

**OFICIO 3000-0262-26**

Bogotá D.C., marzo 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
20221265950	2022-12-19	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-941 PI-MS-1261 PI-MS-1260 PI-MS-1298 PI-MS-1364 PI-MS-1371 PI-MS-1467 PI-MS-1564 PI-MS-1553
20221266231	2022-12-19	AstraZeneca Colombia S.A.	PI-AZ-1526
20221266270	2022-12-19	Kezar Life Sciences	PI-UL-1281
20221271383	2022-12-21	Merck Sharp and Dohme Colombia SAS	PI-MS-941 PI-MS-1467 PI-MS-961 PI-MS-1043 PI-MS-1083 PI-MS-1130 PI-MS-1131 PI-MS-1151 PI-MS-1247 PI-MS-1212 PI-MS-1186 PI-MS-1285 PI-MS-1314 PI-MS-1338 PI-MS-1213 PI-MS-1273

			PI-MS-1235 PI-MS-1261 PI-MS-1260 PI-MS-1298 PI-MS-1364
20221271481	2022-12-21	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1013 PI-MS-1003
20221273308	2022-12-23	Biogen Idec Research Limited	PI-BG-1313
20211089895	2021-05-07	Acerta Pharma, BV	PI-ACE-1000
20211121079	2021-06-22	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-1431 PI-MS-1432
20221276565	2022-12-28	Global Blood Therapeutics, Inc.	PI-GB-1531 PI-GB-1521 PI-GB-1551
20231002266	2023-01-05	GSK Colombia	PI-GS-1532
20231002951	2023-01-06	Bayer S.A.	PI-BH-1408
20231003584	2023-01-10	Shing Poong Pharmaceutical Co., Ltd.	PI-SPP-1582
20231003990	2023-01-11	Global Blood Therapeutics, Inc.	PI-GB-1521
20231003995	2023-01-11	Global Blood Therapeutics, Inc.	PI-GB-1551
20231004022	2023-01-11	Allievex/Labcorp Colombia Services Ltda.	PI-BI-1275
20231005300	2023-01-13	NOVARTIS DE COLOMBIA S.A.	PI-NO-1382
20231006482	2023-01-16	Bayer AG	PI-BH-1412
20231007086	2023-01-17	Gedeon Richter Plc.	PI-GR-1429
20231007141	2023-01-17	Actelion Pharmaceuticals Ltd./PPD Colombia S.A.S.	PI-AC-1227
20231007166	2023-01-17	Janssen Research & Development, LLC	PI-JC-1120
20231007549	2023-1-18	Pfizer S.A.S	PI-PF-1307
20231007765	2023-01-18	Celgene International II Sarl, una subsidiaria de BMS (Bristol-Myers Squibb)	PI-CI-1497
20231009689	2023-01-23	Laboratorios Litaphar S.L.	PI-LL-1415
20231009702	2023-01-23	Celgene International II Sarl una subsidiaria de BMS	PI-CI-1498 PI-CI-1499 PI-CI-1497
20231009717	2023-01-23	Celgene International II Sarl una subsidiaria de BMS	PI-CI-1498 PI-CI-1499 PI-CI-1497
20231019106	2023-01-31	International Vaccine Institute / VAXTRIALS Colombia S.A.S.	PI-IVI-1486

20231019418	2023-02-01	Merck Sharp and Dohme Colombia SAS	PI-MS-1381
20231025597	2023-02-07	Merck Sharp and Dohme Colombia SAS	PI-MS-1300
20231025562	2023-02-07	Merck Sharp and Dohme Colombia SAS	PI-MS-1374 PI-MS-1561 PI-MS-1479 PI-MS-1597
20231025601	2023-02-07	Merck Sharp and Dohme Colombia SAS	PI-MS-1189
20251090745	2025-04-07	Takeda Pharmaceutical Company Limited/IQVIA RDS Colombia S.A.S.	PI-TAK-1664 PI-TAK-1665
20231134739	2023-05-23	Merck Healthcare KgaA	PI-MC-1044
20231139150	2023-05-25	AbbVie SAS	PI-ABS-1211 PI-ABS-1242 PI-ABS-1243
20231139226	2023-05-26	Insmmed Incorporated	PI-INS-1478
20231143114	2023-05-30	NOVARTIS DE COLOMBIA S.A	PI-NO-1280 PI-NO-1329 PI-NO-1537
20231149234	2023-06-06	Boheringer Ingelheim S.A	PI-LBI-1511 PI-LBI-1575
20231158074	2023-06-15	NOVARTIS DE COLOMBIA S.A.	PI-NO-1400
20231158406	2023-06-15	NOVARTIS DE COLOMBIA SA	PI-NO-822
20231161164	2023-06-20	Merck Sharp and Dohme Colombia SAS	PI-ACC-1588 PI-ACC-1560
20231162528	2023-06-21	Parexel International en nombre de ACADIA Pharmaceuticals Inc.	PI-ADP-1271
20231164582	2023-06-22	AstraZeneca Colombia S.A.S	PI-AZ-1576
20231177631	2023-07-07	Janssen Cilag Research & Development/ IQVIA RDS Colombia SAS	PI-JC-722
20231232302	2023-08-30	Novartis Colombia S.A.	PI-NO-1463 PI-NO-1570 PI-NO-1327 PI-NO-1616
20231030737	2023-02-14	Novo Nordisk A/S	PI-NN-1250 PI-NN-1309 PI-NN-1436
20231031164	2023-02-14	ModernaTx, Inc	PI-MOD-1591
20231031173	2023-02-14	Milestone Pharmaceuticals Inc.	PI-MLP-1351
20231036800	2023-02-21	Janssen Cilag Research & Development	PI-AC-1438
20231046213	2023-02-27	Biogen Idec Research Limited	PI-BG-1448
20231046498	2023-02-27	AstraZeneca	PI-AZ-1569 PI-AZ-1450

20231085520	2023-04-04	Gedeon Richter Plc.	PI-ALL-1428 PI-GR-1429
20231096905	2023-04-14	Bristol Myers Squibb de Colombia S.A.	PI-BM-1282
20231101237	2023-04-20	Amgen Inc.	PI-AG-1315 PI-AG-1316
20231106994	2023-04-24	Atea Pharmaceuticals, Inc.	PI-ATI-1574
20231109313	2023-04-26	GSK Biologicals	PI-GS-1457
20231109822	2023-04-26	Bayer S.A.	PI-BH-1466
20231122905	2023-05-10	Janssen Research & Development, LLC	PI-JC-1491
20231122219	2023-05-09	GSK Colombia	PI-GS-1451 PI-GS-1532
20231128350	2023-05-16	National Institute of Allergy and Infectious Diseases (NIAID)	PI-NI-1495
20231128392	2023-05-16	TAKEDA VACCINES INC.	PI-TAK-982
20231047990	2023-02-28	Mirati Therapeutics Inc	PI-MT-1573
20231047999	2023-02-28	Novartis de Colombia S.A	PI-NO-1328 PI-NO-1512
20231050110	2023-03-01	Pfizer S.A.S	PI-PF-1341
20231049968	2023-03-01	Pfizer S.A.S	PI-PF-1383
20231053001	2023-03-02	Merck Sharp and Dohme Colombia SAS	PI-MS-1544 PI-MS-1593
20231062481	2023-03-13	Sarepta Therapeutics, Inc.	PI-ST-1324
20231069418	2023-03-17	Bristol Myers Squibb Company (en Colombia representado por Bristol Myers Squibb de Colombia S.A.)	PI-BM-1202
20231070829	2023-03-21	Acceleron Pharma Inc.	PI-ACC-1560 PI-ACC-1588
20231071204	2023-03-21	Genova, Inc.	PI-GI-1520
2022100627	2022-01-13	AstraZeneca	PI-AZ-1245
20221184734	2022-08-18	Novartis de Colombia S.A	PI-NO-1380 PI-NO-1444
20261047627	2026-02-26	Pfizer S.A.S	PF-06650833
20221187992	2022-08-23	Novartis de Colombia S.A	PI-NO-1029 PI-NO-1199 PI-NO-1290 PI-NO-1384 PI-NO-1362 PI-NO-1403 PI-NO-1367
20231230112	2023-08-28	AstraZeneca Colombia S.A.	PI-AZ-1598

20231230121	2023-08-28	AstraZeneca Colombia S.A.	PI-AZ-1598
20231226374	2023-08-24	Merck Sharp and Dohme Colombia S.A.S	PI-MS-1500 PI-MS-1543
20231225886	2023-08-23	Merck Sharp and Dohme Colombia S.A.S	PI-MS-1179
20231207293	2023-08-03	Apellis Pharmaceutical, Inc./ CTI Clinical Brasil Serviços de Pesquisas e Comercio Ltda	PI-AL-1489
20231204993	2023-08-02	CSL Behring LLC (CSLB)/ Fortrea Colombia Ltda	PI-CS-1244
20231048050	2023-02-28	Janssen Research & Development, LLC	PI-JC-1225
20231034582	2023-02-17	Bayer S.A.	PI-BH-1004 PI-BH-973
20221276628	2022-12-28	Amgen Inc.	PI-AG-1580 PI-AG-1206
20221271408	2022-12-21	Merck Sharp & Dohme Colombia S.A.S.	PI-MS-941 PI-MS-961 PI-MS-1043 PI-MS-1083 PI-MS-1130 PI-MS-1131 PI-MS1151 PI-MS-1247 PI-MS-1212 PI-MS-1186 PI-MS-1285 PI-MS-1314 PI-MS-1338 PI-MS-1213 PI-MS-1273 PI-MS-1235 PI-MS-1261 PI-MS-1260 PI-MS-1298 PI-MS-1364 PI-MS-1371 PI-MS-1467 PI-MS-1564 PI-MS-1015
20221133251	2022-07-05	Janssen Cilag Research & Development	PI-JC-722
20231166933	2023-06-26	Janssen Research & Development/IQVIA RDS Colombia S.A.S	PI-JC-1559
20231177221	2023-07-06	Janssen Research & Development/IQVIA RDS Colombia S.A.S	PI-JC-1455

20231193999	2023-07-23	Celgene International II Sarl una subsidiaria de BMS/PSI CRO Colombia S.A.S	PI-CI-1497
20231194000	2023-07-23	Celgene International II Sarl una subsidiaria de BMS/PSI CRO Colombia S.A.S	PI-CI-1498
20231191172	2023-07-19	Celgene International II Sarl una subsidiaria de BMS/PSI CRO Colombia S.A.S	PI-CI-1499
20231200387	2023-07-28	Clover Biopharmaceuticals AUS Pty Ltd/ Vaxtrials Colombia S.A.S.	PI-VT-1460
20231202323	2023-07-31	Baxalta Innovations GmbH/ IQVIA RDS Colombia S.A.S	PI-BIG-1180
20231206179	2023-08-02	Biogen Idec Research Limited/ IQVIA RDS Colombia S.A.S	PI-BG-1572
20231212229	2023-08-10	Array Biopharma Inc/ PPD Colombia S.A.S	PI-NO-848
20231219542	2023-08-16	Avanir Pharmaceuticals, Inc./ Syneos Health Colombia Ltda	PI-AVP-1487
20231221449	2023-08-18	Novo Nordisk A/S	PI-NN-1250 PI-NN-1436 PI-NN-1309
20231226352	2023-08-24	Sarepta Therapeutics, Inc./PPD Colombia S.A.S	PI-ST-1324
20231228862	2023-08-25	AstraZeneca /Fortrea Colombia Ltda (antes Labcorp Colombia Services Ltda).	PI-AZ-1399
2023122887	2023-08-25	AstraZeneca /Fortrea Colombia Ltda (antes Labcorp Colombia Services Ltda).	PI-AZ-1399
20221095182	2022-05-24	AbbVie S.A.S	PI-ABS-1211 PI-ABS-1242 PI-ABS-1243
20231248355	2023-09-19	ModernaRX, Inc.	PI-MOD-1590
20231115233	2023-05-02	Aurinia Pharmaceutical Inc./Labcorp Colombia Services Ltda.	PI-API-1608
20231115194	2023-05-02	Janssen Cilag SA	PI-JC-1266
20231115315	2023-05-02	Merck Sharp and Dohme Colombia SAS	PI-MS-1556
20231115374	2023-05-02	Merck Sharp and Dohme Colombia SAS	PI-MS-1373 PI-MS-1378 PI-MS-1552
2023107298	2023-03-22	Merck Sharp and Dohme Colombia SAS	PI-MS-1346
20231073310	2023-03-23	Merck Sharp and Dohme Colombia SAS	PI-MS-1288
20231073012	2023-03-22	Merck Sharp and Dohme Colombia SAS	PI-MS-1301
20231078320	2023-03-28	Biogen Idec Research Limited / PPD	PI-BG-1448
20231077835	2023-03-27	Immunic AG / Worldwide Clinical Trials Colombia S.A.S.,	PI-IMU-1589
20231080210	2023-03-29	Novartis de Colombia S.A	PI-NO-1392

20231084047	2023-04-03	Biogen Idec Research Limited / PPD	PI-BG-1550
20231120329	2023-05-08	Merck Sharp and Dohme Colombia SAS	PI-MS-1482
20231115404	2023-05-02	Novartis de Colombia S.A	PI-NO-1256 PI-NO-1398
20231116613	2023-05-03	SK bioscience Co., Ltd / VAXTRIALS Colombia S.A.S.	PI-SB-1641
20231119590	2023-05-08	Esperion Therapeutics , Inc	PI-ET-1127
20231120328	2023-05-08	Merck Sharp and Dohme Colombia SAS	PI-MS-1555
20231145291	2023-06-01	SANOFI-AVENTIS DE COLOMBIA S.A.	LPS15296
20231262792	2023-06-10	Amgen Biotecnologica S.A.S	PI-AG-1586
20231263394	2023-10-09	Bristol Myers Squibb	PI-BM-1554
20231250888	2023-09-22	SHIONOGI INC	PI-SG-1645
20231255211	2023-09-27	Hillevax / VAXTRIALS Colombia S.A.S.	PI-HI-1621
20231259076	2023-10-03	SK Life Science, Inc / PPD Colombia S.A.S	PI-SKL-1646
20231259992	2023-10-04	Chemo Research S.L. / LAT. Research S.A.S	PI-CH-1303
20231257765	2023-10-02	Merck Healthcare KgaA / PAREXEL INTERNATIONAL COLOMBIA S.A.S	PI-MKG-1430
20231262032	2023-10-06	Iveric bio, Inc / Resolution Latin America S.A.S	PI-BI-1386

Atentamente,

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Directora de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica