

OFICIO 3000-0471-24

Bogotá D.C., abril 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
20211004402	2021-01-13	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211004582	2021-01-13	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211004587	2021-01-13	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211004808	2021-01-14	Abbvie S.A.S.	PI-ABS-1259
20211004836	2021-01-14	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20201235976	2020-12-10	Bayer S.A.	PI-BH-776
20201235988	2020-12-10	Bayer S.A.	PI-BH-773
20201236001	2020-12-10	Bayer S.A.	PI-BH-1012

20201236056	2020-12-10	Bayer S.A.	PI-BH-773
20201236072	2020-12-10	Bayer S.A.	PI-BH-1012
20201236110	2020-12-10	Bayer S.A.	PI-BH-1012
20201236902	2020-12-10	Bayer S.A.	PI-BH-1012
20201241266	2020-12-15	Bayer S.A.	PI-BH-1012
20201243044	2020-12-17	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20201244156	2020-12-18	Bayer S.A.	PI-BH-1012
20211000538	2021-01-04	Bayer S.A.	PI-BH-991
20211000557	2021-01-04	Bayer S.A.	PI-BH-773
20211000612	2021-01-05	Bayer S.A.	PI-BH-1012
20211001010	2021-01-05	Bayer S.A.	PI-BH-773
20211003539	2021-01-05	Bayer S.A.	PI-BH-773
20211003787	2021-01-12	Bayer S.A.	PI-BH-1012
20211003797	2021-01-12	Bayer S.A.	PI-BH-1012
20211003868	2021-01-13	Bayer S.A.	PI-BH-1012
20211006447	2021-01-18	Bayer S.A.	PI-BH-773

20211006675	2021-01-18	Bayer S.A.	PI-BH-773
20211006683	2021-01-18	Bayer S.A.	PI-BH-1012
20211006055	2021-01-15	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211006067	2021-01-15	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211006241	2021-01-18	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211006307	2021-01-18	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211006335	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211006345	2021-01-18	Abbvie S.A.S.	PI-ABS-1259
20211006391	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211006405	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211006439	2021-01-18	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211006468	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211006482	2021-01-18	Bayer S.A.	PI-BH-773
20211006583	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211006696	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211006705	2021-01-18	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211006860	2021-01-19	Bayer S.A.	PI-BH-1012
20211008283	2021-01-21	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211008291	2021-01-21	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211008300	2021-01-21	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211008310	2021-01-21	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211008324	2021-01-21	Hospital Universitario San Ignacio	PI-JS-1402
20211014356	2021-02-01	Bayer S.A.	PI-BH-773
20211008366	2021-01-21	Clinica CES	PI-CES-1410
20211008601	2021-01-21	Hospital Universitario San Ignacio	PI-JS-1402

20211009490	2021-01-22	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211009522	2021-01-22	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211009538	2021-01-22	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211009554	2021-01-22	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211009563	2021-01-22	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211011345	2021-01-22	Bayer S.A.	PI-BH-1012
20211011403	2021-01-26	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211011373	2021-01-26	Bayer S.A.	PI-BH-1012
20221140758	2022-07-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211011576	2021-01-26	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211008622	2021-01-26	Bayer S.A.	PI-BH-1012
20211014360	2021-02-01	Bayer S.A.	PI-BH-1012
20211014362	2021-02-01	Bayer S.A.	PI-BH-773

20211011583	2021-01-26	PAREXEL International S.A.S. anteriormente Sanofi Pasteur S.A.	PI-SAP-1319
20211011590	2021-01-26	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211011598	2021-01-26	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211011606	2021-01-26	Eli Lilly & Company/ PPD Colombia S.A.S.	PI-EL-1257
20211012181	2021-01-27	Takeda Vaccines, Inc / PPD Colombia S.A.S.	PI-TAK-982
20211013487	2021-01-29	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211013527	2021-01-29	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211013564	2021-01-29	Astellas Pharma Global Development, Inc / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211013578	2021-01-29	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20211014354	2021-02-01	Abbvie S.A.S.	PI-ABS-1259
20211014358	2021-02-01	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211014733	2021-02-01	Abbvie S.A.S.	PI-ABS-1321
20211014658	2021-02-01	Clinica CES	PI-CES-1410
20211016391	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211016722	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211016755	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211016779	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017072	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017077	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017085	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017091	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017109	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017111	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017121	2021-02-03	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211017216	2021-02-04	Bayer S.A.	PI-BH-1012
20211017219	2021-02-04	Bayer S.A.	PI-BH-1012
20211017226	2021-02-04	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211017240	2021-02-04	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211021042	2021-02-09	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211021214	2021-02-10	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211021251	2021-02-10	Bayer S.A.	PI-BH-1012

Eventos Adversos Serios Internacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20211004416	2021-01-13	Janssen Research & Development	PI-JC-757
20211004514	2021-01-14	Arena Pharmaceuticals / PSI CRO Colombia S.A.S.	PI-APH-1370
20211004317	2021-01-13	Aptevo BioTherapeutics, LLC / PSI CRO Colombia S.A.S.	PI-ABT-1334
20211004607	2021-01-14	Daiichi Sankyo Inc. / IQVIA RDS COLOMBIA SAS	PI-QC-209
20211004616	2021-01-14	Arena Pharmaceuticals / PSI CRO Colombia S.A.S.	PI-APH-13740

20211004631	2021-01-14	Arena Pharmaceuticals / PSI CRO Colombia S.A.S.	PI-APH-13740
20211004837	2021-01-14	Kowa Research Institute, Inc / IQVIA RDS COLOMBIA SAS	PI-KW-1124
20211004862	2021-01-14	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211004869	2021-01-14	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20211004873	2021-01-14	Boehringer Ingelheim Colombia S.A. / PAREXEL International Colombia S.A.S.	PI-LBI-1197
20211004877	2021-01-14	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1206
20211004884	2021-01-14	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1315
20211005350	2021-01-14	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1322
20211005370	2021-01-14	AstraZeneca / Fortrea Colombia Ltda (antes Labcorp Colombia Services Ltda).	PI-AZ-1399

20211005378	2021-01-14	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1368
20211005385	2021-01-14	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1263
20211005393	2021-01-14	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1265
20211004889	2021-01-14	Amgen Inc. / IQVIA RDS COLOMBIA SAS	Patrocinador
20211005442	2021-01-14	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un-Socio de Allergan) / PAREXEL International Colombia S.A.S.	PI-ALL-1264
20211005445	2021-01-14	Galapagos NV / INC Research Colombia Ltda.	PI-GAL-844
20211005526	2021-01-15	Productos Roche S.A.	PI-RO-1116

20201243827	2021-12-17	Bayer S.A.	PI-BH-1012
20211005450	2021-01-14	Productos Roche S.A.	PI-RO-1343
20211005530	2021-01-14	Productos Roche S.A.	PI-RO-1343
20211005543	2021-01-15	Productos Roche S.A.	PI-RO-1031
20211005548	2021-01-15	Productos Roche S.A.	PI-RO-1343
20211005582	2021-01-15	Productos Roche S.A.	PI-RO-1343
20211005591	2021-01-15	Productos Roche S.A.	PI-RO-1031
20211005597	2021-01-15	Productos Roche S.A.	PI-PR-1233
20211005618	2021-01-15	Productos Roche S.A.	PI-RO-887
20211005627	2021-01-15	Productos Roche S.A.	PI-RO-1343
20211005654	2021-01-15	GlaxoSmithKline Colombia S.A.	PI-GS-1369
20211005711	2021-01-15	Productos Roche S.A.	PI-RO-1175
20211005749	2021-01-15	P-(FH) F. Hoffmann- La Roche Ltd / IQVIA RDS COLOMBIA SAS	PI-FH-975

20211005819	2021-01-15	Productos Roche S.A.	PI-RO-1343
20211005781	2021-01-15	Laboratorios Sophia S.A de C.V.	PI-LSO-1135
20211005892	2021-01-15	Takeda Development Center Americas, Inc. / IQVIA RDS COLOMBIA SAS	PI-TAK-1664
20211006019	2021-01-15	Productos Roche S.A.	PI-RO-656
20211006024	2021-01-15	Productos Roche S.A.	PI-RO-1343
20211004306	2021-01-13	IQVIA RDS Colombia S.A.S.	PI-MLP-1351
20211006028	2021-01-15	Productos Roche S.A.	PI-RO-1343
20211006046	2021-01-15	Novo Nordisk A/S	PI-NN-1309
20211004294	2021-01-13	IQVIA RDS Colombia S.A.S.	PI-MEI-1330
20211004727	2021-01-14	IQVIA RDS Colombia S.A.S.	PI-CC-1155
20211006051	2021-01-15	GlaxoSmithKline Research & Development Limited / IQVIA RDS Colombia S.A.S.	PI-GS-1333

20211005325	2021-01-14	Amgen Biotecnológica S.A.S	PI-AG-1115
20211006032	2021-01-15	Productos Roche S.A.	PI-AB-796
20211006037	2021-01-15	Glaxo Smithkline Colombia S.A	PI-GS-1287
20211006041	2021-01-15	Glaxo Smithkline Colombia S.A	PI-BM-968
20211006453	2021-01-18	Sanofi Aventis de Colombia S.A.	PI-SA-1177
20211008175	2021-01-21	GlaxoSmithKline Research & Development Limited / IQVIA RDS Colombia S.A.S.	PI-GS-1333
20211008178	2021-01-21	Aurinia Pharmaceuticals, Inc. / Worldwide Clinical Trials Sucursal Colombia	PI-API-1258
20211011415	2021-01-26	P-(MEI) MedImmune LLC Miembro de compañías Astrazeneca / PPD Colombia S.A.S	PI-MEI-939
20211013543	2021-01-29	Bayer S.A.	PI-BH-773
20211014312	2021-01-31	Bayer S.A.	PI-BH-773
20211014384	2021-02-01	Pfizer Inc. / Syneos Health Colombia Ltda.	PI-PF-1306

20211014907	2021-02-01	Productos Roche S.A.	PI-RO-1343
20211017115	2021-02-03	PAREXEL International S.A.S. anteriormente SANOFI-AVENTIS DE COLOMBIA S.A.	PI-SA-1274
20211021222	2021-02-10	Apellis Pharmaceutical, Inc. / Intriols S.A.S.	PI-AL-1304
20211021243	2021-02-10	NOVO NORDISK COLOMBIA S.A.S	PI-NN-1436

Atentamente,

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Proyectó: Grupo de Investigación Clínica