start with "Class I Medical Devices (non sterile, non measuring)", as they are simple products which are self-registered as a "test case" of how regulatory cohesion can begin, then move on to more sophisticated Medical Devices.

6) Allowing U.S. companies to simply register their "Class I Medical Devices (non sterile, non measuring)" only with the FDA, and E.U. companies only with their in country Ministry of Health will have the immediate, guaranteed impact of saving companies money; which can be used to actually market or sell their products! For example, a U.S. company that wants to sell the simple "Finger Splint" mentioned above in the E.U. currently has to pay several thousand dollars for the rights to do this, even though the product is already registered in the FDA database (again, a public database that provides the traceability that both the U.S. and E.U. want), and this money would be better spent on promoting the product and generating Export Sales (which increase incomes, add to the U.S. tax base, and create jobs)!

I am happy to provide additional information and insights.

Thank you in advance for working to make "Class I Medical Devices (non sterile, non measuring)" a "test case" for U.S.-E.U. regulatory cohesion for Medical Devices!

Sincerely yours,

Brooke Fishback

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