

## SCHEDULE 2

### AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

#### **Regulation (EU) No 528/2012**

**140.**—(1) Annex II is amended as follows.

(2) In paragraph 2—

- (a) in the fourth subparagraph, for “available on the website of the Agency” substitute “to be made available online by the competent authority”;
- (b) in the fifth subparagraph, omit “that will evaluate the dossier”.

(3) For paragraph 4, substitute—

“4. Dossiers must be formatted, prepared and submitted in accordance with the data requirements and guidance as specified by the competent authority.”

(4) In paragraph 6, for “Commission or the Agency” substitute “competent authority”.

(5) In paragraph 8, omit “of the Member State concerned”.