



In-vitro Diagnostic Devices Session

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IVD Session

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In-Vitro Diagnostic Session

- General Information on the Proposed System
- Consultation and Transitional Procedure
- Proposed Framework for IVDs



IVD Session

- Objectives -
 - To update industry and laboratories of a system currently being developed jointly by New Zealand and Australia to regulate IVDs
 - To further consult with stakeholders on the proposals
- The framework will be applied under the Agency to regulate diagnostic devices in both Australia and New Zealand



IVDs

- Draft Rules for regulating IVDs are being developed and will be released for review
- There will be a minimum period of 8 weeks for consultation
- The submissions will be considered and the Rules revised as appropriate
- The Ministerial Council will then approve the Rules



IVDs

- Consultation is required before deciding whether the proposed Australian framework for in-house diagnostics will be adopted in New Zealand
- In-vitro diagnostic devices are currently excluded from the WAND database
- It is expected that New Zealand companies will be given three years once the framework is agreed and in place, to comply with the requirements of the Joint Agency
- During that period companies will be able to continue to market the in-vitro diagnostic devices in New Zealand which they were marketing at the start of the Joint Agency



IVDs

- Once a company obtains a licence to market an IVD under the Joint Agency, they will be able to market the device in both Australia and New Zealand



Agency Database

- A sponsor is required to make only one entry on the Joint Agency database if a group of diagnostic devices have the same:
 - Manufacturer and
 - The same Classification (Class) and
 - Global Medical Device Nomenclature (GMDN code)



Who will have to obtain approval to market a diagnostic device in New Zealand

- A New Zealand sponsor importing an invitro diagnostic device from outside New Zealand and Australia
- If the New Zealand sponsor imports the diagnostic device from Australia it will not be required to be on the database
- A company manufacturing a diagnostic device in New Zealand or a sponsor who arranges for a company to manufacture a diagnostic device in New Zealand
- If an organisation /company purchases a diagnostic device within New Zealand, this organisation will not need to place the device on the database.