Report of the meeting between Cécile Billaux (CAB) and Adrian van den Hoven (European Generic Medicines Association) - 16 October 2015

Present:
Cécile Billaux (CAB), 4.1(b) (DG Trade B3),
Adrian van den Hoven (Director General – European Generic Medicines Association (EGA)), Erick Tyssier (Head of Government Affairs Europe – Teva Pharmaceuticals Europe)

The EGA wished to discuss three points:

The Supplementary Protection Certificate (SPC) Export (Manufacturing) Exception

Not relevant to the request.

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The Transatlantic Trade and Investment Partnership (TTIP)

The US Food and Drug Administration (FDA) had formally adopted guidance on developing and testing biosimilars. This is a very welcome development and is the result of fruitful cooperation between the European Medicines Agency (EMA) and the FDA. The EGA would welcome if the same were to be done for complex generics – where the companies face the same problem of duplication. Generally, EGA argues that there is a need to lower development costs in order to have sustainability. The EU is currently competitive in complex generics and it should be kept that way. This latter issue is supported by the European Consumer Organisation (BEUC). There is effectively no NGO counter-argument. Furthermore it is also a useful pro-TTIP argument as it facilitates access to medicines.

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Although progress can be made in other contexts, EGA view TTIP as an umbrella that covers all these various issues.

4.1(a)

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Mutual Recognition/Reliance/Good Manufacturing Practice (GMP)

Not relevant to the request.