S C H E D U L E S

SCHEDULE 8

Material to accompany an application for a UK marketing authorisation

PART 1

General requirements

4. An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Paragraph 4.