

Suggested minutes for the MoH:

Topic: Pre-submission meeting with Vertex Pharmaceuticals for CF therapies

Date: November 29, 2022

Participants (Vertex):

- Pavel Popely, Vertex Pharmaceuticals
- Adrian Vasiliu, Vertex Pharmaceuticals
- Elisabetta Di Bernardini, Vertex Pharmaceuticals

Participants (MoH):

- Robert Babela, State Secretary, Ministry of Health
- Peter Polak, Director General, Section of Pharmacy and Drug Policy, Ministry of Health
- Patricia Dutkova, Director of the office of the state secretary, Ministry of Health
- Martin Cernak, HTA dept., Section of Pharmacy and Drug Policy, Ministry of Health
- Judita Dugas, HTA dept., Section of Pharmacy and Drug Policy, Ministry of Health

Minutes:

- Introductions by Vertex and MoH.
- Vertex provided an overview on the company, CF, and current CF status in Slovakia.
- Vertex indicated that the company seeks clarity on the new legislation and some of the definitions on innovative pharmaceutical products.
- Vertex discussed its intend to submit dossiers for its CF therapies that are currently available for treatment in Slovakia at the request of the Ministry of Health, as well as a new indication that was recently granted by the EMA.
- MoH indicated that is re-evaluating all orphan drugs that are on the market since ~~2017~~2018.
- MoH is keen on approving new and innovative medicines under reasonable terms. The goal is to preserve access for the current CF patients under treatment and open the discussion for adding new patients, for the benefit of the entire CF population.
- MoH clarified questions about the new legislation and explained the review process.