Dr Andrei Tutoveanu, B MedSc. (Chem), M Pharm. (MPS), B Dent. (Syd), looks at the implications for dentists following the TGA's decision to reschedule codeine.

TGA Codeine Rescheduling…

the what, when and why for Australian Dentists

What

On 20th December 2016, the Therapeutic Goods Administration (TGA) announced its final decision concerning the rescheduling of all low-dose codeine products from their *over-the-counter* (OTC) availability to a *prescription-only* medication. This has resulted in all codeine-based *Schedule 2 and 3* products being up-scheduled to *Schedule 4* (*prescription-only)* medications. This includes many popular pain-relieving products such as Nurofen Plus, Mersyndol, Panadeine and Panadeine Extra. This decision follows several years of evaluations and consultations with a wide range of consumers and industry-leading organisations.

When

The new codeine legislative change will take affect from 1st February 2018 – bringing Australia in line with the United States and United Kingdom.

Why

The TGA has concluded that codeine is far too addictive and misused in the community, especially when combined with other analgesic substances such as paracetamol and ibuprofen.

The TGA has supported the view that there is little evidence of codeine doses less than 30mg, when combined with other analgesics, are in fact any more effective than the accompanying ingredients alone. Furthermore, they have stated the new combination products containing both paracetamol and ibuprofen are more effective than low-dose codeine combination products.

The TGA has debated that *Schedule 2 and 3* products are only intended for acute use of short-term pain. However, evidence suggests many Australians use these products for long-term pain relief. Additionally, the TGA has proposed the widespread codeine availability has created a false public perception of "safety" within our community.

Finally, the TGA references a study by Roxburgh et al (2015), which showed codeine toxicity contributed to 1437 deaths in Australia between 2000 and 2013.

The study highlighted that approximately 24% (343) of deaths were related to a prescription codeine product while a further 16% (229) of deaths resulted from an OTC codeine product. However, there are limitations to the study's data collection. Approximately 60% (865) of cases were unable to be accurately attributed solely to either OTC or prescribed codeine medications, with a combination most likely. Additionally, the study found the rate of accidental deaths linked to codeine increased by 9.3% each year.

Response from the critics

Many organisations such as the Pharmaceutical Guild of Australia (PGA), Pain Australia, The Consumer Health Forum and the majority of community and hospital based pharmacists have agreed with the need to address these underlying issues. However, they have stated their concerns with the final decision, proposing a more conservative approach of monitoring and educating in comparison to up scheduling. Furthermore, the general public has also voiced their concerns regarding the recent rescheduling, opposing the change.

These organisations have debated the following:

- New scheduling will address issues caused by a few while penalising the majority;
- Prescription-only codeine based products will increase pressure on medical GPs, various emergency departments and the entire Pharmaceutical Benefits Scheme *(PBS)*;
- Up-scheduled products will not automatically be PBS-subsidised, resulting in potentially higher costs to patients;
- Increased cost to now include a GP consult in addition to the actual medication;
- Patients with mobility issues or those who are remotely housed will be unfairly penalised;
- Decreasing the availability will force patients to either turn to inappropriate products (i.e. legal and illegal) or be forced to endure poorly controlled or uncontrolled pain;
- Restricting codeine access may encourage 'doctor-shopping' as some patients cannot use other classes of drugs (e.g. *paracetamol, aspirin* and/or *ibuprofen*) for effective pain relief;
- Unfortunately, some dental and medical practitioners do not discuss alternative options, potential side effects or contraindications when prescribing medications for "pain management protocols" (PMPs) which can result in a concerning lack of public awareness.

Other potential consequences

Following implementation of the rescheduling, we as dentists, including some of our medical colleagues, will likely continue to prescribe the "pre-existing" Schedule 4 products containing paracetamol/codeine and ibuprofen - Panadeine Forte and Brufen respectively. This may result in the newly rescheduled products not being frequently prescribed due to their lower strength of active ingredients in comparison to the pre-existing products.

When coupled with the inability of patients to purchase these medications without a prescription, we may see manufacturers discontinuing these particular product lines in the near future.