THERAPEUTIC GOODS ADMINISTRATION — PRESCRIPTION-ONLY CODEINE

Statement

HON SIMON O'BRIEN (South Metropolitan) [9.45 pm]: From time to time, I receive pleas from constituents asking for relief from the rule-makers and bureaucrats who apparently exist just to make life harder. I ask the house tonight to take note of this email of 31 January, in which a lady called Jodie writes to me and states —

> … I have been advised to contact you as I am within your local district regarding my serious concern and dissatisfaction of the change of law … for products containing codeine.
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> I have endometriosis, whiplash due to a car accident and arthritis is my fingers, which I use codeine based products when needed to help the pain I suffer. Paracetamol does not work, I need to take 4 tablets of paracetamol to get a subtle effect to barely relieve any pain.
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> I currently am not able to get in to see my doctor for 3 weeks as they are completely booked out. This timeframe is only going to grow and in the meantime I am going to suffer physically and financially as I will be taking time off work because of the pain I feel because I am unable to access the only medication that helps.
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> It is ridiculous that instead of recording license numbers or identification first, the choice was made to reschedule codeine to a prescription only medication. For the 1% of people who abused the system, the other 99% now have to suffer. All substances and medication have the potential to be addictive. My sister for one was addicted to Advil, friends have been addicted to Panadol, not to mention the millions of people addicted to other substances like caffeine or sugar.
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> Doctors are already booked out, emergency departments are going to suffer because people have a migraine or in pain to a level they need a codeine based product to help, and the government without knowing has just created a black market for codeine. Why skip the step of controlling quantity sold per person to classing it the same as tramadol or morphine when it clearly is not as strong or has the same risks to the 99% using it properly.
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> Please pass this concern to the relevant authority whom has the power to reconsider this horrible legislation and fix the large mistake they made by making codeine prescription only.

In July 2015, the commonwealth government, through the Therapeutic Goods Administration, invited public consultation about several proposals, including what I might now generalise as a ban on over-the-counter preparations containing low-dose codeine. Then, on 1 October 2015, we saw the publication of interim decisions providing for the up-scheduling, as they quaintly called it, of over-the-counter codeine to, in effect, make codeine prescription only. The advice supplied to the scheduling delegate was provided, including that 60 submissions had been received. Of those, 29 submissions supported the proposal. The main points were summarised: to reduce the potential for harm, particularly in paracetamol or ibuprofen products; to reduce the potential for abuse; to prevent ease of access to an opioid; to address numerous studies showing misuse or abuse; that it is not currently possible for pharmacists to monitor and control safe use of low-dose codeine; and, interestingly, that low-dose codeine is not efficacious—so are the claims in support. I think some of those main points are quite debatable, but anyway. Of the 60 submissions, 25 opposed the proposal and I will summarise those in a moment. The rest of the advice in this document seems devoted almost entirely to a single-minded determination by the authors to implement the restrictions that have now become law. There is no contemplation in this document of any of the objections raised. There is no contemplation of what might be the downside to this measure, and there are many. No weight is given to the benefits of the status quo.

That should have set alarm bells ringing, and it did. There was a further round of consultation on that interim decision, and only 14 days was given. This time, there were 127 further submissions, with 14 in favour and 113 in opposition. Some of those submissions, which were clearly from groups and individuals who know what they are talking about, took issue with the fundamental parts of the advice that was provided to government. The submission from an industry body states in part —

> Research by Macquarie University found that the up-scheduling of pharmacist-only analgesics would cost $675 million a year. Almost $170 million would come from Medicare for additional doctor visits. It would cost patients about $70 million. Lost productivity and delayed treatment would cost more than $400 million.
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> There seems to have been no thought given to the fact that these costs—physical and financial—will be borne unduly by the older, sicker and poorer sections of our society. Similarly, people in rural and remote locations with already reduced access to GPs and hospital emergency departments will suffer disproportionate distress, inconvenience and cost.

> The Delegate's suggestion that people—to avoid these painful delays, inconveniences and costs—should have a prescription on hand makes little sense. Not only would such 'just in case' prescriptions put GPs in an ethical dilemma, they would also provide an open door for codeine abusers …

The submission goes on to make the following very good point —

> We also strongly disagree with the unsupported claim that the new non-opioid analgesics (ibuprofen plus paracetamol) can be an automatic replacement for existing codeine medications …

Ibuprofen is not recommended for the large number of adult Australians who have medical conditions. That includes the 3.7 million people with hypertension, the two million people who suffer from asthma, the 440 000 stroke victims, the 350 000 heart attack patients, and the 300 000 pregnant women.

A final determination was made in December 2016 and published on 25 January 2017. The further advice provided with this determination included the astonishing claim on page 9 that there is no evidence that low-dose codeine combination analgesics provide any additional analgesia over optimal dosing of paracetamol, aspirin or ibuprofen. Clearly that flies in the face of the experience of many in this chamber, let alone in the wider community.

In summary, the submissions raised a range of points, including at page 16 that a large majority of people who use codeine-containing products do so safely and effectively; re-scheduling will make pain relief medicines more expensive and more difficult to obtain; there will be substantial costs to Medicare and the Pharmaceutical Benefits Scheme; there are issues with access to and the costs associated with seeing GPs; restriction of codeine to prescription only will not mitigate the risk of misuse or abuse, as it has failed to do in the United States; there are pharmacists who are accessible and suitably qualified to implement risk mitigation strategies; and there is no evidence to suggest cough and flu preparations are subject to misuse; and so on and so on.

All the objections that have been raised appear to me to be reasonable and worthy of serious consideration. In aggregate, they are quite compelling, yet they have simply been ignored. Since 1 February, a number of articles have been written to highlight the realisation of the predicted adverse impacts of the decision to ban over-the-counter codeine. There are shortages of product; indeed, some lines have gone out of production permanently. In reviewing all the material available—there is plenty of it—I have formed the opinion that decision-makers in this matter are misguided and they have it wrong. The advice provided to government from official sources appears to be driven by a zeal to impose and restrict at all costs. It seems to me to be an all too common symptom of publicly funded health mandarins that it is a compulsion to force people to live how they are told to. Today it is over-the-counter codeine, and on other occasions, it is sugar, fat, tea, coffee, alcohol, lollies or whatever. Heaven help us if we want a cigar or tobacco. I agree with the points that my correspondent makes and I know that those points are valid. I appeal to Minister Hunt, who I am sure is a good man, to review this situation.