Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 May 2017

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OUTCOME: 5 - Regulation, Safety and Protection

Topic: E-Cigarettes

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Senator: Griff, Stirling

Question:

Senator GRIFF: If you did receive an application for a therapeutic good would it be treated in the same way as gum and other products?
Dr Skerritt: The essential evidence of showing efficacy, that there is a significant and sustained reduction in smoking cessation and evidence of harm—
I should add that while these products have often been touted as harmless, it is quite important to note that just recently the ACCC successfully prosecuted a number of companies for making a claim of that sort. They found a number of harmful substances in non-nicotine-containing e-cigarettes. We would, as we would for any device or medicine, look at the balance of benefits and harms, and some of those harms would relate to the nicotine but some of the harms might relate to other things in the e-cigarettes depending on what the composition was.
Senator GRIFF: Would you require long-term safety data?
Dr Skerritt: Generally for products we require long-term safety data. How long long-term use is is discussed with the applicant and it depends on the nature of the type of product.
Senator GRIFF: Do you require that with the gum and other equivalent products?
Dr Skerritt: When those products were assessed by TGA, going back some stage, there was safety data over a period. I would have to take on notice how long term long-term was for those products. But, superficially, a smoking cessation product would be asessed. Obviously you want the effect to be both sustained, but you also do not want harm to appear in the longer term. It was some years ago that some of those gums and patches were assessed by TGA, but certainly we could take on notice the sort of toxicology and long-term safety studies that were required.
Senator GRIFF: That would be good on those. Thank you.

Answer:

- Nicotine Replacement Therapy products containing nicotine as the active ingredient and intended as aids to smoking cessation have been on the Australian Register of Therapeutic Goods (ARTG) since the mid-1980s. There are currently 69 Nicotine Replacement Therapy products on the ARTG. All are non-prescription medicines, and they include tablets, lozenge products, chewing gum formulations, transdermal delivery patches and inhalers.

- Before any Nicotine Replacement Therapy product can legally be supplied for therapeutic use, the Therapeutic Goods Administration (TGA) must assess them for safety, quality and efficacy so that the user knows that they are safe to use, properly manufactured and likely to work for the purpose they are being put to.
- Safety assessment of these products include toxicological assessment of the level of nicotine in these products and the proposed levels of excipients, including leachables, extractables and degradation products from the delivery device.
- The minimum toxicological data requirements include studies using the proposed formulation and route of administration.
- Nicotine Replacement Therapy products that are already included in the ARTG have undergone this level of assessment.
- For example, depending on the route of administration, the minimum data and studies required may include investigations of acute toxicity, local tolerance, potential for antigenic/hypersensitivity reactions, possible pharmacokinetic/pharmacodynamics interactions of excipients with nicotine, long-term dermal tolerance studies and studies of sensitising potential.

- Applications to register new Nicotine Replacement Therapy (NRT) products must include a full data package, unless otherwise justified.
- A full data package comprises:
  - Preclinical (toxicology) data
  - Formulation-specific pharmacokinetic data
  - Local tolerance data
  - Clinical efficacy and safety studies (to support the intended use of the product including dose, frequency and duration of use).
- Typically, the clinical safety and efficacy studies submitted for NRT applications cover a period of up to 12 months.
- Toxicology data are required for new NRT dosage forms, NRT used for a new route of administration, and new forms of nicotine (e.g. new salts or complexes).

- The TGA has adopted a number of EU guidelines that are referred to when evaluating trans dermal patches, specifically the ‘Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms’ and the ‘Guideline on the Investigation of Bioequivalence’.”