

PART 1 ADMINISTRATIVE DATA AND SUMMARY OF THE DOSSIER

Part 1 Table of content

1.A Administrative Information

1.A.1 Application form

1.A.2 Annexes

- Annex 5.1
- Annex 5.2
- Annex 5.3
- Annex 5.4
- Annex 5.5
- Annex 5.6
- Annex 5.7
- Annex 5.8
- Annex 5.9
- Annex 5.10
- Annex 5.11
- Annex 5.12
- Annex 5.13
- Annex 5.14
- Annex 5.15
- Annex 5.16
- Annex 5.17
- Annex 5.18
- Annex 5.19

1.B Summary of Product Characteristics, Label and Package Leaflet

1.B.1 Product Information

1.B.2 Mock-up

- Mock-up-1: carton box
- Mock-up-2: label
- Mock-up-3: leaflet

1.C Detailed and Critical Summaries

1.C.1 Quality

1.C.2 Safety

1.C.3 Efficacy