Vaccination and/or Prophylactic Antibiotic Confirmation Form

ASPAVELI® ▼ (pegcetacoplan) Controlled Distribution Programme

IMPORTANT INFORMATION

Pegcetacoplan is authorised under controlled distribution. In patients with a known history of vaccination, it should be ensured that patients have received vaccines against encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B within 2 years prior to starting pegcetacoplan. Drug distribution will only be possible after written confirmation that the patient has received or will receive vaccination against the encapsulated bacteria outlined above, and/or antibiotic prophylaxis is submitted by the prescriber to TCP Homecare. Therefore it is mandatory that this vaccination and/or prophylactic antibiotic confirmation form is completed for each patient and returned by email to TCP Homecare at pharmacy@tcp.ie. For support please contact TCP Homecare at 00 353 1 4291823.

You will also be sent an annual vaccination reminder during April of each year to check each patient's vaccination status according to the current national vaccination guidelines. It is also a requirement that all healthcare professionals ensure that they have read and understood the Guide for healthcare professionals before prescribing pegcetacoplan for any patient. The physician should also discuss the Patient/caregiver information (A guide to pegcetacoplan for patients and caregivers) with the patient or caregiver during consultation and provide it to the patient or caregiver along with the Pegcetacoplan Patient Card.

Prescriber Information

Name of Prescriber:		
Hospital:		Phone Number:
City:	Country: Ireland	Email:

Patient Information

Patient Initials:	Date of Birth (dd/mm/yyyy):

Confirmation of Vaccination Status

Please tick one as appropriate.

☐ I confirm that this patient has received a vaccination against *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y and B, and *Haemophilus influenzae* type B within 2 years prior to starting pegcetacoplan or according to applicable local guidelines.

☐ I confirm that the patient needed immediate treatment and therefore, will receive prophylactic antibiotics from at least the first day of pegcetacoplan treatment and until 2 weeks after vaccination.

Prescriber Commitment

I, the undersigned,_____hereby undertake to ensure or confirm that:

☐ I must explain pegcetacoplan treatment to the patient/caregiver and I must deliver to the patient/caregiver all necessary information, including the pegcetacoplan patient card and relevant educational materials before treatment initiation.

☐ I am requesting specified educational materials and commit to provide these materials to this patient/caregiver.

Risk of serious infection due to encapsulated bacteria

Due to its mechanism of action, the use of pegcetacoplan may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y and B, and *Haemophilus influenzae* type B.

- To reduce the risk of infection, all patients must be vaccinated or revaccinated against *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y and B, and *Haemophilus influenzae* type B according to the current national vaccination guidelines.
- Patients must be vaccinated against encapsulated bacteria at least 2 weeks prior to administering the first dose of pegcetacoplan, unless the risk of delaying therapy outweighs the risk of developing an infection.
- If immediate therapy with pegcetacoplan is required, the required vaccines should be administered as soon as possible, and the patient should be treated with appropriate broad-spectrum antibiotics, in accordance with current national recommendations until 2 weeks after vaccination.
- Vaccination reduces, but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate if an infection is suspected. Promptly treat any known infections.

☐ I confirm that I have read and understood the risk of serious infection due to encapsulated bacteria associated with the use of pegcetacoplan and that the patient has adequate cover in line with the above and in line with the PNH National Service recommendations.

☐ I understand that I will receive annual reminders regarding patient vaccination status, and I confirm that I will review the need for re-vaccinations according to applicable local guidelines.

Signature:	Date (dd/mm/yyyy):

By completing this form, you consent to Sobi holding your name and contact details in accordance with the following Privacy Notice.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events can also be reported to Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.

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Privacy Notice

We, Swedish Orphan Biovitrum Ltd. Registered Number 04369760. Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD ("Sobi"), value your privacy. This Privacy Notice explains how we process (e.g., collect, use, disclose, transfer and store) your personal data ("Personal Data") when we receive a completed vaccination and/or prophylactic antibiotic confirmation form as part of the pegcetacoplan controlled distribution process.

As the marketing authorisation holder (MAH) for pegcetacoplan, Sobi is the controller of any Personal Data we hold about you and your patient.

What Personal Data do we collect from you?

The Personal Data collected by Sobi includes your name and e-mail address. In addition to Personal Data collected directly from you, we collect and obtain Personal Data (patient initials, date of birth and vaccination status) regarding your patient.

Why do we collect your Personal Data and what do we do with it?

The controlled distribution of pegcetacoplan is implemented to ensure that pegcetacoplan is only dispensed after written confirmation that the patient has received vaccination against encapsulated bacteria and/or is receiving prophylactic antibiotics according to national guidelines. This is to reduce and mitigate the risks of serious infections with encapsulated bacteria in these patients.

As such it is necessary to collect some Personal Data of the patient (initials, date of birth and vaccination status), store that information whilst the patient continues to receive pegcetacoplan, as long as the controlled distribution process is in place, and share that information with parts of the supply chain and the pharmacy prior to dispensing of the product.

The Personal Data will be held on a secure database.
We will also contact you annually, to remind you to check your patients' vaccination status.

What is Sobi's legal basis for the processing of your Personal Data?

The Personal Data is to be collected to protect the safety of the subject and therefore protect vital interests of the patient. Processing of the data is necessary for compliance with legal obligation as MAH to comply with legal obligations of setting up a controlled distribution process for the MHRA (and to protect the safety of the patient).

Who might we share your Personal Data with?

In addition, your Personal Data may be shared with other companies within the Sobi group. Sobi may also share your Personal Data with third parties, for example (i) when required by law, (ii) to acquirers or potential acquirers of our business, or (iii) to any supplier engaged or contracted by Sobi that provides services to Sobi, but in this case only to the extent necessary for such suppliers to provide their services to Sobi.

How long do we keep your Personal Data?

Sobi will store your Personal Data only for as long as Sobi has use for it based on the purpose stated above.

Sobi may, instead of destroying or erasing your Personal Data, make it anonymous such that it cannot be associated with or tracked back to you.

What are your rights?

You and your patient have the right to know what personal data we process about you and may request a copy. You are also entitled to have incorrect personal data about you corrected and you may in some cases ask us to delete your personal data.

You can also object to certain personal data about you being processed and request that processing of your personal data be limited. **Please note that the limitation or deletion of your personal data may mean we will be unable to provide services and communications related to the purpose described above and your patients will not be able to receive pegcetacoplan.** You also have the right to receive your personal data in a machine-readable format and have the data transferred to another party responsible for data processing.

If you are dissatisfied with how we process your personal data, you are entitled to report this to the relevant Personal Data Supervisory Authority.

We welcome your inquiries and comments and if you want to get in contact with us please write to PrivacyUK-RoI@sobi.com.

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