



**PHARMACEUTICAL INSPECTION CONVENTION  
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

PS/INF 21/2002 (Rev. 22)  
27 October 2016

**LIST OF PIC/S PARTICIPATING AUTHORITIES**

(in the alphabetical order of the country / entity in which they are located)

|                             | <b>PARTICIPATING AUTHORITY</b>   | <b>ACRONYM</b> |
|-----------------------------|--|----------------|
| Argentina                   | Instituto Nacional de Medicamentos ( <i>National Institute of Drugs</i> )  | INAME          |
| Australia                   | Therapeutic Goods Administration   | TGA            |
| Austria                     | Austrian Agency for Health and Food Safety   | AGES           |
| Belgium                     | Agence Fédérale des Médicaments et des Produits de Santé ( <i>Federal Agency for Medicines and Health Products</i> )   | AFMPS          |
| Canada                      | Health Canada - Regulatory Operations and Regions Branch ( <i>Santé Canada - Direction générale des opérations réglementaires et des régions</i> )                           | RORB           |
| Chinese Taipei              | Taiwan Food and Drug Administration  | TFDA           |
| Croatia                     | Agency for Medicinal Products and Medical Devices of Croatia ( <i>Agencija za lijekove i medicinske proizvode</i> )  | HALMED         |
| Cyprus                      | Pharmaceutical Services  | CyPHS          |
| Czech Republic <sup>1</sup> | Státní Ústav pro Kontrolu Léčiv ( <i>State Institute for Drug Control</i> )  | SÚKL           |
|                             | Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv ( <i>Czech Institute for State Control of Veterinary Biologicals and Medicines</i> )                            | ISCVBM         |
| Denmark                     | Danish Medicines Agency  | DKMA           |
| Estonia                     | State Agency of Medicines  | SAM            |
| Finland                     | Finnish Medicines Agency   | FIMEA          |
| France <sup>2</sup>         | Agence nationale de sécurité du médicament et des produits de santé ( <i>French National Agency for Medicines and Health Products Safety</i> )                               | ANSM           |
|                             | Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail ( <i>French Agency for Food, Environmental &amp; Occupational Health Safety</i> ) | ANSES          |

<sup>1</sup> SÚKL and ÚSKVBL count as two distinct Participating Authorities.

<sup>2</sup> ANSM and ANSES count as two distinct Participating Authorities.

|                      | <b>PARTICIPATING AUTHORITY</b>   | <b>ACRONYM</b> |
|----------------------|--|----------------|
| Germany <sup>3</sup> | Bundesministerium für Gesundheit ( <i>Federal Ministry of Health</i> )   | BMG            |
|                      | Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ( <i>Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices</i> ) | ZLG            |
| Greece               | Εθνικός Οργανισμός Φαρμάκων ( <i>National Organization for Medicines</i> )   | EOF            |
| Hong Kong SAR        | Pharmacy and Poisons Board of Hong Kong  | PPBHK          |
| Hungary              | National Institute of Pharmacy and Nutrition (NIPN)  | NIPN           |
| Iceland              | The Icelandic Medicines Agency   | IMA            |
| Indonesia            | National Agency for Drug and Food Control  | NADFC          |
| Ireland              | Health Products Regulatory Authority   | HPRA           |
| Israel               | Institute for the Standardization and Control of Pharmaceuticals   | ISCP           |
| Italy                | Agenzia Italiana del Farmaco   | AIFA           |
| Japan <sup>4</sup>   | Ministry of Health, Labour and Welfare   | MHLW           |
|                      | Pharmaceuticals and Medical Devices Agency   | PMDA           |
|                      | Japanese Prefectures   | -              |
| Korea (Republic of)  | Ministry of Food and Drug Safety   | MFDS           |
| Latvia               | Zāļu Valsts Aģentūra ( <i>State Agency of Medicines</i> )  | ZVA            |
| Liechtenstein        | Amt für Gesundheit ( <i>Office of Healthcare</i> )   | AG             |
| Lithuania            | State Medicines Control Agency   | SMCA           |
| Malaysia             | National Pharmaceutical Regulatory Agency  | NPRA           |
| Malta                | Medicines Authority Malta  | MAM            |
| Netherlands          | Inspectie voor de Gezondheidszorg ( <i>Dutch Health Care Inspectorate</i> ) <sup>5</sup>   | IGZ            |
| New Zealand          | Medicines and Medical Devices Safety Authority   | Medsafe        |
| Norway               | Norwegian Medicines Agency   | NOMA           |
| Poland               | Main Pharmaceutical Inspectorate   | MPI            |

<sup>3</sup> BMG and ZLG count as one Participating Authority. All German Medicinal Authorities, which are listed on the ZLG web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by ZLG.

<sup>4</sup> MHLW, PMDA and the Japanese Prefectures count as one Participating Authority. The Japanese Prefectures are represented by MHLW.

<sup>5</sup> The competence for GMP/GDP inspections in the Netherlands is allocated to the central authority, Dutch Healthcare Inspectorate (IGZ). IGZ is the PIC/S Participating Authority representing GMP/GDP for human as well as veterinary medicinal products. IGZ performs national and international GMP/GDP inspections representing the Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology as well as the Medicines Evaluation Board - Veterinary Medicinal Products Unit, which is mandated to issue GMP certificates on behalf of the Ministry of Economic Affairs.

|                             | <b>PARTICIPATING AUTHORITY</b>   | <b>ACRONYM</b> |
|-----------------------------|--|----------------|
| Portugal                    | Autoridade Nacional do Medicamento e Produtos de Saúde IP ( <i>National Authority of Medicines and Health Products IP</i> )      | INFARMED IP    |
| Romania                     | National Agency for Medicines and Medical Devices  | NAMMD          |
| Singapore                   | Health Sciences Authority  | HSA            |
| Slovak Republic             | State Institute for Drug Control   | SIDC           |
| Slovenia                    | Agency for Medicinal Products and Medical Devices  | JAZMP          |
| South Africa                | Medicines Control Council  | MCC            |
| Spain                       | Agencia Española de Medicamentos y Productos Sanitarios ( <i>Spanish Agency for Medicines and Medical Devices</i> ) <sup>6</sup> | AEMPS          |
| Sweden                      | Medical Products Agency  | MPA            |
| Switzerland                 | Swiss Agency for Therapeutic Products  | Swissmedic     |
| Thailand                    | Food and Drug Administration   | Thai FDA       |
| Ukraine                     | State Service of Ukraine on Medicines and Drugs Control  | SMDC           |
| United Kingdom <sup>7</sup> | Medicines and Healthcare Products Regulatory Agency  | MHRA           |
|                             | Veterinary Medicines Directorate   | VMD            |
| United States of America    | United States Food and Drug Administration   | US FDA         |

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<sup>6</sup> The competence for GMP/GDP inspections in Spain is shared between the central authority, Spanish Agency for Medicines and Medical Devices (AEMPS), and the Spanish regional authorities, which count as one PIC/S Participating Authority. All Spanish Medicinal Authorities, which are listed on AEMPS' web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by AEMPS.

<sup>7</sup> MHRA and VMD count as two distinct Participating Authorities.