



# Quick NOTES

## Mutual Recognition Agreements

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MRAs



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### WHO DOES THIS APPLY TO:

- Importers of human and veterinarian drug products.

### KEY POINTS:

- Mutual Recognition Agreements (MRAs) with other countries mean that the Good Manufacturing Practices (GMPs) or equivalents used in those countries are recognized by each other.
- Canada is a participant to MRAs, covering human and veterinary drug/medicinal products GMP Compliance Programs, with the following Parties:
  - The European Community (EC):
    - Fourteen (14) of the fifteen (15) original Member States of the EC have signed and effective MRAs.
    - The 14 member states include: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden and United Kingdom. Luxemburg is not included in the operational phase as it does not have a GMP inspection programme.
    - The 10 new Member States include: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia. They joined on May 1st, 2004. Health Canada needs to evaluate and find their respective regulatory agreements (RAs) equivalent before they can be included on the 'signed and effective' list. They will be added to the list progressively as they are found equivalent.
  - Switzerland
  - European Economic Area:
    - European Free Trade Association (EEA – EFTA) member states that include: Republic of Ireland, the Principality of Liechtenstein and the Kingdom of Norway.
  - Australia (awaiting final Australian Parliamentary Treaty process).

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