Bundesinstitut für Arzneimittel
und Medizinprodukte

Reference Member State
Day 209 End of Procedure

1. This document is sent by:

RMS	DE
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Date/Day of procedure	10.09.2014 (Day 209)

2. This document concerns:

Name of the product in the RMS	ATOZET 10 mg/10 mg; 10 mg/20 mg; 10 mg/40 mg; 10 mg/80 mg; Kexrolt 10 mg/10 mg; 10mg/20mg; 10mg/40mg; 10mg/80mg Orvatez 10 mg/10 mg; 10mg/20mg; 10mg/40mg; 10mg/80mg Ezetimib/Atorvastatin MSD 10 mg/10 mg; 10mg/20mg; 10mg/40mg; 10mg/80mg
Name of the active substance	Ezetimib/Atorvastatin
Applicant	Merck Sharp & Dohme Ltd. Hertford Road GB-EN11 9BU Hoddesdon,Heertfordshire
Procedure number	DE/H/3895-3898/01-04/DC

3. Conclusions at Day 209

3.1 Conclusion of the RMS

Our conclusion is that the product is

Approvable ☒

Non-approvable ☐

3.2 Agreement/disagreement between Member States

Based on the Day 210 positions of the CMS and the discussions thereafter it is concluded that

All Concerned Member States are in agreement with the RMS ☒

There is disagreement between the conclusions of the RMS and the CMS (s). Therefore, the matters is forwarded to the Coordination Group ☐

4. Attached documents

4.1 If the product is approvable

Please find attached

the approved SPC ☒

the approved PL ☒

the approved labelling ☒

the Final Assessment Report ☒

the approved specifications ☒

5. Renewal Date and PSUR-cycle

The CRD of the procedure will be on 10.09.2019 based on D210 of the DC procedure.

PSUR cycle:
According to the EURD list the mono-components of this FDC (ezetimibe and atorvastatin) have a PSUR submission cycle of 3 years and these products have a well-known safety/efficacy profiles and therefore the RMS considers that the same PSUR submission frequency of 3 years applies also this this FDC. The applicant can submit the PSURs starting with 3-years cycle. Further to the granting of the MA the RMS will apply for inclusion of this combination in the EURD-list with a PSUR cycle of 3 years.