To: [redacted])[[redacted]@minvws.nl]
From: [redacted].
Sent: Tue 12/1/2020 2:58:50 PM
Subject: FW: tocilizumab
Received: Tue 12/1/2020 2:59:01 PM

Hi [redacted]

Nog wat meer info – onderschrijft mijn eerdere bericht hierover.

Vriendelijke groet,

[redacted]

Van: [redacted], [redacted] <[redacted]@cbg-meb.nl>
Verzonden: dinsdag 1 december 2020 15:43
Aan: [redacted]. <[redacted]@cbg-meb.nl>
CC: [redacted]. <[redacted]@cbg-meb.nl>; [redacted] <[redacted]@cbg-meb.nl>; [redacted] <[redacted]@cbg-meb.nl>
Onderwerp: FW: tocilizumab

Hoi [redacted]

Even iedereen die relevant is ingekopieerd.
Nee, er is nog geen aanvraag ingediend. Er is wel wat aan interactie geweest.

MVG, [redacted]

[redacted]: [redacted] <[redacted]@legemiddelverket.no>
Verzonden: dinsdag 1 december 2020 13:15
Aan: [redacted], [redacted] <[redacted]@cbg-meb.nl>
Onderwerp: RE: tocilizumab

It is listed (https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#research-and-development-section) on the website, I am just not sure when exactly they came and for what.

Unfortunately all my pleads to have an updated excel file with products is falling on deaf ears so I have difficulties to know the exact details as I have really no possibility to follow all of the submissions myself.

I think they came very early but maybe then only with Q and NC, not sure.

[redacted]

Best regards

[redacted]
Lead Methodologist in Regulatory and Pharmacoeconomic Statistics, NoMA
Chair Scientific Advice Working Party, EMA
www.noma.no

Norwegian Medicines Agency

From: 5.1.2e, 5.1.2e <5.1.2e @cbg-meb.nl>
Sent: 01 December 2020 12:54
To: 5.1.2e <5.1.2e @legemiddelverket.no>
Subject: tocilizumab

Hi 5.1.2e

In the Netherlands there is quite some interest in using tocilizumab in the setting of Covid – a study was performed by Dutch investigators. The ministry is considering asking Roche to submit a type II variation, but would want to know if the company had already approached us for SA or a variation procedure. Did you hear anything at the ETF, perhaps?

Kind regards,

5.1.2e

5.1.2e5.1.2e
5.1.2e
CBG-MEB, Pharmacotherapy group II
SAWP member (EMA)

Professor of Drug Regulatory Science
Department Clinical Pharmacy and Pharmacology, UMCG

Medicines Evaluation Board
5.1.2e@cbg-meb.nl
Graadt van Roggenweg 500, 3531 AH Utrecht, The Netherlands

GOOD MEDICINES USED BETTER

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