



**Parexel International Romania s.r.l.**

Metropolis Center - Str. Grigore Alexandrescu, Nr 89-97,  
Sector 1, 010624 Bucharest, Romania  
J40/9291 /2004; CUI: RO 16494261  
Phone: +40 5.1.2.e  
Fax: +40 5.1.2.e  
[www.parexel.com](http://www.parexel.com)

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

03-Nov-2021

---

Development Safety Update Report (DSUR): MHS552-DSUR-001-002  
Investigational Medicinal Product Code: MHS552

Dear Madam/Sir,

On behalf of Novartis, PAREXEL International Romania s.r.l. herewith notifies DSUR no. 002, regarding the investigational medicinal product MHS552, covering the period from 09-Sep-2020 to 08-Sep-2021.

Currently, in The Netherlands, 1 clinical trial with this IMP is 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 Trial:**

Sponsor Code	EudraCT no.
CMHS552A12101	2018-004233-33

Please note that Investigator Brochure (IB) Editions 2 (dated 07 Apr 2020) and 3 (dated 25-Mar-2021) served as the Reference Safety Information (RSI) for Individual Case Safety Reporting (ICSR) during this reporting period. Novartis will use IB Edition 4 (dated 03-Sep-2021) as the RSI for ICSR in the coming DSUR period.

There is no change in RSI with IB Edition 4, which will take effect 60 days post DSUR cut-off date on 07-Nov-2021.

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.

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

Yours faithfully,

[Redacted signature block]  
5.1.2.e

---

**PAREXEL International**

[Redacted]  
5.1.2.e  
89-97, Grigore  
Alexandrescu Street  
Bucharest, Romania, 010624  
T +4 0 [Redacted] 5.1.2.e  
F +4 0 [Redacted] 5.1.2.e  
Email: [Redacted] 5.1.2.e@novartis.com

**Table of Contents for this Application**

No.	Document	Date of document
1.0	Cover Letter DSUR	03-Nov-2021
2.0	MHS552-DSUR-001-002	27-Oct-2021