Meeting Europabio 14.10.2020

Europabio: [redacted]
SANTE: [redacted]

The meeting was organised at the request of Europabio. The following topics were discussed:

- ***Application of the GMO legislation to medicinal products:*** Europabio explained the problems faced by developers and noted that this is hindering the ability to conduct clinical trials with gene therapy in the EU. SANTE acknowledged the difficulties faced by developers, explained actions taken so far, and indicated that this issue will be examined in the context of the Pharmaceutical Strategy. Europabio suggested that products with no environmental risks should be exempted and that, for other products (*e.g.* replicating viruses or bacteria), the assessment should be led by the medicinal competent authorities.

- ***Hospital exemption:*** Europabio considered that the HE is valuable in so far as it is not used to circumvent the requirements for demonstration of efficacy and safety and provided that adequate monitoring of clinical effects is implemented. Europabio complained about the fact that different practices have emerged across the EU (e.g. regarding interpretation of "non-routine" or the requirements to obtain authorisation under hospital exemption) and that, in some cases, the application of the HE may put patients at risk and hinder investments and the competitiveness of the EU industry. There was a request for SANTE to issue GLs and a request was made for more transparency. SANTE noted that concerns about the HE have come out prominently in the public consultation about the Pharma Strategy. The question was asked, however, how to deal with cases where approved ATMPs are not reimbursed and also about Europabio's request for follow up of patients under HE.

- ***Review of BTC legislation:*** Europabio asked about plans regarding BTC. SANTE noted that an impact assessment is being carried out.