Working to improve your health

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New Zealand codeine restrictions set for November

AFT Pharmaceuticals (NZX:AFT, ASX:AFT) today welcomes Medsafe's announcement that all codeine and codeine-containing medicines will become prescription only from 5 November 2020.

Medsafe, which made the decision to reschedule all codeine and codeine-containing medicines last year, announced the timetable to give effect to the decision in a letter to the pharmaceutical industry released earlier this week.

The letter is attached to this release.

AFT Pharmaceuticals Managing Director Dr Hartley Atkinson said: "We are pleased Medsafe has set a firm date for the rescheduling of codeine. We expect the move, which is aimed at reducing codeine overdoses and poisonings, will increase demand for alternative pain relief treatments including, AFT's patented paracetamol and ibuprofen combination treatment Maxigesic."

"In the 12 months after Australia rescheduled codeine containing medicines in 2018, sales of Maxigesic tablets increased by more than 50%. While it is unclear whether the New Zealand market will respond in a similar way, we expect the move to assist the growth of Maxigesic in New Zealand in the current financial year."

- Released for and on behalf of AFT Pharmaceuticals limited by Chief Financial Officer Malcolm Tubby

For more information

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About AFT Pharmaceuticals

AFT is a growing multinational pharmaceutical company that develops, markets and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over the counter (OTC), prescription and hospital. Our product portfolio comprises both proprietary and in-licensed products, and includes patented, branded and generic drugs. Our business model is to develop and in-license products for sale by our own dedicated sales teams in our home markets of Australia and New Zealand and in certain Southeast Asian markets, and to out-license our products to local licensees and distributors to the rest of the world.

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To Whom It May Concern,

Reclassification of Codeine

As you are aware, Medsafe has been looking further into the implementation of the reclassification of codeine subsequent to the 63rd meeting of the Medicines Classification Committee on 10 October 2019. Medsafe has been working with the pharmaceutical industry and pharmacy and the Ministers' Delegate has decided to support the recommendation that all codeine products are reclassified as prescription medicines. As codeine-only products (Controlled Drugs C2) are already prescription medicines, the reclassification affects only products that combine codeine with one or more other active ingredients (Controlled Drugs C6).

The minutes of the 63rd meeting and the rationale behind the recommendation can be found on the Medsafe website (https://www.medsafe.govt.nz/profs/class/Minutes/2016-2020/mccMin10Oct2019.htm).

Medsafe will gazette this change on 5 November 2020. On this date, codeine and codeine-containing combination products will only be able to be supplied in accordance with a prescription.

Regulation 15(4) and (5) of the Medicines Regulations 1984 allow some transition periods for the relabelling of stock. At wholesale level, the Regulations allow for three months from the date of notification of a classification change for stock to be relabelled, and for stock at retail level the Regulations allow for 6 months for relabelling. **However, from 5 November, regardless of how stock is labelled and regardless of the labelling transition period, stock will only be able to be supplied on a prescription.** This gives affected sponsors of product and healthcare professionals until 5 May 2021 to transition to fully compliant prescription labelled codeine-containing products.

Please note that as codeine in combination is a Class C6 Controlled Drug under the Misuse of Drugs Act, it cannot be granted any labelling exemptions under the Medicines Act 1981 except for the transitional arrangements for labelling under Regulations 15(4) and (5) of the Medicines Regulations. Any consequential changes in labelling will have to be achieved through a Changed Medicine Notification.

Products on pharmacy shelves will have to be removed from self-selection or pharmacist recommendation on or before 5 November 2020.

New labelling should be available at wholesale level by 5 February 2021.

Yours sincerely

Jacinta Patel
Secretary
Medicines Classification Committee