

Report meeting Commissioner and Medicines for Europe (17 July 2018)

Present on behalf of SANTE: Commissioner, Annika Nowak (CAB), [REDACTED] (B.5).

Present on behalf of Medicines for Europe: [REDACTED] (Vice-President MfE); [REDACTED] (Director General MfE), [REDACTED] (Director Government Relations Fresenius Kabi), [REDACTED]

1. Supplementary Protection Certificate (SPC) Manufacturing Waiver

MfE raised the following concerns:

- SPC waiver in current form very difficult to use, as it will only be applicable 10 – 15 years after coming into force of the proposal.
- There should be the possibility of a day-1 launch for European patients.
- Some of the current notification requirements (supply chain, markets to launch in) require too much commercially confidential information to be disclosed (and could even lead to anti-competition behaviour).
- SPC waiver is both about employment in Europe and access to medicines for European patients.

Cssner explained that the proposal is a reflection of different interests, and that it is now in the hands of the legislators (Council and Parliament). It ascertained that more work needs to be done to communicate about this proposal.

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

