EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

Brussels
SANTE.DDG1.B.5/[redacted]/[redacted](2020)3473646

BTO MEETING DG SANTE/DG GROW WITH MSF
8 JUNE 2020

MSF: [redacted] (MSF Brussels); [redacted] (MSF Geneva)

SANTE: [redacted].

GROW: [redacted]

The objective of the meeting was for MSF to present their recently published paper (attached): 'The SPC and their impact on access to medicines', and to present its main findings and recommendations.

After a brief presentation of its paper (attached) by MSF, **SANTE** asked about the costs of development and whether the findings related to the three products could be extrapolated to other medicines. **MSF** explained that, in order to make any conclusions about development costs (R&D), proxies had to be used, e.g. acquisition costs of the initiator of a product that was bought by a larger company. A brief discussion followed whether the same situation would apply to other medicines. MSF indicated that it chose these three medicines, as they were highly profitable and there was in a way transparency about the development. Justification for SPC extension was therefore not there.

SANTE pointed out that the use of incentives such as SPC (Supplementary Protection Certificates – max. 5 years extension of the patent duration) can lead to very long periods of protection for companies. This was also revealed in the findings of the case-studies, but it should be kept in mind that the Copenhagen Economics (CE) Study overall concluded that the effective protection period has overall decreased for companies. However, at the same time, it is important to put these findings into perspective as CE concluded that this overall decrease of effective protection does not take into account secondary use patents and asked MSF whether data/studies have been conducted on this

important issue. On this matter, MSF stressed that, in the context of COVID-19 related medicines, the issue of secondary use patents is key as many products will be repurposed.

MSF concluded that the SPC incentive should be closely reviewed, including its grounds for application. There should be a better link also to healthcare expenditure and exclusivities with extensive public health impact should be eliminated. One could argue that there should be no SPC at all as the current patent system already provides sufficient exclusivity.

MSF main recommendations to the Commission:

1) Review of the SPC as part of the Pharmaceutical Strategy, especially on the impact on accessibility of medicinal products;
2) A 'waiving system' to bee used also for SPC in case a compulsory license would be given in a public health urgency;
3) Need to look at appropriate incentives in support of new antibiotics, in the context of the ongoing discussions at the Pharmaceutical Committee;
4) Need to relocate manufacturing to the EU.

SANTE indicated that – as part of the pharmaceutical strategy – a Roadmap was recently published. This covers amongst others issues ranging from R&D to availability and access. Moreover, manufacturing back to the EU is also a major topic in this strategy.

GROW briefly elaborated their work around the evaluation of the SPC (ongoing, to be finalised before the end of the year). **GROW** also explained that the SPC is very often not the incentive last to expire, and therefore not necessarily the main 'obstruction' to generic access.

MSF was asked to also provide their comments on the functioning of the SPC in writing.

[redacted]