Novartis Pharmaceuticals UK Limited
2nd Floor
The WestWorks Building
White City Place
195 Wood Lane
London
W12 7FQ

Date: 15th April 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Sandimmun concentrate for solution for infusion 50mg/ml (ciclosporin):
Interim Supply of German Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Novartis Pharmaceuticals UK Limited is currently experiencing supply disruption with Sandimmun concentrate for solution for infusion 50mg/ml (ciclosporin) in the UK

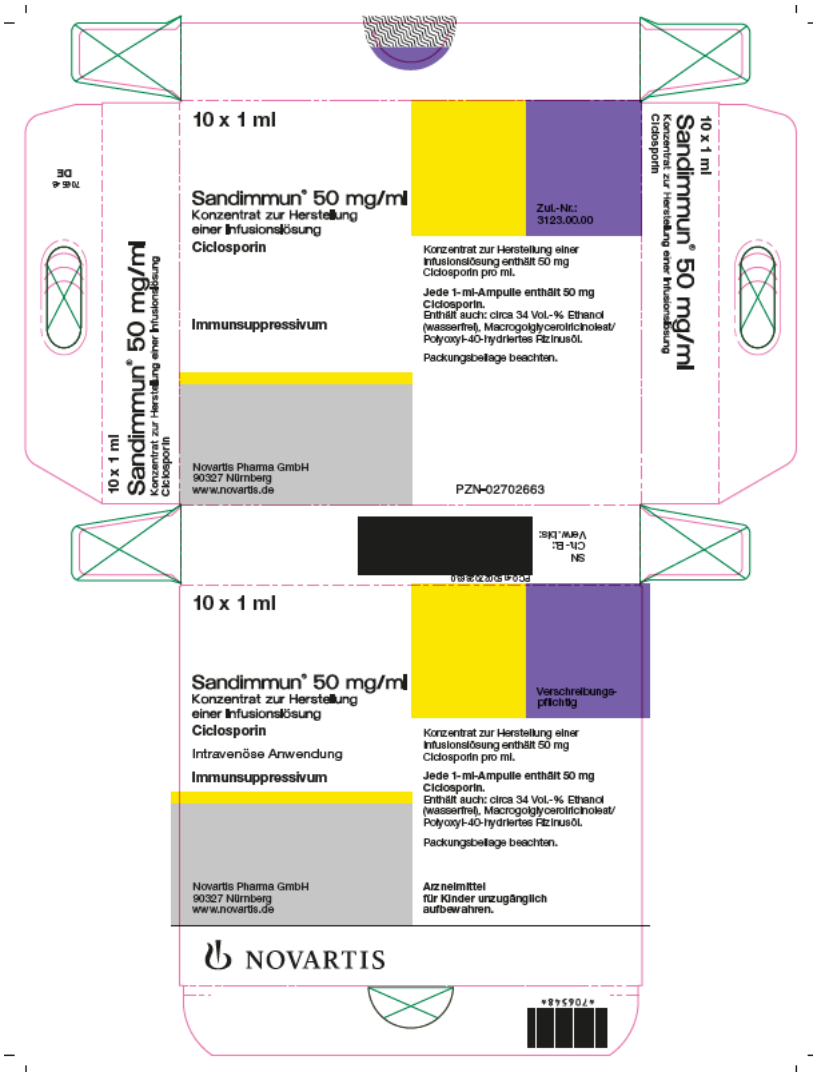
To ensure continuity in supply, Novartis Pharmaceuticals UK Limited has obtained approval from the MHRA to supply German product (batch number P0186, consisting of 751 packs) which is expected to be on the UK market from approximately 29 April 2024 to 10 June 2024.

Please note the following:

- This product is considered licensed in the UK.
- The product from Germany has the same as the UK product.
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the German and UK product information. Please ensure the UK Patient Information Leaflet (PIL) is followed.
- Please refer to the UK approved PIL supplied with the German packs. Discard the Germany leaflet in the pack.
- For additional copies of the leaflet, please refer to SANDIMMUN Concentrate for Solution for Infusion 50mg/ml - Patient Information Leaflet (PIL) - (emc) (medicines.org.uk) or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012 and according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Sandimmun concentrate for solution for injection and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Please see below an image of the German outer carton as it differs from the standard UK product:



Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or require more information about Sandimmun concentrate for solution for infusion, please contact Novartis Pharmaceuticals UK Limited Medical Information department on 01276 698370 or email medinfo.uk@novartis.com

Yours faithfully,

Gerrit Zijlstra
Chief Medical Officer UK
Novartis Pharmaceuticals UK Ltd