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OFICIO 3000-0040-21

Bogotá D.C., febrero de 2021

Asunto: Acuso Recibo de Eventos Adversos Serios

Dando cumplimiento a lo estipulado en la Resolución No. 2011020764 del 10 de junio de 2011 “*Por la cual se establece el reglamento relativo al contenido y periodicidad de los reportes de eventos adversos en la fase clínica con medicamentos en humanos de que trata el artículo 146 del decreto 677 de 1995*”, la Dirección de Medicamentos y Productos Biológicos del **Invima**, da acuso de recibo de la información allegada con los siguientes radicados, correspondientes al reporte de eventos adversos serios nacionales e internacionales y otros documentos relacionados. El Invima en cualquier momento y como parte del proceso de análisis de la información, podrá requerir datos adicionales, para efectos de Inspección, Vigilancia y Control.

Eventos Adversos Serios Nacionales

| RADICADO | FECHA RADICADO | PATROCINADOR o CRO | CODIGO INVIMA |
|-------------|----------------|--|--|
| 20201009661 | 20/01/2020 | Bayer S.A | PI-BH-1012 |
| 20201009685 | 20/01/2020 | Bayer S.A | PI-BH-1012 |
| 20201007427 | 15/01/2020 | MSD | PI-MS-1043 PI-MS-1273 PI-MS-1299 PI-MS-1248 PI-MS-1260 |
| 20201008198 | 17/01/2020 | Pfizer S.A.S / ICON Clinical Research representado en Colombia por ICON Holdings Clinical Research International Sucursal Colombia | PI-PF-899 |
| 20201008199 | 17/01/2020 | Pfizer S.A.S / ICON Clinical Research representado en Colombia por ICON Holdings Clinical Research International Sucursal Colombia | PI-PF-1146 |
| 20201008303 | 17/01/2020 | Amgen Biotecnológica S.A.S | PI-AG-1115 |
| 20201006637 | 15/01/2020 | Boehringer Ingelheim Colombia S.A | PI-LBI-1121 |



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| 20201013961 | 24/01/2020 | Bayer S.A. | PI-BH-773 |
| 20201013966 | 24/01/2020 | Bayer S.A. | PI-BH-773 |
| 20201014795 | 27/01/2020 | Amgen Biotecnológica S.A.S | PI-AG-1115 |
| 20201015634 | 28/01/2020 | Pfizer S.A.S | PI-PF-1146 |
| 20201015957 | 28/01/2020 | Bayer S.A. | PI-BH-991 |
| 20201015970 | 28/01/2020 | Bayer S.A. | PI-BH-1012 |
| 20201212851 | 13/11/2020 | Universidad Nacional | PI-UN-1391 |
| 20211004574 | 14/01/2021 | Janssen Vaccines & Prevention B.V. / IQVIA RDS Colombia S.A.S | PI-JC-1419 |
| 20191215933 | 01/11/2019 | Pfizer Colombia S.A.S. | PI-PF-899 |
| 20191216052 | 01/11/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191216054 | 01/11/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191216056 | 01/11/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191216165 | 01/11/2019 | Amgen Inc | PI-AG-1115 |
| 20191216192 | 01/11/2019 | Bayer S.A. | PI-BH-1012 |
| 20191216240 | 01/11/2019 | Novo Nordisk A/S | PI-NN-1250 |
| 20191216300 | 01/11/2019 | Merck Sharp & Dohme Colombia S.A.S. | PATROCINADOR |
| 20191216923 | 05/11/2019 | Pfizer Inc. | PI-PF-1146 |
| 20191217419 | 05/11/2019 | Amgen Inc | PI-AG-1115 |
| 20191214788 | 31/10/2019 | Pfizer Inc. | PI-PF-1146 |
| 20191215062 | 31/10/2019 | Amgen Inc | PI-AG-1115 |
| 20191215205 | 31/10/2019 | Bayer S.A. | PI-BH-1012 |



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| 20191215209 | 31/10/2019 | Bayer S.A. | PI-BH-1012 |
| 20191213928 | 30/10/2019 | Novartis Colombia S.A. | PI-NO-1111 |
| 20191228213 | 19/11/2019 | Bayer S.A. | PI-BH-773 |
| 20191228214 | 19/11/2019 | Bayer S.A. | PI-BH-1010 |
| 20191228222 | 19/11/2019 | Bayer S.A. | PI-BH-1012 |
| 20191228223 | 19/11/2019 | Bayer S.A. | PI-BH-773 |
| 20191228226 | 19/11/2019 | Bayer S.A. | PI-BH-1012 |
| 20191228227 | 19/11/2019 | Bayer S.A. | PI-BH-773 |
| 20191228229 | 19/11/2019 | Bayer S.A. | PI-BH-1012 |
| 20191228233 | 19/11/2019 | Bayer S.A. | PI-BH-1004 |
| 20191229143 | 20/11/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191229136 | 20/11/2019 | Novartis Colombia S.A. | PI-NO-1111 |
| 20191231924 | 25/11/2019 | Pfizer Inc. | PI-PF-1146 |
| 20191231928 | 25/11/2019 | Pfizer Inc. | PI-PF-899 |
| 20191232208 | 25/11/2019 | Sanofi Aventis de Colombia S.A. | PI-SA-1176 |
| 20191233140 | 26/11/2019 | Bayer S.A. | PI -BH-773 |
| 20191233148 | 26/11/2019 | Bayer S.A. | PI -BH-773 |
| 20191233151 | 26/11/2019 | Bayer S.A. | PI -BH-773 |
| 20191233227 | 26/11/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191233604 | 26/11/2019 | Amgen Inc | PI-AG-1115 |
| 20191232236 | 25/11/2019 | Novartis Colombia S.A. | PI-NO-1111 |
| 20191233145 | 26/11/2019 | Bayer S.A. | PI-BH-1012 |
| 20191233168 | 26/11/2019 | Bayer S.A. | PI-BH-1010 |
| 20191233175 | 26/11/2019 | Bayer S.A. | PI-BH-1012 |
| 20191248819 | 13/12/2019 | Pfizer Inc. | PI-PF-899 |



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| 20191249181 | 13/12/2019 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1235 |
| 20191249239 | 13/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191249247 | 13/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191250388 | 16/12/2019 | Novartis Colombia S.A. | PI-NO-1111 |
| 20191250714 | 16/12/2019 | Bayer S.A. | PI-BH-1010 |
| 20191250719 | 16/12/2019 | Bayer S.A. | PI-BH-1010 |
| 20191257847 | 23/12/2019 | Astrazeneca | PI-AZ-25 |
| 20191258305 | 24/12/2019 | Bayer S.A. | PI - BH-773 |
| 20191259109 | 27/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191259134 | 27/12/2019 | Bayer S.A. | EO-BH-169 |
| 20191259439 | 30/12/2019 | Novartis Colombia S.A. | PI-NO-1111 |
| 20191247599 | 12/12/2019 | Amgen Inc | PI-AG-1115 |
| 20191251874 | 17/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191251925 | 17/12/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191252610 | 18/12/2019 | Abbvie SAS | PI-ABS-1259 |
| 20191252639 | 18/12/2019 | Pfizer Inc. | PI-PF-1146 |
| 20191252720 | 18/12/2019 | Novo Nordisk A/S | PI-NN-1250 |
| 20191252886 | 18/12/2019 | Amgen Inc | PI-AG-1115 |
| 20191252973 | 18/12/2019 | Boehringer Ingelheim Colombia S.A. | PI-LBI-1121 |
| 20191253055 | 18/12/2019 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1130 |
| 20191254909 | 19/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191254914 | 19/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191254916 | 19/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191256842 | 20/12/2019 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1260 |



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| 20191256911 | 20/12/2019 | Bayer S.A. | PI-BH-1012 |
| 20191257817 | 23/12/2019 | Amgen Inc | PI-AG-1115 |
| 20191258303 | 23/12/2019 | Bayer S.A. | PI-BH-773 |
| 20191258307 | 24/12/2019 | Bayer S.A. | PI-BH-773 |
| 20191258522 | 24/12/2019 | Pfizer Inc. | PI-PF-1146 |
| 20191258965 | 27/12/2019 | AstraZeneca | PI-AZ-1245 |
| 20191259547 | 30/12/2019 | Amgen Inc | PI-AG-1115 |
| 20191259568 | 30/12/2019 | Sanofi Aventis de Colombia S.A. | PI-SA-1295 |
| 20191244117 | 09/12/2019 | Novartis Colombia S.A. | PI-NO-1111 |
| 20191252977 | 18/12/2019 | Boehringer Ingelheim Colombia S.A. | PI-PP-423 |

Eventos Adversos Serios Internacionales

| RADICADO | FECHA | PATROCINADOR o CRO | CODIGO INVIMA |
|-----------------|--------------|---|----------------------|
| 20201004146 | 13/01/2020 | Akebia Therapeutics, Inc./IQVIA RDS Colombia S.A.S | PI-AT-1142 |
| 20201004147 | 13/01/2020 | Kowa Research Institute, Inc / IQVIA RDS Colombia S.A.S | PI-KW-1124 |
| 20201009674 | 20/01/2020 | Bayer S.A | PI-BH-1139 |
| 20201020166 | 03/02/2020 | Bayer S.A | PI-BH-1034 |
| 20201020195 | 03/02/2020 | Bayer S.A | PI-BH-773 |
| 20201022024 | 05/02/2020 | Abbvie S.A.S | Abbvie S.A.S |
| 20201023904 | 07/02/2020 | CSL Behring LLC (CSLB)/Covance Colombia | PI-CS-1244 |



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| | | Services Ltda. | |
| 20201021922 | 05/02/2020 | Novo Nordisk | PI-NN-1250 |
| 20201019882 | 03/02/2020 | Apellis | n/a |
| 20201020208 | 03/02/2020 | Bayer S.A | BAY-A2502 / IMPACT:16027 |
| 20201021403 | 05/02/2020 | CHEMO , SL C/LAT Research S.A.S | PI-CH-1303 |
| 20201021553 | 05/02/2020 | Sistema General de Regalías, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio de Bogotá/JSS Medical Research Latam S.A.S. | PI-JS-1249 |
| 20201023878 | 07/02/2020 | MSD | MSD |
| 20201013982 | 24/01/2020 | Bayer S.A | PI-BH-1237 |
| 20191217886 | 06/11/2019 | Merck KGaA | PATROCINADOR |
| 20191219402 | 06/11/2019 | Aurinia Pharmaceuticals, Inc. | PI-API-1147 |
| 20191219406 | 06/11/2019 | Neovacs SA | PI-NE-1006 |
| 20191219408 | 07/11/2019 | Aurinia Pharmaceuticals, Inc. | PI-API-1258 |
| 20191219421 | 07/11/2019 | GlaxoSmithkline Research & Development Limited | PI-GS-1132 |
| 20191219424 | 07/11/2019 | Amryt Research limited | PI-AR-1208 |
| 20191220905 | 08/11/2019 | Genentech, Inc./Banner Alzheimer Institute | PI-GNT-1262 |
| 20191220908 | 08/11/2019 | Productos Roche S.A. | PI-RO-994 |
| 20191220912 | 08/11/2019 | Productos Roche S.A. | PI-RO-1182 |
| 20191220913 | 08/11/2019 | Productos Roche S.A. | PI-RO-1175 |



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| 20191220915 | 08/11/2019 | Productos Roche S.A. | PI-RO-1031 |
| 20191220918 | 08/11/2019 | Productos Roche S.A. | PI-RO-656 |
| 20191220922 | 08/11/2019 | Productos Roche S.A. | PI-RO-1205 |
| 20191220924 | 08/11/2019 | Genetech, Inc | PI-GNT-1087 |
| 20191220929 | 08/11/2019 | F. Hoffmann- La Roche Ltda | PI-RO-789 |
| 20191220931 | 08/11/2019 | Roche S.A. | PI-RO-701 |
| 20191216197 | 01/11/2019 | Bayer S.A | PI-BH-773 |
| 20191216201 | 01/11/2019 | Bayer S.A. | PI-BH-1010 |
| 20191217357 | 01/11/2019 | Bayer S.A. | PI-BH-1010 |
| 20191218483 | 01/11/2019 | Merck Sharp & Dohme Colombia S.A.S. | PI-MS-1235 |
| 20191219415 | 01/11/2019 | GlaxoSmithKline Biologicals SA | PI-GS-1287 |
| 20191219425 | 07/11/2019 | P-(ALL) ALLERGAN | PI-ALL-996 |
| 20191219452 | 07/11/2019 | Shire Human Genetic Therapies Inc | PI-SH-1238 |
| 20191219441 | 07/11/2019 | Shire Human Genetic Therapies, Inc. (Shire) | PI-SH-1217 |
| 20191239641 | 03/12/2019 | Bayer S.A. | PI-BH-773 |
| 20191240325 | 03/12/2019 | Novo Nordisk A/S | PI-NN-1250 |
| 20191240404 | 04/12/2019 | Novo Nordisk A/S | PI-NN-1309 |
| 20191241358 | 05/12/2019 | Abbvie S.A.S. | PI-ABS-1016 |
| 20191241365 | 05/12/2019 | Abbvie S.A.S. | PI-ABS-1016 |
| 20191241368 | 05/12/2019 | Abbvie S.A.S. | PI-ABS-1211 |



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| 20191241369 | 05/12/2019 | Abbvie S.A.S. | PI-AB-909 |
| 20191241362 | 05/12/2019 | Abbvie S.A.S. | PI-ABS-1099 |
| 20191256899 | 20/12/2019 | Bayer S.A. | PI-BH-1010 |

Atentamente,

GUILLERMO JOSÉ PÉREZ BLANCO

Director Técnico de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica