DRAFT STATUTORY INSTRUMENTS

2018 No.

The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018

Amendment of Schedule 2 to the Principal Regulations

8.—(1) Schedule 2 to the Principal Regulations (directions for securing compliance with the first, second and third directives) is amended as follows—

(a) for the heading substitute—

"Directions for securing compliance with the first, second, third and fourth Directives";

(b) for paragraph 1(b) (traceability and coding system), substitute—

"(b) in relation to the coding of information, compliance with—

(i) the requirements of paragraph 1 of Article 25 of the first Directive (coding of information);

(ii) the requirements of paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article;

(iii) the requirements of Article 10a of the third Directive (format of the Single European Code); and

(iv) the requirements of paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).";

(c) after paragraph 1, insert—

"**1A.** Directions must require information that the Authority considers appropriate to secure compliance with the requirements of paragraph 1(g) of Article 10b of the third Directive to be provided to the Authority.";

(d) for paragraph 2, substitute—

"**2.** Directions given for the purposes of paragraph 1(a) must include directions requiring designated individuals to ensure that third parties responsible for human application retain the information listed in Annex VI to the third Directive (minimum data to be kept in accordance with Article 9(2).";

(e) at the end of paragraph 3 (reporting obligations), insert "and Article 8(1) (register of importing tissue establishments) of the fourth Directive";

(f) after paragraph 4 (serious adverse events and serious adverse reactions), insert—

"**4A.** Directions must require that importing licence holders are required to—

(a) notify the Authority of any serious adverse events or serious adverse reactions notified to the importing licence holder by that person's third country supplier (including events or reactions which that supplier suspects are serious adverse events or reactions); and

(b) provide any information specified in the direction which the Authority requires for the purposes of securing compliance with the requirements of Article 6(2) of the fourth Directive (updated information).";

(g) after paragraph 14 (requirements for holding a licence under Schedule 1 for tissue and cell preparation processes), insert—

"**15. Updated information**

(1) Directions must require that importing licence holders must not make any substantial changes in connection with any qualifying import made by that licence holder unless the requirement in sub-paragraph (2) or (3) is met.

(2) The requirement of this sub-paragraph is where the substantial change would require the variation of a condition of the licence authorising the qualifying import—

(a) the importing licence holder has made an application to the Authority to vary the licence under paragraph 8(2) of Schedule 3 to the 2004 Act, as applied by regulation 8, to reflect the change; and

(b) the Authority has made that variation.

(3) The requirement in this sub-paragraph is where the substantial change does not fall within sub-paragraph (2), the Authority has approved the change in writing.

(4) Directions must require that importing licence holders must notify the Authority—

(a) if the licence holder ceases to make qualifying imports; and

(b) of any changes in circumstances of the importing licence holder's third country supplier of which the importing licence holder is aware.

(5) In this paragraph—

"changes of circumstances" means any changes in circumstances of the description specified in the direction in question in accordance with the provision made in Article 6(3) of the fourth Directive (notification of revocation of third country's authorisation);

"qualifying import" means the import into the United Kingdom from a third country of tissues or cells intended for human application;

"qualifying tissues or cells" means tissues or cells intended for human application; and

"substantial changes" means changes of the description specified in the direction in question in accordance with the provision as to the meaning of substantial changes made in Article 3(3) of the fourth Directive (requirements where substantial changes made to import activities).

16. Written agreements

16. Directions must specify the requirements to be made by all importing licence holders to secure compliance with the requirements of Article 7 of the fourth Directive (written agreements).".