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| **Country Information** |
| 1. Country identification and size of population | [ ]  AT [ ] BE [ ]  BG [ ]  CY [ ]  CZ [ ]  DE [ ]  DK [ ]  EE [ ]  EL [ ]  ES[ ]  FI [ ]  FR [ ]  HU [ ]  IE [x]  IS [ ]  IT [ ]  LI [ ]  LT [ ]  LU [ ]  LV[ ]  MT [ ] NL [ ]  NO [ ]  PL [ ]  PT [ ] RO [ ] SE [ ]  SI [ ]  SK [ ]  UK Population size: 320 000  |
| **Agency Information** |
| 2. Agency title and contact details | Name:Icelandic Medicines Agency Address:Vinlandsleid 14, 113 Reykjavík Phone:  +354 520 2100 Fax: +354 561 2170 E-mail: ima@ima.is  |
| 3. Head of Agency contact details  | Please fill CV below on page 4. |
| 4. Regular Representative at HMA Meetings | Please fill CV below on page 5 (if needed). |
| 5. Contact Person for HMA Issues | Name: Rannveig Gunnarsdóttir Phone:+ 354 520 2100 Mobile: +354 820 0211 Fax:+ 354 561 2170 E-mail: rannveig@ima.is  |
| 6. Type of agency / entity | [x]  Independent body[ ]  General Directorate. Please specify which Ministry:       [ ]  Other, please specify:        |
| 7. Date of establishment of the Agency | Date: 1. November 2000 Please provide any complementary information you may consider relevant:       |
| 8. Areas of competence[x]  Human medicinal products [x]  Veterinary medicinal productsx Medical Devices[ ]  Cosmetics[x]  Others  (please specify): Inspections, Clinical trials  |  |

Information updated on:

20.04.2012

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| **9. Responsibilities** | **Human** | **Veterinary** | **Medical Devices** | **Cosmetics** |
|  | Pharmacological (incl. chemical and biological/biotech) | Immunological | Homeopathic | Blood products | Herbals | Advanced therapies | Pharmacological | Immunological | Homeopathic | Blood products |  |  |
| Authorisation / registration | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | x[ ]  | [ ]  |
| Clinical Trials / Investigation | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | x[ ]  | [ ]  |
| Pharmacovigilance / Vigilance / Surveillance | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | x[ ]  | [ ]  |
| Inspection /Compliance | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | x[ ]  | [ ]  |
| Quality Control | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [ ]  | [ ]  |
| Batch release | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Pricing | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Health Technology Assessment (HTA) / Reimbursement | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Regulatory and scientific advice | [x]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Information to patients | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [ ]  | [ ]  |
| Information to healthcare professionals | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [ ]  | [ ]  |
| Advertising control | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [x]  | [ ]  | [ ]  |
| Residues monitoring | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Designation and supervision of Notified Bodies | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Other (please specify) |        |

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| **Human Resources** |
| 10. Total Number of Employees:57 Full Time: 44 Part-Time: 13 Full-Time equivalence: 51 Outsourced activities:  |
| 11. Identification of Internal Experts | Total Number:  |
| Areas of Expertise / Number of Experts |
| [x]  Quality  4 [x]  Pre-clinical  1 x[ ]  Clinical  7 [ ]  Species       [x]  Inspections 4 [ ]  Ecotoxicity       [ ]  Residues       [x]  Pharmacovigilance 2 [ ]  Others Please specify which:        |
| 12. Identification of External Experts (including outsource) | Total Number:        |
| Areas of Expertise / Number of Experts |
| Quality [x]  Pre-clinical 1 [x]  Clinical 2 Species 2 Inspections [ ]  Ecotoxicity       [ ]  Residues       Pharmacovigilance [ ]  Others Please specify which:        |
| **Funding** |
| 13. Funding | [ ]  Budget (state budget) % of budget:      x Fees (Industry fees/taxes) % of budget: 100% [ ]  Other Please specify which:        |
| 14. Total of expenses (Euros) | 2010: 2,5, m  | 2011: 2.7 m  |
| 15. Total of revenues (Euros) | 2010: 2,5 m  | 2011: 2.7 m  |
| **Activities** |
| 16. Mission of the organisation (max. 200 characters):Is to promote the health of humans and animals by evaluating the efficacy, quality and safety of human and veterinary medicinal products and quality and safety of medical devices. |
| 17. Complementary information | In the case you may consider it useful, please provide complementary information which could clarify any of the issues mentioned above or any specific understanding of your agency on any specific issue or activity (max 200 characters):      |

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| Name of the person responsible for completing this questionnaire: | Rannveig Gunnarsdóttir  | Information updated on: 20.04.2012  |

**Head of Agency**

**Curriculum Vitae**

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| **Name of Head of Agency:** |  | *1* |
|   Rannveig Gunnarsdóttir  |  |  |
| **Academic / Professional title:** | M.Sc.,Exec.Director  |  |  |
| **Name of Agency:** | Icelandic Medicines Agency  |  |  |

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| **Country:**  |
| [ ]  AT [ ] BE [ ]  BG [ ]  CY [ ]  CZ [ ]  DE [ ]  DK [ ]  EE [ ]  EL [ ]  ES [ ]  FI [ ]  FR [ ]  HU [ ]  IE [x]  IS [ ]  IT [ ]  LI [ ]  LT [ ]  LU [ ]  LV [ ]  MT [ ] NL [ ]  NO [ ]  PL [ ]  PT [ ] RO [ ] SE [ ]  SI [ ]  SK [ ]  UK       |

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| **Contact details:** |
| Address: Vinlandsleid 14, 113 Reykjavík Telephone: +354 520 2100 Mobile: +354 820 0211 Fax: +354 561 2170 E-mail: rannveig@ima.is  |

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| **Years within the agency:** | 12 |

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| **Education** (Institution, area/field pf expertise, country, date) (max. 300 characters):: |
| 1999 University of Iceland - course in Management in Health Care1976 London University, Chelsea College, M.Sc. Biopharmacy1972 University of Iceland, pharmacy degree |

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| **Professional experience** (Institution/company, country, position, date. Please provide only information on your current and last 2 jobs). (max. 400 characters): |
| Executive Director IMA 2000-Managing Director, The State Pharmaceutical Committee 1996-2000Director Pharmaceutical Affairs- Ministry of Health and Social Securities 1995-1996Director, Hospital Pharmacy – The National Hospital, Landspitali, Reykjavik, 1990-1995 |

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| **Specialisation**Please provide details (max. 300 characters): |
|  M.Sc. Bioapharmacy , trained for 7 months at Middlesex Hospital London, employed at the University Hospital Iceland from 1976. Course in management in health care 1997-1999 at the University of Iceland |

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| **Member of any HMA Working Group:** | Availability Task Force- human MPs.  | Information updated on: 20.04.2012  |