

TTIP Meeting with EGA and Fresenius on Generic pharmaceuticals 09/12/2015

Participants:

- [REDACTED], [REDACTED], [REDACTED] (TRADE)
- [REDACTED] (European Generics Association), [REDACTED] (Fresenius)

Summary:

- Industry noted strong support for TTIP and active communication work being carried out by Fresenius CEO across Germany. A list of press articles/public statements on support to TTIP was provided. EGA has also been active in all TTIP stakeholder events and civil society meetings.
- Industry inquired about state of play of EU generics paper. COM informed that the paper is in final phase of consultation and is expected to be sent to the US soon.
- Biosimilars – industry noted that biosimilars name does not need to have a qualifier as, in their opinion, that qualifier creates confusion. EGA provided comments to US FDA (Notice and Comment procedure) and suggested that same approach as the one taken in the EU (i.e. non qualifier) is adopted.
- GMP – Industry is following up with interest GMP works and would like to know when FDA will be in a position to make its determination. COM noted that work is ongoing and that there is expectation that by beginning of 2016 the next steps in the process are defined.