

Making a Submission

Please provide your responses in the relevant spaces in this response template. The questions below provide discussion points, it is not a requirement to comment on all sections or provisions of the Code.

This template is intended to assist you with your submission, IVD Australia welcomes any other submission format that is more suitable to you or your association. The text boxes will expand automatically when you enter text, however should you need more space than provided in the template, please add more information (by uploading a file) at the end of the each page.

*** 1. THIS SUBMISSION WAS MADE BY...**

Name

**On behalf of
(organisation/company)**

Email Address

General Questions

This section relates to the objectives, format and content.

2. Is the format of the Code user friendly and is it easy to find relevant sections?

Yes

No

Other (please specify)

3. Is the Code wording clear and easy to understand? Are there any specific sections that you think could be reworded to make them clearer?

Yes

No

Other (please specify)

4. Are all the major ethical issues regarding company interactions with healthcare professionals and consumers covered?

Yes

No

Other (please specify)

5. Are there any new and emerging issues that the Code should cover?

Yes

No

Other (please specify)

6. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part A: Introduction to the Code

These questions relate to the High Level Principles, Background & Purpose, Objectives and Scope.

7. Are the high level principles appropriate (Clause 1)?

- Yes
- No

Other (please specify)

8. Is there any text that should be included in the Background and Purpose (Clause 2)?

9. Are the Objectives (Clause 3) appropriate?

- Yes
- No

Other (please specify)

10. Do you agree with the approach IVD Australia has taken with regard to the scope being applicable to all of the Industry?

- Yes
- No

Other (please specify)

11. IVD Australia has elected to monitor (for 12 months) direct sponsorship of individual HCPs, whether as delegates or faculty, to Third Party Educational Events as of 1 January 2018. This has not been a significant issue in Australia to date. Do you agree?

- Agree
- Neither agree nor disagree
- Disagree

Other (please specify)

12. Do you think the Principles add value to the Code?

- Yes
- No

Other (please specify)

13. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part B: Provisions of the Code

Clause 6: Interaction with Consumers

Although the IVD industry currently has limited interactions with Consumers; in some cases, Consumers are able to directly purchase IVD products for their personal use.

14. Do the principles in Clause 6 meet the needs of Consumers?

Yes

No

Other (please specify)

15. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part B: Provisions of the Code

Clause 7: Interaction with Healthcare Professionals

The IVD industry interacts with a variety of customers, including pathologists and other medical practitioners, laboratory scientific and administrative staff, practice nurses and other Healthcare Professionals. The Code is intended to provide guidance on the interactions that Members and Member Representatives have with Healthcare Professionals in the promotion and supply of IVD Products.

This section is at the heart of the Code, dealing with the relationship between industry members and healthcare professionals in a variety of situations.

Please review each of the subsections which make up this section of the Code and provide comments where appropriate. Some questions which may guide your consideration of these subsections are...

16. Does this subsection cover all the relevant issues, including new & emerging promotional activities?

Yes

No

Other (please specify)

17. Does this subsection restrict or compromise the relationship between industry members and healthcare professionals?

Yes

No

Other (please specify)

18. Comments on Clause 7.1 Product Education, Demonstration and Training

19. Comments on Clause 7.2 Hospitality

20. Comments on Clause 7.3 Third Party Conferences

21. Comments on Clause 7.4 Sales & Promotion Meetings

22. Comments on Clause 7.5 Consulting Arrangements

23. Comments on Clause 7.6 Gifts

24. Comments on Clause 7.7 Donations & Grants

25. Comments on Clause 7.8 Advertising & Promotion

26. Comments on Clause 7.9 Company Commissioned Articles

27. Comments on Clause 7.10 Competitions

28. Comments on Clause 7.11 Market Research

29. Need more space for comments?

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Part B: Provisions of the Code

Clause 8: Social Media

This Clause applies to advertising on websites (including e-Newsletters accessible via the internet), podcasts and social media directed to Healthcare Professionals.

30. Does this subsection cover all the relevant issues, including new & emerging promotional activities?

Yes

No

Other (please specify)

31. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part B: Provisions of the Code

Clause 9: Company Representatives

32. Does this clause cover all the relevant issues?

33. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part B: Provisions of the Code

Clause 10: Financial Interests held by Healthcare Professionals

Where a Healthcare Professional owns a material, financial or other significant interest in a Member Company.

34. Does this clause cover all the relevant issues?

35. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part C: Administration of the Code

36. The formal procedures for conduct of complaints and appeals shall be determined by the Board of IVD Australia and reviewed annually to reflect best industry practice. The procedure shall be disseminated to members and published on the IVD Australia website on the page dedicated to the Code of Practice.

Is this appropriate?

Yes

No

Other (please specify)

37. Are the requirements for the Code Administration Committee appropriate?

Agree

Neither agree nor disagree

Disagree

Other (please specify)

38. Are the requirements for the Code Complaints Committee appropriate?

Agree

Neither agree nor disagree

Disagree

Other (please specify)

39. Is it appropriate for IVD Australia to publish upheld complaints?

- Agree
- Neither agree nor disagree
- Disagree

Other (please specify)

40. Are the definitions of breach severity appropriate?

- Yes
- No

Other (please specify)

41. Are the sanctions appropriate?

- Yes
- No

Other (please specify)

42. Are the requirements for Appeals Committee appropriate?

- Agree
- Neither agree nor disagree
- Disagree

Other (please specify)

43. Need more space for comments?

If you need more space to make comments, please upload a doc, docx, or pdf file here.

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Part D: Appendices to the Code

This section relates to interpretations, definitions, reference sources and resources.

44. IVD Australia has included a disclaimer to minimise inappropriate use of the Code. Is the disclaimer adequate?

- Agree
- Neither agree nor disagree
- Disagree

Other (please specify)

45. Do you have any comments on:

Interpretation	<input style="width: 100%; height: 20px;" type="text"/>
Definitions	<input style="width: 100%; height: 20px;" type="text"/>
References	<input style="width: 100%; height: 20px;" type="text"/>
Resources	<input style="width: 100%; height: 20px;" type="text"/>

46. Need more space for comments?

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OTHER COMMENTS

47. OTHER COMMENTS

IF YOU HAVE ANY OTHER COMMENTS THAT YOU WOULD LIKE TO MAKE, PLEASE ATTACH A FILE HERE

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