

ANNEX IV

CONTACT LIST FOR THE NETWORK OF COMPETENT AUTHORITIES FOR IVMPs

Annex to procedure for application of Article 81 and procedure for application of Article 82 in the European Community

For the purpose of rapid information exchange and exchange of certificates of non-compliance the Competent Authorities or their officially designated representatives should be contacted.

(compiled e-mails list at the end of the document)

| Contacts | Competent Authority | OMCL For IVMP |
|---|---|----------------------|
| <u>European Union Member States</u> | | |
| AUSTRIA | | |
| Organisation: Austrian Federal Office for Safety in Health Care (BASG) Traisengasse 5 1200 WIEN Contact: Dieter PULLIRSCH Phone: +43 50555 36369 Fax: +43 1 50555 36309 E-mail: omcl-at@ages.at | YES | √ |
| BELGIUM | | |
| Organisation: Sciensano Rue Juliette Wytsman 14 1050 BRUSSELS Contact: Aude DELFERRIERE / Sidney LEVI Phone : +32 2 642 50 51 E-mail: batchrelease@sciensano.be ; | Officially designated to act on behalf of the CA | √ |
| BULGARIA | | |
| Organisation: Bulgarian Food Safety Agency Directorate for Control of Veterinary Medicinal Products 7 Shose Bankya Str. 1331 SOFIA Contact: Vladislav PETKOV Phone: +359 882 469 651 Fax: +357 2 925 14 35 E-mail: vpetkov@itp.bg | YES | √ |

| Contacts | Competent Authority | OMCL For IVMP |
|--|---------------------|---------------|
| CROATIA | | |
| <p>Organisation: Croatian Veterinary Institute Zagreb Savska cesta 143 10 000 ZAGREB</p> <p>Contact: TBD Phone: E-mail:</p> | - | √ |
| CYPRUS | | |
| <p>Organisation: Veterinary Services Ministry of Agriculture, Veterinary Public Health Division 1417 NICOSIA</p> <p>Contact: Apostolos MAZERIS Phone: + 357 22 805 208 Fax: +357 22 332803 E-mail: amazeris@vs.moa.gov.cy</p> | YES | - |
| CZECH REPUBLIC | | |
| <p>Organisation: Institute for State Control of Veterinary Biologicals and Medicaments Hudecova, 56a 621 00 BRNO - MEDLÁNKY</p> <p>Contact: Dana PIVODOVÁ Phone: +42 05 41 51 82 42 Fax: +42 05 41 21 00 26 E-mail: batchrelease@uskvbl.cz</p> | YES | √ |
| DENMARK | | |
| <p>Organisation: Danish Health and Medicines Authority Axel Heides Gade 1 2300 KØBENHAVN S</p> <p>Contact: Leif Kongskov Larsen Phone: +45 93 59 02 03 Fax: +45 44 94 36 76 E-mail: biologi@dkma.dk</p> | YES | √ |
| ESTONIA | | |
| <p>Organisation: State Agency of Medicines 1 Nooruse Street 50411 TARTU</p> <p>Contact: Eveli HOLST Phone: +372 7 374 154 / +372 7 374 140 Fax: +372 7 374 142 E-mail: Eveli.Holst@ravimiamet.ee / info@ravimiamet.ee</p> | YES | - |

| Contacts | Competent Authority | OMCL For IVMP |
|--|---------------------|---------------|
| FINLAND | | |
| <p>Organisation: Finnish Food Authority Virology Unit - PO Box 100 00027 FINNISH FOOD AUTHORITY</p> <p>Contact: Niina TAMMIRANTA Phone: +358 40 4893377 Fax: +358 29 5304363 E-mail: niina.tammiranta@foodauthority.fi / niina.tammiranta@ruokavirasto.fi; batch.release@foodauthority.fi, batch.release@ruokavirasto.fi</p> | YES | √ |
| FRANCE | | |
| <p>Organisation: ANSES - ANMV 14 rue Claude Bourgelat - Parc d'activités de la Grande Marche – Javené - CS 70611 35306 FOUGÈRES</p> <p>Contact: Mickaëlle SACHET / Valérie LE COUTOUR Phone: +33 299 94 66 65 Fax: +33 299 94 66 71 E-mail: mickaelle.sachet@anses.fr / valerie.lecoutour@anses.fr</p> | YES | - |
| <p>ANSES - LRFSN Technopole Agricole et Vétérinaire Bat H CS 40 009 54220 MALZEVILLE</p> <p>Contact: Marine WASNIEWSKI / Alexandre SERVAT Phone: +33 383 29 89 50 Fax: +33 383 29 89 58 E-mail: marine.wasniewski@anses.fr / alexandre.servat@anses.fr</p> | - | √ |
| GERMANY | | |
| <p>Organisation: Paul-Ehrlich-Institut Paul Ehrlich Str. 51-59 63225 LANGEN</p> <p>Contact: Michael MUEHLEBACH Phone: +49-6103 77 4005 Fax: +49 6103 77 1254 E-mail: veterinaermedizin@pei.de</p> | YES | √ |
| GREECE | | |
| <p>Organisation: National Organisation for Medicines 284 Mesogeion Avenue, Cholargos 15562 ATHENS</p> <p>Contact: Vassilis VIOLAKIS Phone: +30 213 2040331, -221 Fax: +30 213 2040562 E-mail: vviolakis@eof.gr</p> | YES | - |

| Contacts | Competent Authority | OMCL For IVMP |
|---|---------------------|---------------|
| HUNGARY | | |
| <p>Organisation: NFCSO Directorate of Veterinary Medicinal Products Szállás u. 8 1107 BUDAPEST</p> <p>Contact: Gábor KULCSAR Phone: : + 36 1 43 00 33 Fax: +36 1 262 28 39 E-mail: kulcsarg@nebih.gov.hu</p> | YES | - |
| <p>NFCSO Food Chain Safety Laboratory Directorate Control Laboratory of Veterinary Medicinal Products and Animal Facility Szállás u. 8 1107 BUDAPEST</p> <p>Contact: Tamás GAZSÓ / Réka FELFÖLDINÉ LÉVAI Phone: +36 30 6122685 / +36 70 9039579 E-mail: gazsot@nebih.gov.hu; levair@nebih.gov.hu</p> | - | √ |
| IRELAND | | |
| <p>Organisation: Irish Medicines Board Kevin O'Malley House Earlsfort Terrace D02 XP77 - DUBLIN 2</p> <p>Contact: Kevin O'DONNELL Phone: +353 1 676 4971 Fax: +353 1 676 7836 E-mail: kevin.odonnell@hpra.ie</p> | YES | √ |
| ITALY | | |
| <p>Organisation: Ministero della Salute (Ministry of Health) Direzione Generale della Sanità Animale e dei Farmaci Veterinari (Direction General for Animal Health and Veterinary Medicinal Products) Ufficio 05 Viale Giorgio Ribotta 5 00144 ROMA</p> <p>Contact: Virgilio DONINI Phone: +39 06 59 94 65 90 Fax: +39 06 59 94 69 49 E-mail: v.donini@sanita.it</p> | YES | - |

| Contacts | Competent Authority | OMCL For IVMP |
|--|---------------------|---------------|
| LATVIA | | |
| <p>Organisation: Division of the Marketing Authorisation for Veterinary Medicinal Products Food and Veterinary Service Peldu Str.30 1050 RIGA</p> <p>Contact: Santa ZIRNITE Phone: +371 67 08 46 17 Fax: +371-67 32 27 27 E-mail: santa.zirnite@pvd.gov.lv</p> | YES | - |
| LITHUANIA | | |
| <p>Organisation: State Food and Veterinary Service Republic of Lithuania Siesikų Str. 19 07170 VILNIUS</p> <p>Contact: Sigitas SIRIUKAITIS Phone: +370 5 249 16 26 Fax: + 370 5 240 43 62 E-mail: sigitas.siriukaitis@vmvt.lt</p> | YES | - |
| LUXEMBOURG | | |
| <p>Organisation: Laboratoire National de Santé Service de Chimie Pharmaceutique 1, Rue Louis Rech 3555 DUDELANGE</p> <p>Contact: Claude MARSON Phone: +352 28100 651 (Secrétariat)/+352 28100 657 (Claude Marson) Fax: +00352 28100 652 E-mail: claudemarson@lms.etat.lu</p> | YES | - |
| MALTA | | |
| <p>Organisation: Ministry of Rural Affairs and Environment Food and Veterinary Regulatory Division Albertown GBY-MARSA</p> <p>Contact: Stephan PSAILA Phone: +356 2590 5376 Fax: +356 2123 8105 E-mail: stephan.psaila@gov.mt</p> | YES | - |

| Contacts | Competent Authority | OMCL For IVMP |
|--|---|---------------|
| NETHERLANDS | | |
| <p>Organisation: Medicines Evaluation Board-Veterinary Medicinal Products Unit Graadt van Roggenweg 500 3531 AH UTRECHT</p> <p>Contact: Tom VAN DER HEIJDEN Phone: +31 88 224 8097 Fax: +31 88 224 8001 E-mail: t.vd.heijden@cbg-meb.nl</p> | Officially designated to act on behalf of the CA | |
| POLAND | | |
| <p>Organisation: National Veterinary Research Institute 57 Partyzantów Avenue 24-100 PUŁAWY</p> <p>Contact: Katarzyna SZYMANEK Phone: +48 81 889 3322 Fax: +48 81 887 71 00 E-mail: katarzyna.szymanek@piwet.pulawy.pl</p> | YES | √ |
| PORTUGAL | | |
| <p>Organisation: Ministério da Agricultura e do Mar Direção Geral de Alimentação e Veterinária Campo Grande nº 50 1700-093 LISBOA</p> <p>Contact: Ana Sofia CANTO/Antonio BATISTA Phone: +351 217 808 204 Fax: +351 213 463 518 E-mail: ana.canto@dgav.pt, abatista@dgav.pt</p> | YES | - |
| ROMANIA | | |
| <p>Organisation: Institute for Control of Veterinary Biological Products and Medicines 39, Dudului Street, Sector 6 060603 BUCHAREST</p> <p>Contact: Steluța ROȘU Phone: +40 21 22 02 112 Fax: +40 21 22 13 171 E-mail: icbmv@icbmv.ro</p> | YES | √ |

| Contacts | Competent Authority | OMCL For IVMP |
|---|---------------------|---------------|
| SLOVAK REPUBLIC | | |
| <p>Organisation: Institute for State Control of Vet. Biologicals and Medicines USKVBL Biovetská, 34 P.O. Box 52c 94901 NITRA</p> <p>Contact: Katarína MASSÁNYIOVÁ Phone: +421 37 65 15 506 (or 507) Fax: +421 37 65 17 915 E-mail: massanyiova@uskvbl.sk</p> | YES | √ |
| SLOVENIA | | |
| <p>Organisation: National Laboratory of Health, Environment and Food Prvomajska ulica 1 2000 MARIBOR</p> <p>Contact: Anja KNEŽEVIĆ Phone: +386 8 2006 328 Fax: +386 1 237 35 90 E-mail: posebna.kontrola@nlzoh.si</p> | YES | √ |
| SPAIN | | |
| <p>Organisation: Agencia Española de Medicamentos y Productos Sanitarios Calle Campezo 1 28022 MADRID</p> <p>Contact: Dra Consuelo RUBIO Phone: +34 91 822 54 03 Fax: +34 91 822 54 43 E-mail: vet.vaccines.spain@aemps.es</p> | YES | - |
| SWEDEN | | |
| <p>Organisation: Medical Products Agency Dag Hammarskjölds väg 42 Box 26 - SE-75103 UPPSALA</p> <p>Contact: Karl-Henrik JÖNSSON / Peter STJARNKVIST Phone: +46 18 17 4600 Fax: +46 18 54 8566 E-mail: karl-henrik.jonsson@mpa.se / peter.stjarnkvist@mpa.se</p> | YES | √ |

| <u>EEA MEMBER STATES</u> | | |
|--|------------------|---|
| ICELAND | | |
| Organisation: Institute for Experimental Pathology University of Iceland, Keldur - 8540 128 REYJAVIK Contact: Eggert GUNNARSSON Phone: +354 5 67 47 69 Fax: +354 5 67 39 79 E-mail: eggun@hi.is | YES | - |
| NORWAY | | |
| Organisation: Norwegian Medicines Agency Sven Oftedals vei 6 8 0950 OSLO Contact: Ane Marit KVINGEDAL Phone: +47 22 89 77 66 Fax: +47 22 89 77 99 E-mail: ane.kvingedal@legemiddelverket.no | YES | - |
| <u>Mutually Recognised Partners</u> | | |
| SWITZERLAND | | |
| Organisation: Institut für Viruskrankheiten and Immunoprophylaxe (IVI) Sensemattstrasse 293 3147 MITTELHÄUSERN Contact: Hans-Peter OTTIGER / Nathalie ALBRECHT Phone: +41 318 489 211 Fax: +41 318 489 222 E-mail: vaccinovigilance@ivi.admin.ch | YES | √ |
| <u>European Commission – DG Health and Consumers *</u> | | |
| Organisation: European Commission Unit E5 - “Animal nutrition, veterinary medicines”, Directorate-General for Health and Food Safety – “Food and feed safety, innovation” 1049 BRUSSELS BELGIUM Contact: Eva ZAMORA ESCRIBANO Phone: +32 2 29 98682 E-mail: eva-maria.zamora-escribano@ec.europa.eu ; sante-consult-e5@ec.europa.eu | Official Contact | |
| <u>European Medicines Agency *</u> | | |
| Organisation: EMA - European Medicines Agency Domenico Scarlattilaan 6 1083 HS AMSTERDAM THE NETHERLANDS Contact: Javier POZO GONZALEZ Telephone: +31 (0) 88 781 7558 E-mail: javier.pozogonzalez@ema.europa.eu | Official Contact | |

European Directorate for the Quality of Medicines *

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* Note: EC, EMA and EDQM contacts should receive all information circulated to the CAs or their designated representatives

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niina.tammiranta@foodauthority.fi; batch.release@foodauthority.fi; batch.release@ruokavirasto.fi
valerie.lecoutour@anses.fr; mickaelle.sachet@anses.fr; marine.wasniewski@anses.fr;
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v.donini@sanita.it; sigitas.siriukaitis@vmvt.lt; claudemarson@lms.etat.lu; stephan.psaila@gov.mt;
t.vd.heijden@cbg-meb.nl; katarzyna.szymanek@piwet.pulawy.pl ; ana.canto@dgav.pt; abatista@dgav.pt;
icbm@icbm.ro; massanyiova@uskvbl.sk; santa.zirnite@pvd.gov.lv; posebna.kontrola@nlzoh.si;
vet.vaccines.spain@aemps.es; karl-henrik.jonsson@mpa.se; eggund@hi.is;
ane.kvingedal@legemiddelverket.no; vaccinovigilance@ivi.admin.ch; eva-maria.zamora-escribano@ec.europa.eu; sante-consult-e5@ec.europa.eu; BatchReleaseVet@edqm.eu;
javier.pozogonzalez@ema.europa.eu; kulcsarg@nebih.gov.hu; levair@nebih.gov.hu; gazsot@nebih.gov.hu;
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