

OFICIO 3000-0213-26

Bogotá D.C., febrero de 2026

ASUNTO: Acuso recibo Informe Anual de seguridad.

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 de investigación clínica con medicamentos en humanos de que trata el artículo 146 del decreto 677 de 1995*” (Artículo Sexto: Informes de Seguridad), 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 informes anuales de seguridad.

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.

RADICADO	FECHA RADICADO	PATROCINADOR/CRO	CÓDIGO INVIMA
20211255224	2021-12-01	H. Lundbeck S/A ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-HL-1108 PI-HL-1109 PI-HL-1508
20211257495	2021-12-01	Productos Roche S.A	PI-RO-1343
20211257517	2021-12-01	Productos Roche S.A	PI-RO-994 PI-RO-1343
20211257529	2021-12-01	Productos Roche S.A	PI-BA-796 PI-GNT-1262
20211257550	2021-12-01	Productos Roche S.A	PI-RO-1175
20211257556	2021-12-01	Productos Roche S.A	PI-RO-1343
20211257677	2021-12-01	Productos Roche S.A	PI-RO-1063 PI-RO-1116 PI-RO-1182 PI-RO-1192 PI-RO-1343
20211272881	2021-12-07	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1013 PI-MS-1003
20211257711	2021-12-01	Productos Roche S.A	PI-RO-1343
20211237121	2021-11-09	SANOFI PASTEUR S.A	PI-SA-1465
20211237706	2021-11-10	Arena Pharmaceuticals, Inc.	PI-APH-1350 PI-APH-1340 PI-APH-1370 PI-APH-1439

20211238559	2021-11-10	Arena Pharmaceuticals, Inc.	PI-APH-1350 PI-APH-1340 PI-APH-1370 PI-APH-1439
20211238765	2021-11-10	Bayer S.A.	PI-BH-1012 PI-BH-1010 PI-BH-1408
20211257815	2021-12-01	Productos Roche S.A	PI-RO-1343
20211257856	2021-12-01	Productos Roche S.A	PI-FH-975
20211257834	2021-12-01	Productos Roche S.A	PI-RO-1343
20211269513	2021/12/03	Productos Roche S.A	PI-RO-789
20211269505	2021/12/03	Productos Roche S.A	PI-RO-656
202111269658	2021/12/03	Productos Roche S.A	PI-RO-1343
202111269740	2021/12/03	Productos Roche S.A	PI-RO-1031
202111269814	2021/12/03	Boehringer Ingelheim	PI-LBI-1475
20211238949	2021/11/11	R-Pharm /IQVIA RDS Colombia SAS	PI-RPH-1084 PI-RPH-1085 PI-RPH-1133
20211239483	2021/11/11	Bayer S.A.	PI-BH-1012
20211242698	2021/11/17	OPKO Biologics Ltda. / JSS Medical Research Latam SAS	PI-OB-1171
20211249465	2021/11/24	Galapagos NV/ INC Research Colombia Ltda.	PI-GAL-844
20211254463	2021/11/30	Regeneron Pharmaceuticals, Inc/ ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-RPH-1185
20211254480	2021/11/30	H.Lundbeck, A/S /ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-HL-1108 PI-HL-1109 PI-HL-1508
20211254519	2021/11/30	H.Lundbeck, A/S /ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-HL-1108 PI-HL-1109 PI-HL-1508
20221007291	2022/01/14	Novartis	PI-NO-1328 PI-NO-1512
20221007564	2022/01/14	Actelion Pharmaceuticals Ltd./PPD Colombia S.A.S	PI-AC-1227
20221007595	2022/01/14	Janssen Research & Development, LLC	PI-JC-1120
20221093458	2022-05-23	Merck Healthcare KgaA	PI-MC-1044
20221022000	2022-02-01	Merck Sharp and Dohme Colombia SAS	PI-MS-1189

20221103451	2022-06-02	Insmmed Incorporated	PI-INS-1478
20221020850	2022-01-31	Merck Sharp and Dohme Colombia S.A.S.	PI-MS-1374 PI-MS-1561 PI-MS-1479
20221094557	2022-05-24	NOVARTIS DE COLOMBIA S.A.	PI-NO-1400
20221094780	2022-05-24	NOVARTIS DE COLOMBIA S.A.	PI-NO-1280 PI-NO-1329 PI-NO-1537
20221097574	2022-05-26	NOVARTIS DE COLOMBIA S.A.	PI-NO-1140
20221097962	2022-05-26	GlaxoSmithKline	PI-HGS-723
20221103757	2022-06-02	ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-IPI-1524
20221107186	2022-06-06	SANOFI-AVENTIS DE COLOMBIA S.A.	PI-AZ-25
20221107895	2022-06-06	Synairgen Research Ltd.	PI-SR-1484
20221117365	2022-06-15	Bayer S.A.	PI-BH-773
20221121352			
20221119810	2022-06-17	Boheringer Ingelheim S.A	PI-LBI-1511
20221121819	2022-06-21	Allergan Sales, LLC (AbbVie Company)	PI-ALL-1336
20221128347	2022-06-28	Daiichi Sankyo Inc.	PI-DSK-1194
20221129204	2022-06-29	Pharma Mar S.A.	PI-PM-1514
20221129242	2022-06-29	ACADIA Pharmaceuticals Inc.	PI-ADP-1271
20221129273	2022-06-29	ACADIA Pharmaceuticals Inc.	PI-ADP-1270
20221133548	2022-07-05	NOVARTIS DE COLOMBIA S.A.	PI-NO-843 PI-NO-927 PI-NO-1231 PI-NO-843
20221133809	2022-07-05	Janssen Cilag Research & Development	PI-JC-1455
20221140246	2022-07-11	Geron Corporation	PI-GCO-1565
20221143529	2022-07-14	Astellas Pharma Global Development, Inc.	PI-AS-1267
20221148133	2022-07-19	Kowa Research Institute	PI-KW-1124
20221154270	2022-07-25	Boehringer Ingelheim S.A	PI-LBI-1197
20221157295	2022-07-27	Apellis Pharmaceuticals, Inc.	PI-AL-1489
20221157358	2022-07-27	CSL Behring	PI-CS-1244
20221016357	2022-01-25	Allievex/Labcorp Colombia Services Ltda.	PI-BI-1275
20221145016	2022-07-15	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1432 PI-MS-1527

20211271222	2021-12-16	Productos Roche S.A.	PI-PR-1233 PI-FH-1360 PI-QC-49
20211271239	2021-12-16	Productos Roche S.A.	PI-RO-1343
20211271229	2021-12-16	Productos Roche S.A.	PI-RO-701 PI-RO-1343
20221158600	2021-07-28	Productos Roche S.A.	PI-VT-1460
20221163249	2022-08-01	Novartis de Colombia S.A.	PI-NO-1241 PI-ALR-997
20221170620	2022-08-02	Mirum Pharmaceuticals, Inc	PI-MPI-1345 PI-MPI-1471
20221170722	2022-08-02	Boehringer Ingelheim S.A.	PI-LBI-1197
20221179034	2022-08-11	Novartis de Colombia S.A.	PI-NO-1352
20221171812	2022-08-03	Baxalta Innovations GmbH	PI-BIG-1180
20221172455	2022-08-04	Baxalta Innovations GmbH	PI-BIG-1092
20221117352	2022-06-15	Bayer S.A.	PI-BH-773
20221157200	2022-07-27	PFIZER S.A.S.	PI-NO-848
20201227975	2020-12-03	ICON Clinical Research	PI-HL-1108
20211274022	2021-12-09	Amryt Research, Ltd./ Syneos Health	PI-AR-1208
20211274696	2021-12-09	Bayer S.A.	PI-BH-991
20211274640	2021-12-09	Novo Nordisk A/S	PI-NN-1436
20211275854	2021-12-10	Millennium Pharmaceuticals, Inc	PI-MP-696
20211280818	2021-12-14	AstraZeneca Colombia S.A.S	PI-AZ-1427
20211281186	2021-12-14	Pontificia Universidad Javeriana, Ministerio de Ciencia y Tecnología de Colombia (Minciencias)	PI-JS-1402
20211284591	2021-12-16	Laboratorios Sophia SA de CV / Laboratorios Sophia de Colombia Ltda.	PI-LSO-1135
20211284868	2021-12-16	Novartis de Colombia S.A.	PI-NO-1382
20211287811	2021-12-20	Amgen Inc.	PI-AG-1206
20211290668	2021-12-21	Esperion	PI-ET-1127
20211290905	2021-12-22	Merck Sharp and Dohme Colombia SAS	PI-MS-941
20211293299	2021-12-23	Bristol Myers Squibb Company	PI-BM-1332
20211296668	2021-12-28	Janssen Cilag Research & Development	PI-AC-1447
20211302784	2021-12-07	RPS COLOMBIA LTDA. (PRA Health Sciences)	PI-AZ-1170
20211302775	2021-12-30	Bayer S.A.	PI-BH-1408
20211302769	2021-12-30	Bayer S.A.	PI-BH-1408
20211302691	2021-12-30	RPS COLOMBIA LTDA. (PRA Health Sciences)	PI-AZ-1170

20211272997	2021-12-30	Merck Sharp and Dohme Colombia SAS	PI-MS-1248
20221000911	2022-01-04	Bayer AG	PI-BH-1412
20221227143	2022-09-28	Morphosys AG	PI-MAG-1519
20221193942	2022-08-29	Novartis de Colombia SA	PI-NO-1229
20221193942	2022-08-29	Novartis de Colombia SA	PI-NO-1296
20221199105	2022-09-05	Avanir Pharmaceuticals, Inc.	PI-AVP-1487
20221202537	2022-09-08	Novartis de Colombia S.A	PI-NO-1463
20221202537	2022-09-08	Novartis de Colombia S.A	PI-NO-1327
20221211401	2022-09-14	Janssen Cilag Research & Development	PI-JC-1240
20221211179	2022-09-13	Monash University	PI-MU-1522
20221211407	2022-09-14	PRA Health Sciences Colombia Ltda	PI-CV-1459
20221211707	2022-09-14	Bristol Myers Squibb Company	PI-BM-1065 PI-BM-100 PI-BM-1095 PI-BM-1158 PI-BM-1424 PI-BM-1325 PI-BM-1320 PI-BM-1201 PI-BM-911 PI-BM-1027
20221212101	2022-09-14	Novartis de Colombia S.A	PI-NO-1352
20221220482	2022-09-23	Parexel International en nombre de UCB Pharma SRL	PI-UCB-1416
20221221203	2022-09-23	NOVARTIS DE COLOMBIA S.A.	PI-NO-1326
20221226973	2022-09-28	Bristol Myers Squibb Company	PI-BM-1554
20221227043	2022-09-28	Durata Therapeutics International B.V.	PI-DT-1138
20211048501	2021-03-15	Bayer S.A	PI-BH-1010 PI-BH-1012 PI-BH-1408
20211050523	2021-03-16	SANOFI-AVENTIS DE COLOMBIA S.A.	PI-SA-499
20211063191	2021-04-05	Merck Sharp and Dohme Colombia SAS	PI-MS-1318
20211063849	2021-04-06	Regeneron Pharmaceuticals, Inc/ ICON Holdings Clinical Research International Limited Sucursal Colombia.	PI-RPH-1089
20211069983	2021-04-13	Eirgenix Inc	PI-EG-1297
20211076756	2021-04-21	Bristol Myers Squibb Company	PI-BM-1202
20211077983	2021-04-22	Amgen INC.	PI-AG-1315 PI-AG-1316

20211083262	2021-04-29	NOVARTIS DE COLOMBIA S.A.	PI-NO-1406
20221279476	2022-12-30	BAYER S.A.	PI-BH-1408
20221279530	2022-12-30	Parexel International Colombia S.A.S	PI-BV-1509 PI-BV-1539
20231002210	2023-01-05	PRA Health Sciences Colombia Ltda.	PI-EP-1461
20231002221	2023-01-05	Janssen Cilag Research & Development	PI-JC-1445 PI-JC-1419
20221020857	2022-01-31	Merck Sharp and Dohme Colombia SAS	PI-MS-1381 PI-MS-1385
20221264896	2022-12-16	Merck Sharp and Dohme Colombia SAS	PI-MS-1013 PI-MS-1003
20221265497	2022-12-16	Janssen Cilag Research & Development	AC-055-315 AC-055-312
20221265500	2022-12-16	Millennium Pharmaceuticals, Inc	PI-MP-969
20221265646	2022-12-19	Amgen Inc.	PI-AG-1206
20221265652	2022-12-19	Amgen Inc	PI-AG-1501 PI-AG-1323
20221265925	2022-12-19	Atea Pharmaceuticals, Inc.	PI-ATI-1574

Atentamente,

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Proyectó: Grupo de Investigación Clínica