AstraZeneca

European Medicines Agency (EMA)
EMA/IRIS Submission - COMP
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

AstraZeneca AB
SE-151 85 Södertälje, Sweden
[redacted]
astrazeneca.com

Date: 8 September 2020

CONFIDENTIAL

[redacted]

ASTRAZENECA AB
EMA Product Reference: H0005299

Dear Madam, Dear Sir,
In accordance with Council Regulation (EC) No 726/2004 the Applicant AstraZeneca AB, has submitted on 14 October 2019 a Marketing Authorisation Application (MAA) as per Article 8(3) of Directive 2001/83/EC as amended, for a new medicinal product [redacted] 100mg, hard capsules. The CHMP provided a positive opinion on 23 July 2020. The COMP provided a List of Questions (LoQ) on 18 July 2020. Following the oral explanation meeting on 8 September 2020 with a remaining negative trend for the COMP Opinion, the Sponsor AstraZeneca AB has decided to request removal of orphan designation of [redacted] with designation numbe[redacted] from the European Commission's Community register of orphan medicinal products

Submission particulars
AstraZeneca confirms that the submission media are free from computer viruses according to the software package used.

Sincerely,

For and on behalf of
AstraZeneca AB (publ)

[redacted]

8 September 2020
Date

AstraZeneca AB
SE-151 85
Södertälje
Sweden