

3 February 2009

Proposal to extend funding for pegylated interferon alpha-2a (Pegasys) to include Hepatitis B, and to award sole supply to Pegasys.

As a result of a Request for Proposals for the sole supply of pegylated interferon and ribavirin PHARMAC and Roche Products (New Zealand) Limited have entered into a provisional agreement for the funding of Roche's range of interferon (Roferon-A) and pegylated interferon products (Pegasys), and ribavirin (Copegus).

In summary the proposal would result in:

- a widening of existing subsidised access to include patients with chronic Hepatitis C, genotype 2 and 3 who do not have cirrhosis;
- provision of subsidies for patients with chronic Hepatitis B, where patients are treatment naïve;
- restriction on the funding of the Pegatron brand of pegylated interferon alpha-2B (Schering-Plough) to existing patients (i.e. those with active approved Special Authorities), followed by delisting of Pegatron on completion of all existing treatment courses (i.e. at the end of the 11 month Special Authority validity period).
- For the avoidance of doubt this proposal does not affect interferon alpha-2B (Intron-A) supply status.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm on **Wednesday 18 February 2009** to:

Mike Bignall	Email: mike.bignall@pharmac.govt.nz
Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

- Pegasys, Pegasys RBV combination Pack, Roferon-A and Roferon RBV Combination Pack would all be listed in Section B of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST) from 1 April 2009:

Chemical	Formulation	Brand	Pack size	Price and subsidy
Pegylated interferon alpha-2A	135 µg prefilled syringe	Pegasys	1	\$362.00
	180 µg prefilled syringe		1	\$450.00
Pegylated interferon alpha-2A and ribavirin	135 µg prefilled syringe * 4 plus 112 * 200 mg ribavirin	Pegasys RBV Combination Pack	1 OP	\$1,799.68
	135 µg prefilled syringe * 4 plus 168 * 200 mg ribavirin		1 OP	\$1,975.00
	180 µg prefilled syringe * 4 plus 112 * 200 mg ribavirin		1 OP	\$2,059.84
	180 µg prefilled syringe * 4 plus 168 * 200 mg ribavirin		1 OP	\$2,190.00
	3 m IU prefilled syringe		1	\$31.32
Interferon alpha-2a	4.5 m IU prefilled syringe	Roferon-A	1	\$46.98
	6 m IU prefilled syringe		1	\$62.64
	9 m IU prefilled syringe		1	\$93.96
	18 m IU multidose cartridge		1	\$187.92
	18 m IU multidose cartridge * 2 starter pack		1	\$357.84
	18 m IU multidose cartridge * 2 plus 168 * 200 mg ribavirin		1 OP	\$1,375.84
	18 m IU multidose cartridge * 2 plus 168 * 200 mg ribavirin with pens and needles		1 OP	\$1,375.84

- a confidential rebate would apply to Pegasys, Pegasys RBV Combination Pack and Roferon RBV Combination Pack.
- Pegasys and Pegasys RBV Combination Pack would be the sole supply brand of pegylated interferon and pegylated interferon and ribavirin combination packs until 31 December 2012.
- The current Special Authority number SA0802 would be deleted and Pegasys and Pegasys RBV combination Pack would be subject to the following Special Authority restrictions:

Special Authority for Subsidy**PEGYLATED INTERFERON IN CHRONIC HEPATITIS C**

Initial application - (genotype 1, 4, 5 or 6 infection or co-infection with HIV) from any specialist. Approvals valid for 11 months for applications meeting the following criteria:

1. Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
2. Patient has chronic hepatitis C and is co-infected with HIV.

Note: Consider stopping treatment if serum HCV RNA level at Week 12 remains detectable by PCR and has not reduced by at least 2 logs from the baseline level as this is predictive of treatment failure

Note: Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (<50IU/mL) AND Baseline serum HCV RNA is <400,000IU/mL

Initial application - (genotype 2 or 3 infection without co-infection with HIV) from any specialist. Approvals valid for 6 months for applications where the patient has chronic hepatitis C, genotype 2 or 3 infection.

PEGYLATED INTERFERON IN TREATMENT-NAÏVE CHRONIC HEPATITIS B

Initial application only from a gastroenterologist, infectious disease specialist, or general physician. Approved dose is 180 mcg once weekly. Approvals valid for 48 weeks unless notified for applications meeting the following criteria:

1. Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
 2. Patient is Hepatitis B treatment-naïve; and
 3. ALT > 2 times Upper Limit of Normal; and
 4. HBV DNA < 10 log₁₀ IU/mL; and
- Any of the following:
- 4.1. HBeAg positive; or
 - 4.2 serum HBV DNA ≥ 2,000 units/ml and significant fibrosis (≥ Metavir Stage F2);
5. All of the following:
 - 5.1 Compensated liver disease; and
 - 5.2 No continuing alcohol abuse or intravenous drug use; and
 - 5.3 Not co-infected with HCV, HIV or HDV; and
 - 5.4 Neither ALT nor AST greater than 10 times upper limit of normal; and
 - 5.5 No history of hypersensitivity or contraindications to pegylated interferon.

Notes for Pegylated Interferon:

The recommended dose of Pegylated Interferon-alpha 2a is 180 mcg once weekly.

In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alpha 2a dose should be reduced to 135 mcg once weekly

In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.

Pegylated Interferon-alpha 2a is not approved for use in children.

Background to Proposal

The Anti-Infective Subcommittee of the Pharmacology Therapeutics Advisory Committee (PTAC) considered pegylated interferon for sole supply in 2007.

The Subcommittee considered that both pegylated interferon alpha-2a and pegylated interferon alpha-2b gave the same or similar therapeutic benefits and risks in hepatitis C patients.

The Subcommittee considered that it would be reasonable to have only one brand of pegylated interferon (either pegylated interferon alpha-2a or pegylated interferon alpha-2b) and one brand ribavirin (tablets or capsules) fully funded on the pharmaceutical schedule for the treatment of patients with Hepatitis C.

The Subcommittee recommended that access to pegylated interferon alpha-2a with ribavirin on the Pharmaceutical Schedule be widened to include treatment for up to 24 weeks for all patients with hepatitis C genotype 2 and 3 infection.

On 25 November 2005, the Hepatitis B Subcommittee of PTAC reviewed Pegasys for use in Hepatitis B, The Subcommittee recommended that pegylated interferon be listed on the pharmaceutical Schedule with medium priority for HBeAg negative patients without cirrhosis.

On 15 October 2008 PHARMAC ran a Request for Proposals for Sole Subsidised Supply of Pegylated Interferon and Ribavirin. Submissions closed on the 7th of November 2008. The submissions were evaluated clinically and some clinical issues raised were presented to the Anti-infective Subcommittee at its December 2008 meeting. The 2008 minutes are not available for publishing at this point, however the Subcommittee reviewed its 2007 decision and maintained that there was no clinical reason not to proceed with a Sole Supply arrangement for pegylated interferon.