STATUTORY INSTRUMENTS

2006 No. 2013

The Blood Safety and Quality (Amendment) Regulations 2006

Amendment of regulation 3 of the principal Regulations

- **3.**—(1) Regulation 3 of the principal Regulations (requirement for authorisation) is amended as follows.
 - (2) In paragraph (2)—
 - (a) in sub-paragraph (a), at the end, omit "and";
 - (b) in sub-paragraph (b), at the end insert "; and "; and
 - (c) after sub-paragraph (b), insert the following sub-paragraph—
 - "(c) the import of blood or blood components from a third country.".
 - (3) In paragraph (3)—
 - (a) in sub-paragraph (a), omit "or";
 - (b) in sub-paragraph (b)—
 - (i) for "and pursuant", substitute "or pursuant"; and
 - (ii) at the end, insert "; and"; and
 - (c) after sub-paragraph (b), insert the following sub-paragraph—
 - "(c) the import of blood and blood components from a third country when undertaken by—
 - (i) a manufacturer, or
 - (ii) a person acting on behalf of and pursuant to a contractual arrangement with a manufacturer,

for the purposes of manufacturing a medicinal product within the meaning of the Medicines act 1968 or the Medical Devices Regulations 2002;".