Australian Government

Department of Health

Expert Review Implementation Committee (ERIC)

Minutes of the Meeting of 5 October 2017

9.00am, Executive Boardroom

Member participants

Adj Prof John Skerritt (Chair)	Deputy Secretary, Health Products Regulation Group
Ms Kerrie-Anne Luscombe	Principal Legal and Policy Adviser
Ms Adriana Platona	FAS, Medical Devices and Product Quality Division
Dr Larry Kelly	FAS, Medicines Regulation Division
Mr Ross Hawkins	A/g FAS, Regulatory Practice and Support Division
s22(1) [redacted]	

Apologies

Adj Prof Tim Greenaway	Chief Medical Adviser
Mr Daniel McCabe	FAS, Information Technology Division

Attendees

Dr Mark McDonald	AS, Complementary & OTC Medicines Branch
Mr Vinod Mahajan	A/g AS, Regulatory Services and Improvement Branch
s22(1) [redacted]	
Mr Adrian Bootes (Item 5)	AS, Prescription Medicines Authorisation Branch
s22(1) [redacted]	

1. Minutes of previous meeting

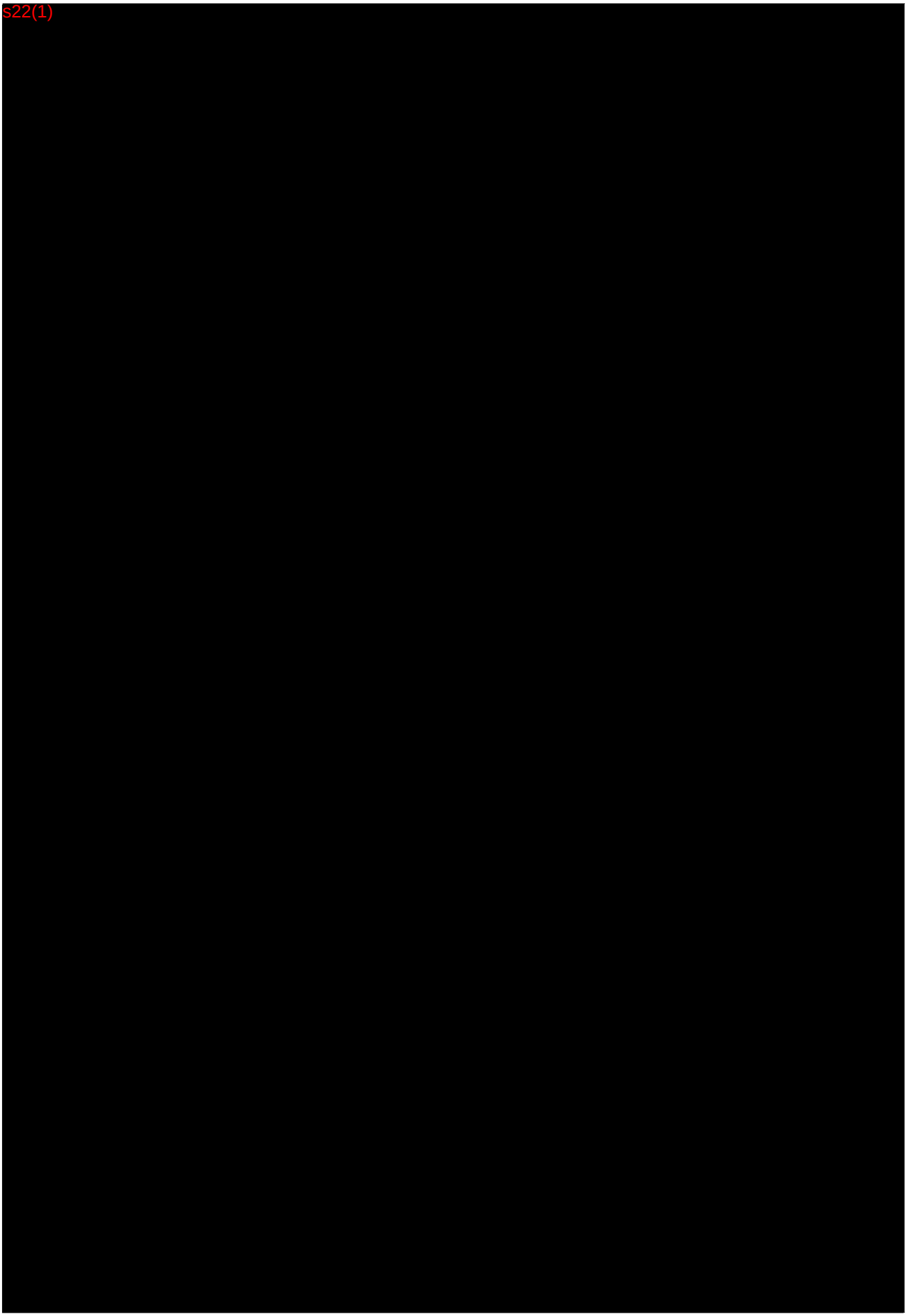
Minutes from the meetings of 6 September and 27 September 2017 were accepted as an accurate reflection of the meetings.

s22(1) [redacted]

s22(1)

[redacted]

s22(1)



s22(1)

[redacted]

6. Specific policy proposals for the future regulation of 'low risk' products

The Minister's approval will be sought on a range of specific policy proposals for the future regulation of 'low risk' products. The specific policy proposals reflect consolidated TGA positions. Implementation of the specific policy proposals will need to be staged.

The background processes to arrive at the consolidated TGA position should be included in the policy approval Ministerial Submission. A key initial component of the 'low risk' products review was a tool (developed with consultants from Melbourne University) to help objectively define 'low risk' products. A facilitated internal workshop in October 2016 demonstrated and validated the tool. Further stages have included workshops, targeted industry consultation and the public consultation paper 'Options for the future regulation of 'low risk' products'.

The TGA Regulatory Reforms team also met with other APS agencies (Australian Competition and Consumer Commission, Australian Pesticides and Veterinary Medicines Authority, and Food Standards Australia New Zealand).

Internal consultation on the specific policy proposals has involved Complementary & Over-the-Counter Medicines, Medical Devices, Manufacturing Quality and Pharmacovigilance and Special Access Branches on the proposed options for products in their respective areas.

s47C

[redacted]

s47C [redacted]

s22(1) [redacted]

s22(1)

[redacted]