

Labelling/TGO 92 update

Non prescription medicines

Dr Michael Carland

Scientific Evaluation Branch

Department of Health, Disability and Ageing, TGA



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

tga.gov.au

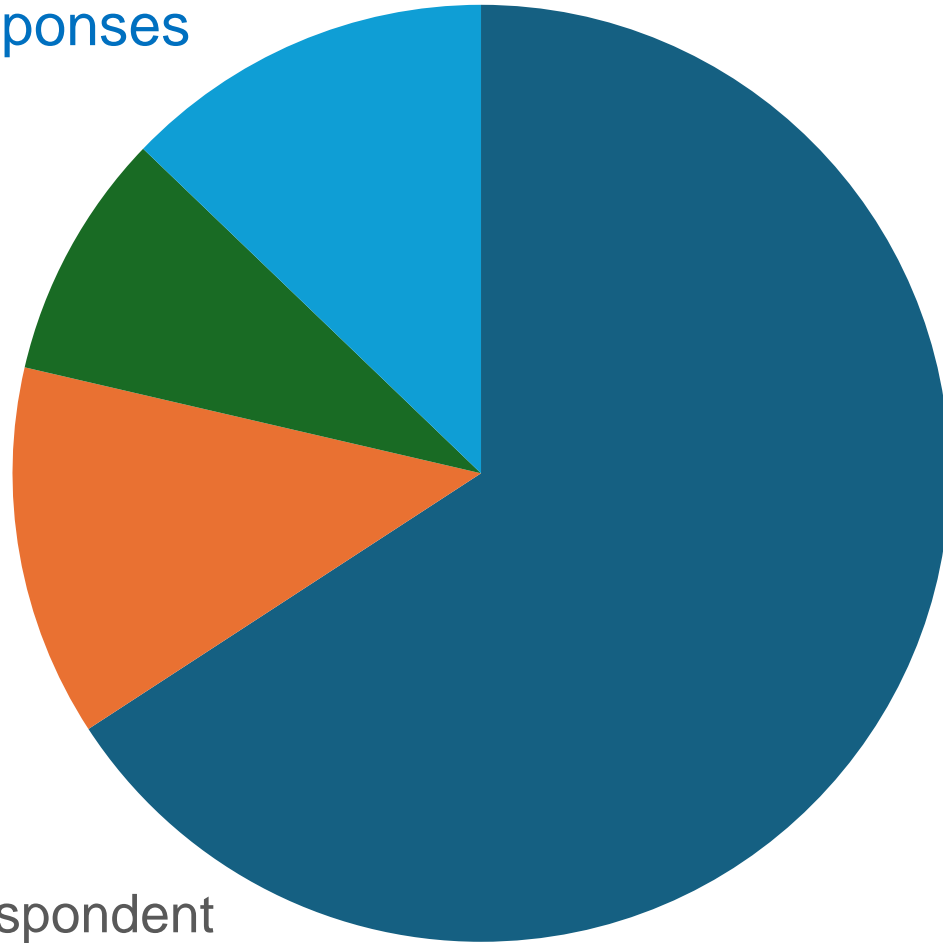
Where we are

- Consultation closed on March 17 (was open for 13 weeks)
- 120 responses
- Responses analysed:
 - Adopt as proposed
 - Adopt with amendments
 - Reject/further consider



Who responded?

120 Responses



Type of respondent

- Commercial Entities
- Associations
- Government agencies
- Individuals



Who responded?

22 associations, including:

- Royal Australian College of Physicians
- Asthma Australia
- Allergy and Anaphylaxis Australia
- Australian Homeopathic Association
- Consumer Healthcare Products NZ

- Accord Australia
- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia
- Coeliac Australia
- One foreign country's trade board

- National Centre for Naturopathic Medicine
- Consumer Healthcare Products Australia
- Naturopaths & Herbalists Association of Australia
- Australian College of Nursing

Who responded?

120 Responses

10 Agencies, including:

- Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Nursing and Midwifery Office
- National Aboriginal Community Controlled Health Organisation (NACCHO)
- State and federal agencies



Who responded?

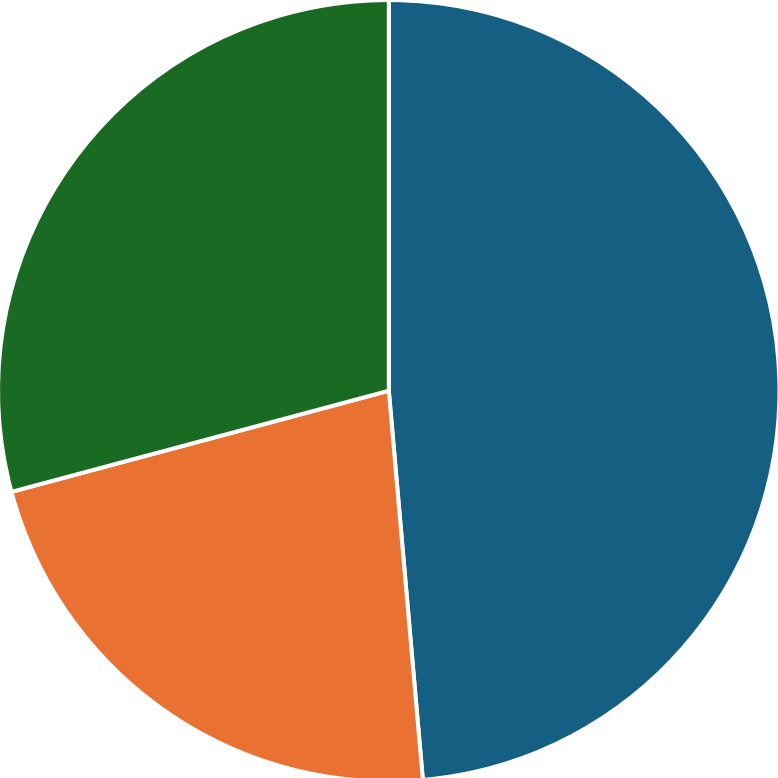
77 Commercial entities, including:

- Sponsors from across the spectrum
- Medicine Manufacturers
- Regulatory Consultants
- PI and substance manufacturers

69 respondents either did not want their response published, or published anonymously



Disposition of proposals



Adopt as proposed ~35
Adopt with amendments ~16
Further consideration ~21

Proposals

- Adopt
- Adopt with amendments
- Further consideration



Transition periods

Three years was proposed

- Changes would not become mandatory until October 2029.
- Feedback was strongly in favor of longer transition periods:

Option	Total
Yes	26
No, I think they should be shorter	3
No, I think they should be longer	49
Neither agree nor disagree	7
Unsure	7
Not Answered	18



Topics

Schedule 1 – declaring substances (1-17)	Vaccine requirements (21, 52)	Large dosage forms (43)	Warning statements (42, 44)
QR Codes (45)	Parenteral dosage forms (25, 26, 27, 29, 61, 62,)	Modified release warning (41)	Contact details (51)
Batchand expiry and embossing (49, 50)	Cohesive unit requirements (36)	Dispensing Space (55)	Red font for potassium (35)
Sunscreen requirements (58)	Active ingredient names (salts, hydrates etc) (19, 20)	Vitamin/Herbal/Enzyme/Probiotics Names (32, 33, 34, 56, 57)	Retinol equivalents (31)
Graphic Guidance (65)	Excipients on labels (54)	Colour Contrast (64)	Instructions for preparation (47, 48)
Continuous, uninterrupted rules (39, 40)	Font size of the active (22)	Plastic Ampoules (59)	Differentiating medicines (66)



Schedule 1 Feedback

1 Declaring wheat

Yes	42
Partially agree	24
No	16
Unsure	5
Not Answered	23

3 Declaring tree nuts

Yes	41
Partially agree	20
No	18
Unsure	7
Not Answered	24

2 Declaring mollusc

Yes	58
Partially agree	9
No	4
Unsure	9
Not Answered	30

4 Lactose

Yes	35
Partially agree	12
No	4
Unsure	19
Not Answered	40

FEEDBACK

Schedule 1 Feedback

5 Declaring sulfites

Yes	52
Partially agree	22
No	7
Unsure	9
Not Answered	20

7 Gluten source

Yes	33
Partially agree	10
No	34
Unsure	9
Not Answered	24

6 Gluten limit

Yes	39
Partially agree	7
No	38
Unsure	5
Not Answered	21

8 Propolis, pollen, royal jelly

Yes	39
Partially agree	20
No	6
Unsure	16
Not Answered	29

FEEDBACK

Schedule 1 Feedback

9 Pollen source

Yes	29
Partially agree	7
No	26
Unsure	20
Not Answered	28

11 Aspartame

Yes	40
Partially agree	11
No	22
Unsure	10
Not Answered	27

10 Declaring substances (PMs)

Yes	42
Partially agree	12
No	9
Unsure	10
Not Answered	37

12 Phenylalanine

Yes	50
Partially agree	11
No	7
Unsure	13
Not Answered	29

FEEDBACK

Schedule 1 Feedback

13 Parabens

Yes	41
Partially agree	22
No	13
Unsure	10
Not Answered	24

15 Preservatives P2

Yes	47
Partially agree	22
No	9
Unsure	6
Not Answered	26

14 Preservatives

Yes	62
Partially agree	9
No	5
Unsure	10
Not Answered	24

16 Lecithin

Yes	45
Partially agree	21
No	5
Unsure	12
Not Answered	27

FEEDBACK

Active ingredient proposals feedback

19 Hydrates and solvates in the cohesive unit

Yes	50
Partially agree	21
No	5
Unsure	12
Not Answered	22

21 Vaccine actives in the cohesive unit

Yes	26
Partially agree	10
No	1
Unsure	32
Not Answered	41

20 Salts in the cohesive unit

Yes	41
Partially agree	21
No	5
Unsure	14
Not Answered	29

22 Active ingredient font size

Yes	36
Partially agree	12
No	31
Unsure	9
Not Answered	22

FEEDBACK

Active ingredient proposals feedback

19 Hydrates and solvates in the cohesive unit

Yes	50
Partially agree	21
No	5
Unsure	12
Not Answered	22

21 Vaccine actives in the cohesive unit

Yes	26
Partially agree	10
No	1
Unsure	32
Not Answered	41

20 Salts in the cohesive unit

Yes	41
Partially agree	21
No	5
Unsure	14
Not Answered	29

22 Active ingredient font size

Yes	36
Partially agree	12
No	31
Unsure	9
Not Answered	22

FEEDBACK

Active ingredients, single use feedback

23 Listed actives on side panels

Yes	50
Partially agree	6
No	2
Unsure	25
Not Answered	27

25 Insulin-containing medicines

Yes	28
Partially agree	6
No	0
Unsure	29
Not Answered	47

24 Repeating actives on NPMs

Yes	52
Partially agree	3
No	4
Unsure	21
Not Answered	30

26 Single use injectables

Yes	38
Partially agree	8
No	4
Unsure	20
Not Answered	40

FEEDBACK

Proposals feedback

27 Injectable total volume guidance

Yes	41
Partially agree	8
No	4
Unsure	18
Not Answered	39

29 UI or weight on injectables

Yes	36
Partially agree	7
No	3
Unsure	19
Not Answered	45

28 Microgram expression

Yes	48
Partially agree	16
No	26
Unsure	6
Not Answered	14

30 Parental nutrition

Yes	20
Partially agree	2
No	1
Unsure	36
Not Answered	51

FEEDBACK

Proposals feedback

31 Retinol equivalents

Yes	25
Partially agree	2
No	3
Unsure	31
Not Answered	49

33 Non-viable organisms

Yes	18
Partially agree	25
No	2
Unsure	35
Not Answered	30

32 Units for enzymes

Yes	39
Partially agree	5
No	0
Unsure	29
Not Answered	37

34 Dual units for Vit D

Yes	48
Partially agree	9
No	7
Unsure	20
Not Answered	26

FEEDBACK

Proposals feedback

35 Potassium in red font

Yes	21
Partially agree	9
No	4
Unsure	30
Not Answered	46

37 Guidance for actives

Yes	49
Partially agree	21
No	2
Unsure	17
Not Answered	21

36 Cohesive unit on side or rear

Yes	40
Partially agree	4
No	31
Unsure	13
Not Answered	22

38 name of the medicine presentation

Yes	30
Partially agree	15
No	6
Unsure	19
Not Answered	40

FEEDBACK

Proposals feedback

39 Looser cont., uninterrupted

Yes	28
Partially agree	26
No	7
Unsure	24
Not Answered	25

41 Modified release warning

Yes	48
Partially agree	25
No	5
Unsure	10
Not Answered	22

40 Looser dosage form rules

Yes	61
Partially agree	10
No	7
Unsure	13
Not Answered	19

42 warning statements guidance

Yes	43
Partially agree	8
No	4
Unsure	17
Not Answered	38

FEEDBACK

Proposals feedback

43 Large dosage forms

Yes	24
Partially agree	26
No	10
Unsure	21
Not Answered	29

45 QR Code rules

Yes	49
Partially agree	30
No	9
Unsure	6
Not Answered	16

44 Prominent warning statement

Yes	35
Partially agree	9
No	20
Unsure	19
Not Answered	27

46 Machine-readable codes guidance

Yes	51
Partially agree	13
No	3
Unsure	12
Not Answered	31

FEEDBACK

Proposals feedback

47 & 48 Instructions for use

Yes	22
Partially agree	14
No	16
Unsure	19
Not Answered	39

50 Prefixes

Yes	59
Partially agree	17
No	4
Unsure	9
Not Answered	21

49 Embossing

Yes	37
Partially agree	11
No	26
Unsure	13
Not Answered	23

51 Contact details

Yes	44
Partially agree	27
No	9
Unsure	10
Not Answered	20



FEEDBACK

Proposals feedback

47 & 48 Instructions for use

Yes	22
Partially agree	14
No	16
Unsure	19
Not Answered	39

50 Prefixes

Yes	59
Partially agree	17
No	4
Unsure	9
Not Answered	21

49 Embossing

Yes	37
Partially agree	11
No	26
Unsure	13
Not Answered	23

51 Contact details

Yes	44
Partially agree	27
No	9
Unsure	10
Not Answered	20



FEEDBACK

Proposals feedback

52 Vaccine excipients

Yes	27
Partially agree	5
No	3
Unsure	33
Not Answered	42

54 Excipients on NPMs

Yes	28
Partially agree	7
No	30
Unsure	18
Not Answered	27

53 Injectable diluent guidance

Yes	25
Partially agree	6
No	5
Unsure	27
Not Answered	47

55 Dispensing Space

Yes	32
Partially agree	8
No	10
Unsure	18
Not Answered	42

FEEDBACK

Proposals feedback

56 Vitamin names (B6 int)

Yes	34
Partially agree	22
No	3
Unsure	24
Not Answered	27

58 Sunscreens

Yes	26
Partially agree	8
No	7
Unsure	31
Not Answered	38

57 Herbal ingredients

Yes	24
Partially agree	20
No	4
Unsure	31
Not Answered	31

59 Plastic ampoules

Yes	35
Partially agree	6
No	5
Unsure	23
Not Answered	41

FEEDBACK

Proposals feedback

56 Vitamin names (B6 int)

Yes	34
Partially agree	22
No	3
Unsure	24
Not Answered	27

58 Sunscreens

Yes	26
Partially agree	8
No	7
Unsure	31
Not Answered	38

57 Herbal ingredients

Yes	24
Partially agree	20
No	4
Unsure	31
Not Answered	31

59 Plastic ampoules

Yes	35
Partially agree	6
No	5
Unsure	23
Not Answered	41

FEEDBACK

Proposals feedback

56 Vitamin names (B6 int)

Yes	34
Partially agree	22
No	3
Unsure	24
Not Answered	27

58 Sunscreens

Yes	26
Partially agree	8
No	7
Unsure	31
Not Answered	38

57 Herbal ingredients

Yes	24
Partially agree	20
No	4
Unsure	31
Not Answered	31

59 Plastic ampoules

Yes	35
Partially agree	6
No	5
Unsure	23
Not Answered	41

FEEDBACK

Proposals feedback

60 Blister pack guidance

Yes	50
Partially agree	8
No	2
Unsure	20
Not Answered	30

63 Vaginal RoA

Yes	25
Partially agree	11
No	17
Unsure	25
Not Answered	32

61 and 62 Conc. injectables

Yes	39
Partially agree	3
No	1
Unsure	24
Not Answered	43

64 Colour contrast guidance

Yes	42
Partially agree	17
No	13
Unsure	13
Not Answered	25

FEEDBACK

Proposals feedback

65 PM graphics guidance

Yes	33
Partially agree	9
No	6
Unsure	20
Not Answered	42

67 Osmotic pumps

Yes	11
Partially agree	2
No	1
Unsure	45
Not Answered	51

66 Differentiating medicines

Yes	39
Partially agree	3
No	1
Unsure	24
Not Answered	43

68 Exempting compounded meds

Yes	43
Partially agree	3
No	4
Unsure	21
Not Answered	39

FEEDBACK

Proposals feedback

69 Purpose on practitioner-only

Yes	42
Partially agree	6
No	2
Unsure	25
Not Answered	46

71 Definition of main label

Yes	51
Partially agree	15
No	0
Unsure	16
Not Answered	28

70 Correct text size error in TGO 92

Yes	56
Partially agree	2
No	1
Unsure	22
Not Answered	29

73 Split the guidance

Yes	66
Partially agree	5
No	1
Unsure	12
Not Answered	26

FEEDBACK



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