

OFICIO 3000-0690-24

Bogotá D.C., junio de 2024

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
20211046696	2021-03-11	Bayer S.A.	PI-BH-1012
20211046708	2021-03-11	Bayer S.A.	PI-BH-1012
20211046599	2021-03-11	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211040259	2021-03-04	Clínica CES	PI-CES-1410
20211046934	2021-03-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211046940	2021-03-12	Bayer S.A.	PI-BH-1012
20211046980	2021-03-12	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267

20211047579	2021-03-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211047752	2021-03-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211047771	2021-03-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211047797	2021-03-12	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211047821	2021-03-12	Bayer S.A.	PI-BH-773
20211048223	2021-03-15	Bayer S.A.	PI-BH-1012
20211048235	2021-03-15	Bayer S.A.	PI-BH-1012
20211048242	2021-03-15	Bayer S.A.	PI-BH-1012
20211048250	2021-03-15	Bayer S.A.	PI-BH-1012
20211048253	2021-03-15	Bayer S.A.	PI-BH-991
20211048299	2021-03-15	Bayer S.A.	PI-BH-1012
20211048309	2021-03-15	Apellis Pharmaceutical, Inc. / Intrials S.A.S.	PI-AL-1304
20211048363	2021-03-15	Clínica CES	PI-CES-1410
20211048734	2021-03-15	GlaxoSmithKline Research & Development Limited / IQVIA RDS Colombia S.A.S.	PI-GS-1333
20211050605	2021-03-16	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211050608	2021-03-16	Regeneron Pharmaceuticals Inc. / PAREXEL International Colombia S.A.S.	PI-RPH-1361
20211050658	2021-03-16	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211050665	2021-03-17	Bayer S.A.	PI-BH-1012
20211050690	2021-03-17	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211050726	2021-03-17	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211050747	2021-03-17	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211053258	2021-03-19	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211053388	2021-03-19	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211053568	2021-03-19	Bayer S.A.	PI-BH-1408
20211056574	2021-03-24	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211056595	2021-03-24	Bayer S.A.	PI-BH-1034

20211056692	2021-03-24	Bayer S.A.	PI-BH-1012
20211056701	2021-03-24	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211056707	2021-03-24	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211056725	2021-03-24	Bayer S.A.	PI-BH-1408
20211056741	2021-03-24	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211056743	2021-03-24	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211056770	2021-03-24	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211056782	2021-03-24	Bayer S.A.	PI-BH-773
20211056793	2021-03-24	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211057560	2021-03-25	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211057577	2021-03-25	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211057590	2021-03-25	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211063175	2021-04-05	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211063181	2021-04-05	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211063184	2021-04-05	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211063188	2021-04-05	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211063889	2021-04-06	Bayer S.A.	PI-BH-1034
20211066116	2021-04-08	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211066135	2021-04-08	Janssen Vaccines & Prevention B.V.	PI-JC-1445
20211057617	2021-03-25	Janssen Vaccines & Prevention B.V.	PI-JC-1445
20211066202	2021-04-08	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211066209	2021-04-08	RedHill Biopharma Ltd./ JSS Medical Research Latam S.A.S	PI-RB-1443
20211066218	2021-04-08	Boehringer Ingelheim Colombia S.A. / IQVIA RDS Colombia SAS	PI-LBI-1121
20211066881	2021-04-09	Pfizer Inc. / ICON Clinical Research	PI-PF-1146

20211066945	2021-04-09	Regeneron Pharmaceuticals Inc. / PAREXEL International Colombia S.A.S.	PI-RPH-1361
20211067265	2021-04-09	Clínica CES	PI-CES-1410
20211067284	2021-04-09	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211067337	2021-04-09	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211067468	2021-04-09	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211067896	2021-04-12	Bayer S.A.	PI-BH-773
20211067903	2021-04-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211067909	2021-04-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211067918	2021-04-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211067930	2021-04-12	Regeneron Pharmaceuticals Inc. / PAREXEL International Colombia S.A.S.	PI-RPH-1361
20211067945	2021-04-12	AstraZeneca	PI-AZ-1337
20211067956	2021-04-12	Janssen Vaccines & Prevention B.V.	PI-JC-1445

20211067963	2021-04-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211068003	2021-04-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211068215	2021-04-12	RedHill Biopharma Ltd./ JSS Medical Research Latam S.A.S	PI-RB-1443
20211068355	2021-04-12	Bayer S.A.	PI-BH-773
20211069963	2021-04-13	Janssen Vaccines & Prevention B.V.	PI-JC-1419

Eventos Adversos Serios Internacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20211045900	2021-03-11	Daiichi Sankyo Inc. / ATHENEX – CIDAL COLOMBIA S.A.S.	PI-DSK-1194
20211045936	2021-03-11	Productos Roche S.A.	PI-RO-1031
20211045942	2021-03-11	Roche S.A.	PI-RO-656
20211045961	2021-03-11	Productos Roche S.A.	PI-RO-1343

20211045971	2021-03-11	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1270
20211045986	2021-03-11	Bayer S.A.	PI-BH-1408
20211046020	2021-03-11	Galapagos NV / INC Research Colombia Ltda.	PI-GAL-844
20211046021	2021-03-11	Novartis de Colombia S.A. / PAREXEL International Colombia S.A.S.	PI-NO-1268
20211046051	2021-03-11	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1075
20211046060	2021-03-11	Boehringer Ingelheim Colombia S.A. / PAREXEL International Colombia S.A.S.	PI-LBI-1197
20211046075	2021-03-11	GlaxoSmithKline Colombia S.A.	PI-GS-1369
20211046089	2021-03-11	Amryt Research limited / INC Research Colombia	PI-AR-1208
20211046104	2021-03-11	Productos Roche S.A.	PI-RO-1343
20211046126	2021-03-11	Productos Roche S.A.	PI-RO-1116
20211046148	2021-03-11	Productos Roche S.A.	PI-RO-1343
20211046167	2021-03-11	Productos Roche S.A.	PI-RO-1343

20211046177	2021-03-11	Productos Roche S.A.	PI-RO-1343
20211046186	2021-03-11	Productos Roche S.A	PI-PR-1233
20211046199	2021-03-11	Productos Roche S.A.	PI-RO-1343
20211046211	2021-03-11	Productos Roche S.A.	PI-RO-887
20211046286	2021-03-11	Regeneron Pharmaceuticals, Inc.	PI-RPH-1185
20211046397	2021-03-11	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1206
20211046557	2021-03-11	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1322
20211046576	2021-03-11	GlaxoSmithKline Research & Development Limited / IQVIA RDS COLOMBIA SAS	PI-GS-1333
20211046631	2021-03-11	Kowa Research Institute, Inc / IQVIA RDS COLOMBIA SAS	PI-KW-1124
20211046675	2021-03-11	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1265

20211046918	2021-03-12	Glaxo Smithkline Colombia S.A	PI-GS-1287
20211046926	2021-03-12	Regeneron Pharmaceuticals, Inc. / ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-RPH-1089
20211046950	2021-03-12	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1265
20211046970	2021-03-12	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1265
20211046994	2021-03-12	Bayer S.A.	PI-BH-1412
20211048225	2021-03-12	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1264
20211048258	2021-03-14	Aurinia Pharmaceuticals, Inc. / Worldwide Clinical Trials Sucursal Colombia	PI-API-1258
20211056813	2021-03-24	P-(MEI) MedImmune LLC Miembro de compañías Astrazeneca / PPD Colombia S.A.S	PI-MEI-939

20211046962	2021-03-12	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1265
20211063170	2021-04-05	Pfizer Inc. / InVentiv Health Clinical Colombia S.A.S.	PI- PF-1114
20211063882	2021-04-06	Bayer S.A.	PI-BH-773
20211063897	2021-04-06	Bayer S.A.	PI-BH-1412
20211065201	2021-04-08	Abbvie S.A.S.	PI-ABS-1211
20211066141	2021-04-08	CSL Behring LLC (CSLB) / Fortrea Colombia Ltda (antes Labcorp Colombia Services Ltda).	PI-CS-1244
20211066192	2021-04-08	GlaxoSmithKline Colombia S.A	PI-GS-1414
20211044903	2021-03-12	lqvia rds colombia S.A.S.	PI-MEI -1331
20211045952	2021-03-12	Roche	PI-BA-796
20211045952	2021-03-12	Roche	PI-RO-1343
20211045968	2021-03-12	lqvia rds colombia S.A.S.	PI-APH-1340

20211045995	2021-03-12	lqvia rds colombia S.A.S.	PI-TAK-982
20211046008	2021-03-12	lqvia rds colombia S.A.S.	PI-MLP-1351
20211046064	2021-03-12	Glaxo Smithkline Colombia S.A	PI-BM-968
20211046321	2021-03-12	lqvia rds colombia S.A.S.	PI-BIG-1092
20211046341	2021-03-12	lqvia rds colombia S.A.S.	PI-BIG-1180
20211046370	2021-03-12	lqvia rds colombia S.A.S.	PI-MEI-1330
20211046420	2021-03-12	Amgen Biotecnológica S.A.S.	PI-AG-1115
20211063172	2021-03-12	ICON	PI-CT-140
20211063186	2021-04-05	Lat Research S.A.	PI-CH-1303
20211063858	2021-04-05	BAYER S.A.	PI-BH-991
20211065219	2021-04-08	JJS Medical Research Latam S.A.S.	PI- RB- 1443
20211066172	2021-04-08	Resolution Latin America	PI-IB-1386

20211066986	2021-04-09	Allievex Corporation / Fortrea Colombia Ltda. (antes Labcorp Colombia Services Ltda).	PI-BI-1275
20211067366	2021-04-12	Bayer S.A. / ICON HOLDINGS CLINICAL RESEARCH INTERNATIONAL LIMITED SUCURSAL COLOMBIA	PI-BH-1034
20211068191	2021-04-12	OPKO Biologics Ltda./ JSS Medical Research Latam SAS	PI-OB-1171
20211068247	2021-04-12	Edesa Biotech Research Inc. / JSS Medical Research Latam S.A.S.	PI-EB-1453
20211068277	2021-04-12	Abbvie S.A.S.	PI-ABS-1016
20211068321	2021-04-12	Abbvie S.A.S.	PI-ABS-1049
20211069952	2021-04-13	UCB Biopharma SRL / PAREXEL International Colombia S.A.S.	PI-UCB-1416

Atentamente,

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Director Técnico de Medicamentos y Productos Biológicos

Proyectó: Grupo de Investigación Clínica