

## ANNEXES

### ANNEX II

#### TECHNICAL DOCUMENTATION

#### 5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

The documentation shall contain information on:

- (a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and
- (b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

**Status:**

Point in time view as at 31/01/2020.

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, Division 5..