

# Labelling | TGO 92 update

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Australian Government

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Therapeutic Goods Administration

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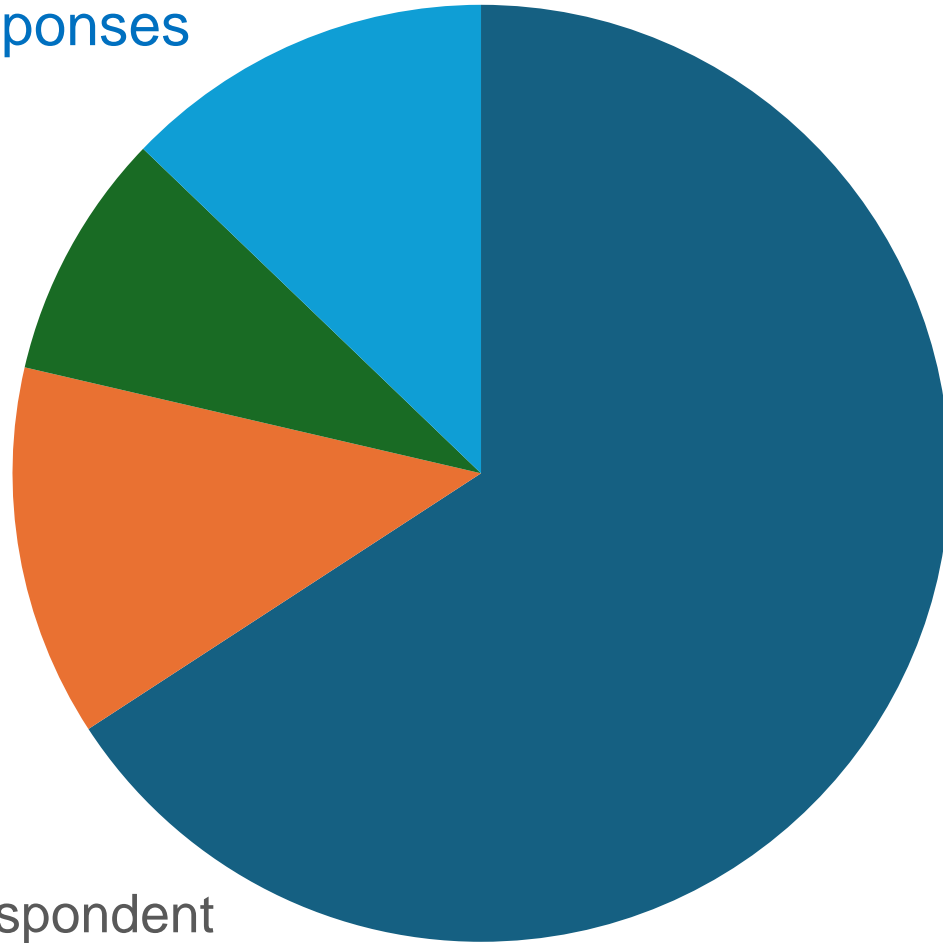
## Where we are

- 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?

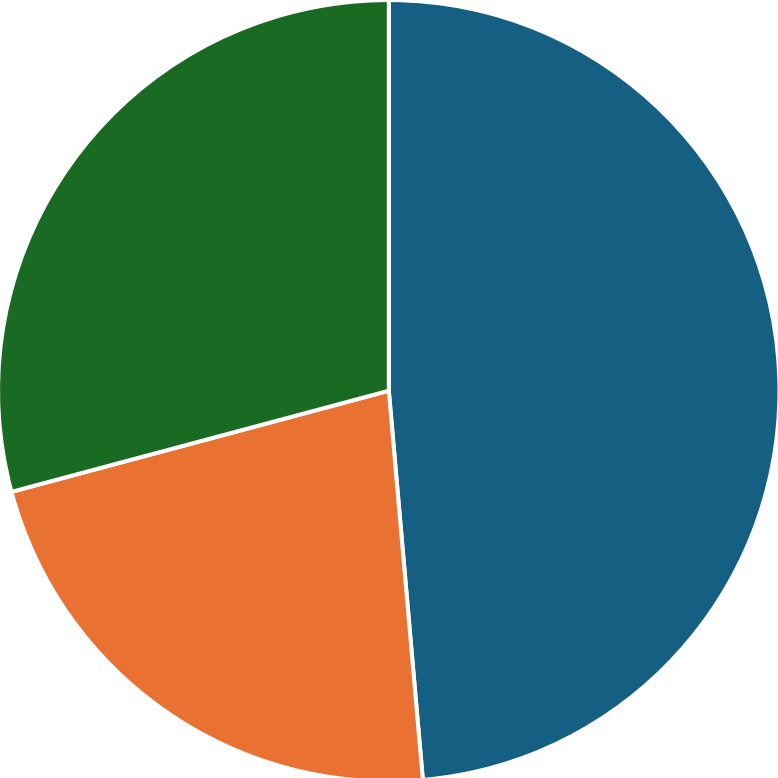
77 Commercial entities, including:

- 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:

<b>Option</b>	<b>Total</b>
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**



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