

**To:** ccmo\_frontoffice[frontoffice@ccmo.nl]  
**From:** ccmo\_bi  
**Sent:** Thur 5-9-2019 12:07:12  
**Subject:** FW: Development Safety Update Report (DSUR): CNP520-DSUR-001-005  
**Received:** Thur 5-9-2019 12:07:15  
[1.0 Cover letter DSUR.pdf](#)  
[2.0 CNP520-DSUR-001-005.pdf](#)

Jaarlijkse veiligheidsrapportage voor Marjolein.

Groet 5.1.2.e

**Van:** 5.1.2.e @novartis.com > Namens 5.1.2.e  
**Verzonden:** woensdag 4 september 2019 14:05  
**Aan:** ccmo\_bi <bi@ccmo.nl>  
**CC:** 5.1.2.e @novartis.com  
**Onderwerp:** Development Safety Update Report (DSUR): CNP520-DSUR-001-005

**The Centrale Commissie Mensgebonden  
Onderzoek (CCMO)  
Postbus 16302  
2500 BH The Hague  
t.a.v. bevoegde instantie (BI)  
Netherlands  
[bi@ccmo.nl](mailto:bi@ccmo.nl)**

04-Sep-2019

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Development Safety Update Report (DSUR): CNP520-DSUR-001-005  
Investigational Medicinal Product Code: CNP520

Dear Madam/Sir,

On behalf of Novartis, PAREXEL International Romania s.r.l. herewith notifies DSUR no. 5, regarding the investigational medicinal product CNP520, covering the period from 11-Jul-2018 to 10-Jul-2019.

Currently, in The Netherlands, 2 clinical trials with this IMP are authorized pursuant to the regulation in force.

Please note that this DSUR is submitted as single submission to avoid multiple parallel submissions by different Novartis legal entities acting as sponsor.

**Clinical Trials:**

Sponsor Code	EudraCT no.
buiten reikwijdte verzoek	buiten reikwijdte verzoek
CCNP520A2202J	2016-002976-28

Please note that the Investigator Brochure (IB) served as the Reference Safety Information (RSI) for Individual Case Safety Reporting (ICSR) during this reporting period. The IB Edition 5 (dated 21-Aug-2018) served as the RSI the submission of the current DSUR. Novartis will begin to use IB, Edition 6 (dated 23-Aug-2019) as the RSI for ICSR in the coming DSUR period. The change in RSI for ICSR will take effect 60 days post DSUR cut-off date on 08-Sep-2019.

For any wet-ink originals to be sent in response to this DSUR notification, please kindly use the following correspondence address:

Parexel International Romania SRL  
CP 166, OP 63, Ghiseu 2, Sos. Stefan cel Mare nr. 2  
Bucharest, 014950, Romania.

**Table of Contents for this Application**

No.	Document	Date of document
1.0	Cover Letter DSUR	04-Sep-2019
2.0	CNP520-DSUR-001-005	27-Aug-2019

We trust this notification fulfils your requirements, however, in the event of any queries, please do not hesitate to contact us.

Yours faithfully,

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**PAREXEL International**

5.1.2.e

89-97, Grigore Alexandrescu Street

Bucharest, Romania, 010624

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**Onderzoek (CCMO)**

**Postbus 16302**

**2500 BH The Hague**

**t.a.v. bevoegde instantie (BI)**

**Netherlands**

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04-Sep-2019

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