OFICIO 3000-0874-26

Bogotá D.C., octubre 2026

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	PATROCINADOR	CÓDIGO INVIMA
20241053276	2024/05/03	Bayer S.A.	PI-BH-1663
20241055420	2024/03/07	Bayer S.A.	PI-BH-1663
20241055278	2024/03/07	Janssen Cilag S.A.	PI-JC-1559
20241055543	2024/03/07	Allergan SalesLLC	PI-ALL-1336
20241055203	2024/03/07	Pfizer S.A.S	PI-GB-1521
20241055423	2024/03/07	Janssen Cilag S.A.	PI-AC-1447
20241055613	2024/03/07	Janssen Cilag S.A.	PI-JC-1455
20241055211	2024/03/07	Janssen Cilag S.A.	PI-AC-1447
20241055225	2024/03/07	Janssen Cilag S.A.	PI-AC-1447
20241056422	2024/03/08	Sanofi Pasteur	PI-SAP-1513
20241056471	2024/03/08	Amgen INC	PI-AG-1586
20241056511	2024/03/08	Bristol Myers Squibb de Colombia S.A.	PI-BM-1282
20241056551	2024/03/08	Bristol Myers Squibb de Colombia S.A.	PI-BM-1325
20241057550	2024/03/08	AstraZeneca Colombia S.A.S.	PI-AZ-1576
20241056633	2024/03/08	AstraZeneca Colombia S.A.S.	PI-AZ-1667
20241057997	2024/11/03	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241058722	2024/11/03	Sanofi Pasteur	PI-SAP-1513
20241059879	2024/12/03	GlaxoSmithKline	EO-GS-262
20241059942	2024/12/03	Novo Nordisk	PI-NN-1309
20241059954	2024/12/03	SK bioscience Co., Ltd	PI-SB-1641
20241059998	2024/12/03	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241060002	2024/12/03	Janssen Cilag S.A / IQVIA	PI-JC-1455
20241060048	2024/12/03	Janssen Cilag S.A / IQVIA	PI-JC-1455
20241060138	2024/12/03	Janssen Cilag S.A / IQVIA	PI-JC-1455
20241039505	2024/02/20	Bayer S.A.	PI-BH-1408

20241039506	2024/02/20	Bayer S.A.	PI-BH-1408
20241040350	2024/02/21	Novo Nordisk Colombia S.A.S.	PI-NN-1309 PI-NN-1436 PI-NN-1671 PI-NN-1715
20241042077	2024/02/23	Abbvie S.A.S	PI-ABS-1259
20241042449	2024/02/23	Sanofi Pasteur S.A.	PI-SAP-1513
20241042080	2024/02/23	Bayer S.A.	PI-BH-1408
20241041775	2024/02/22	Bayer S.A.	PI-BH-1663
20241042473	2024/02/23	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241042090	2024/02/23	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241041777	2024/02/22	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241042493	2024/02/23	Janssen Cilag S.A	PI-JC-1455
20241042507	2024/02/23	Janssen Cilag S.A	PI-JC-1455
20241043541	2024/02/26	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241043544	2024/02/26	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241043754	2024/02/26	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241066746	2024-03-19	Boehringer Ingelheim S.A.	PI-LBI-1511
20241060867	2024-03-14	International Vaccine Institute / ICON	PI-SB-1641
20241060923	2024-03-13	AstraZeneca	PI-AZ-1337
20241060242	2024-03-12	AstraZeneca	PI-AZ-1337
20241063724	2024-03-15	Sanofi Pasteur	PI-SAP-1513
20241062959	2024-03-14	ABBVIE	PI-ABS-1259
20241063515	2024-03-15	Amgen	PI-AG-1586
20241065362	2024-03-18	Amgen	PI-AG-1580
20241063790	2024-03-15	International Vaccine Institute/ICON	PI-SB-1641
20241063519	2024-03-15	Bristol Myers Squibb de Colombia S.A.	PI-BM-1332
20241065405	2024-03-18	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241066953	2024-03-18	International Vaccine Institute / ICON	PI-SB-1641
20241066764	2024-03-19	AstraZeneca	PI-AZ-1337
20241066776	2024-03-19	Janssen research y development LLC IQVIA RDS Colombia SAS	PI-JC-1455
20241069123	2024-03-20	Boehringer Ingelheim S.A.	PI-LBI-1511
20241069685	2024-03-21	GlaxoSmithKline	EO-GS-262
20241069707	2024-03-21	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241069981	2024-03-21	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241069717	2026-03-21	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241071380	2026-03-22	BAYER S.A.	PI-BH-1408
20241071108	2026-03-22	BAYER S.A.	PI-BH-1663
20241070806	2026-03-21	BAYER S.A.	PI-BH-1408

20241045152	2024/02/27	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241044812	2024/02/26	International Vaccine Institute / ICON	PI-SB-1641
20241045166	2024/02/27	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241097364	2024/04/23	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241097540	2024/04/23	Sanofi Pasteur S.A.	PI-SAP-1513
20241098375	2024/04/24	Pfizer S.A.S.	PI-GB-1531
20241101177	2024/04/25	Novo Nordisk Colombia S.A.S.	PI-NN-1309 PI-NN-1436 PI-NN-1671 PI-NN-1715
20241100049	2024/04/25	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241101468	2024/04/25	Janssen Cilag S.A.	PI-NO-1607
20241101430	2024/04/26	Bristol Myers Squibb	PI-BM-1325
20241101717	2024/04/26	ICON	PI-SB-1641
20241102206	2024/04/26	Abbvie S.A.S.	PI-ALL-1336
20241103104	2024/04/29	Janssen Cilag S.A.	PI-JR-1712
20241104188	2024/04/29	Janssen Cilag S.A / IQVIA	PI-AC-1447
20241102231	2024/04/26	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241104202	2024/04/29	Bayer S.A.	PI-BH-1408
20241104211	2024/04/29	Bayer S.A.	PI-BH-1663
20241105675	2024/04/30	Sanofi Pasteur S.A.	PI-SA-1465
20241105676	2024/04/30	Sanofi Pasteur S.A.	PI-SAP-1513
20241106310	2024/05/02	Janssen Cilag S.A.	PI-JR-1712
20241106523	2024/05/02	Janssen Cilag S.A.	PI-JR-1712
20241106470	2024/05/02	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241105679	2024/04/30	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241106272	2024/05/02	IQVIA RDS Colombia S.A.S.	PI-CHT-1571
20241108348	2024/05/03	Astrazeneca Colombia S.A.S.	PI-AZ-1576
20241108834	2024/05/03	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241108837	2024/05/05	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241108840	2024/05/05	Amgen Biotecnológica S.A.S.	PI-AG-1580
20241108844	2024/05/05	Abbvie S.A.S.	PI-ALL-1336
20241108848	2024/05/05	Bristol Myers Squibb	PI-BM-745
20241045945	2024/02/27	Janssen Cilag S.A.	PI-JC-1559
20241046497	2024/02/28	Janssen Cilag S.A.	PI-JC-1559
20241046227	2024/02/27	Janssen Cilag S.A.	PI-JC-1559
20241046500	2024/02/28	Sanofi Pasteur S.A.	PI-SAP-1513
20241046229	2024/02/27	Bayer S.A.	PI-BH-1408
20241046208	2024/02/27	Bayer S.A.	PI-BH-1408

20241046230	2024/02/27	Bayer S.A.	PI-BH-1408
20241045894	2024/02/27	Bayer S.A.	PI-BH-1408
20241046212	2024/02/27	Bayer S.A.	PI-BH-1408
20241046232	2024/02/27	Sanofi Pasteur S.A.	PI-SAP-1513
20241047423	2024/02/28	Janssen Cilag S.A.	PI-JC-1559
20241047432	2024/02/28	Janssen Cilag S.A.	PI-JC-1559
20241047841	2024/02/28	Janssen Cilag S.A.	PI-JC-1559
20241048690	2024/02/29	International Vaccine Institute	PI-SB-1641
20241048868	2024/02/29	AstraZeneca Colombia S.A.S.	PI-AZ-1576
20241048626	2024/02/29	Abbvie S.A.S.	PI-ABS-1259
20241049179	2024/03/01	Sanofi Pasteur S.A.	PI-SAP-1513
20241049182	2024/03/01	Bristol Myers Squibb	PI-BM-1282
20241049192	2024/03/01	Boehringer Ingelheim S.A	PI-LBI-1511
20241050888	2024/03/04	Bristol Myers Squibb	PI-BM-1325
20241053282	2024/03/05	Janssen Cilag S.A.	PI-NO-1607
20241053039	2024/03/05	Novo Nordisk Colombia S.A.S	PI-NN-1436
20241055368	2024/03/07	Sanofi Pasteur S.A.	PI-SAP-1513
20241053275	2024/03/05	Janssen Cilag S.A.	PI-NO-1607
20241055394	2024/03/07	Pfizer S.A.S	PI-GB-1551
20241053106	2024/03/05	Janssen Cilag S.A.	PI-NO-1607
20241055404	2024/03/07	Bayer S.A.	PI-BH-1408
20241053126	2024/03/05	Bayer S.A.	PI-BH-1408
20241053144	2024/03/05	Bayer S.A.	PI-BH-1408
20241046226	2024/02/27	Janssen Cilag S.A.	PI-AC-1447
20241071738	2024/03/22	Bayer S.A.	PI-BH-1408
20241070808	2024/03/21	Bayer S.A.	PI-BH-1408
20241071129	2024/03/22	Bayer S.A.	PI-BH-1663
20241070810	2024/03/21	Bayer S.A.	PI-BH-1663
20241071156	2024/03/22	Astrazeneca	PI-AZ-1337
20241071785	2024/03/22	Boehringer Ingelheim	PI-LBI-1511
20241073191	2024/03/26	Sanofi Pasteur Inc	PI-SAP-1513
20241073214	2024/03/26	Novo Nordisk SA	PI-NN-1309
20241073404	2024/03/26	Amgen	PI-AG-1580
20241081997	2024/04/08	Bayer S.A.	PI-BH-1408
20241073421	2024/03/26	Amgen	PI-AG-1580
20241074060	2024/03/27	PAREXEL International en nombre de UCB Biopharma SRL	PI-UCB-1614
20261278957	2026-08-03	Boehringer Ingelheim / IQVIA	PI-LBI-1851

20241078517	2024/04/03	Amgen	PI-AG-1580
20241078573	2024/08/03	Shionogi Inc/IQVIA RDS Colombia S.A.S.	PI-SG-1645
20241078619	2024/04/03	Shionogi Inc/IQVIA RDS Colombia S.A.S.	PI-SG-1645
20241079117	2024/04/04	Parexel International Colombia S.A.S/ Sanofi Pasteur Inc	PI-SAP-1513
20241080481	2024/04/05	Janssen Cilag S.A / IQVIA RDS Colombia S.A.S	PI-AC-1447
20241080499	2024/04/05	Bristol Myers Squibb de Colombia S.A.	PI-BM-1282
20241080537	2024/04/05	Novo Nordisk SA	PI-NN-1309
20241081973	2024/04/08	Boehringer Ingelheim S.A/ IQVIA RDS Colombia S.A.S.	PI-LBI-1511
20241081976	2024/04/08	Janssen Cilag S.A / IQVIA RDS Colombia S.A.S	PI-AC-1447
20241080876	2024/04/05	Amgen	PI-AG-1580
20241081984	2024/04/08	Amgen	PI-AG-1580
20241080894	2024/04/05	Parexel International Colombia S.A.S/ Sanofi Pasteur Inc	PI-SAP-1513
20241080921	2024/04/05	Pfizer S.A.S / PPD Colombia S.A.S	PI-GB-1551
20241081040	2024/04/05	International Vaccine Institute / ICON	PI-SB-1641
20241081066	2024/05/04	PPD Colombia S.A.S. / ModernaTX, Inc.	PI-MOD 1591
20241081995	2024/04/08	Abbvie S.A.S.	PI-ABS-1259
20241080508	2024/04/05	BAYER S.A.	PI-BH-1408
20241080517	2024/04/05	BAYER S.A.	PI-BH-1408
20241081084	2024/04/05	BAYER S.A.	PI-BH-1408
20241081997	2024/04/08	BAYER S.A.	PI-BH-1408
20241080525	2024/04/05	BAYER S.A.	PI-BH-1408
20241081099	2024/04/05	BAYER S.A.	PI-BH-1663
20241080531	2024/04/05	BAYER S.A.	PI-BH-1663
20241080553	2024/04/05	Janssen Cilag S.A / IQVIA RDS Colombia S.A.S	PI-NO-1607
20241081236	2024/04/05	Pfizer S.A.S / PPD Colombia S.A.S	PI-GB-1551
20241081289	2024/04/05	Pfizer S.A.S / PPD Colombia S.A.S	PI-GB-1551
20241080957	2024/04/05	Pfizer S.A.S / PPD Colombia S.A.S	PI-GB-1521
20241082018	2024/04/08	Astrazeneca	PI-AZ-1337
20241083849	2024/04/09	Sanofi Pasteur	PI-SAP-1513
20241083871	2024/04/09	International Vaccine Institute / ICON	PI-SB-1641
20241083650	2024/04/09	Shionogi Inc/IQVIA	PI-SG-1645
20241084028	2024/04/09	Amgen	PI-AG-1580
20241084047	2024/04/09	Bristol Myers Squibb Company	PI-BM-1325
20241084054	2024/04/09	Bristol Myers Squibb Company	PI-BM-1325

20241087315	2024/04/09	Bristol Myers Squibb Company	PI-BM-1325
20241084039	2024/04/09	Bristol Myers Squibb Company	PI-BM-1325
20241087346	2024/04/12	Novo Nordisk S.A.	PI-NN-1309
20241083905	2024/04/09	Novo Nordisk S.A.	PI-NN-1715
20241087354	2024/04/12	Boehringer Ingelheim S.A.	PI-LBI-1511
20241083924	2024/04/09	Chinook Therapeutics U.S., Inc. / IQVIA RDS Colombia S.A.S.	PI-CHT-1571
20241084701	2024/04/10	Actelion Pharmaceuticals Ltd. / IQVIA RDS Colombia S.A.	PI-AC-1447
20241084962	2024/04/10	Janssen Cilag S.A. / IQVIA	PI-AC-1447
20241084705	2024/04/10	BAYER S.A.	PI-BH-1408
20241084978	2024/04/10	BAYER S.A.	PI-BH-1408
20241087389	2024/04/12	BAYER S.A.	PI-BH-1408
20241084711	2024/04/10	BAYER S.A.	PI-BH-1408
20241084999	2024/04/10	ORGANIZACIÓN MUNDIAL DE LA SALUD	PI-OMS-1536
20241084721	2024/04/10	Pfizer S.A.S / PPD Colombia S.A.S	PI-GB-1551
20241087444	2024/04/12	Pfizer S.A.S / PPD Colombia S.A.S	PI-GB-1551
20241087499	2024/04/12	Bristol Myers Squibb Company	PI-BM-1325
20241086349	2024/04/11	Bristol Myers Squibb Company	PI-BM-1325
20241087523	2024/04/12	Boehringer Ingelheim S.A.	PI-LBI-1511
20241086395	2024/04/12	Boehringer Ingelheim S.A.	PI-LBI-1511
20241108850	2024/05/05	Bristol Myers Squibb Company	PI-BM-745
20241108852	2024/05/05	Bristol Myers Squibb Company	PI-BM-745
20241108853	2024/05/05	Bristol Myers Squibb Company	PI-BM-745
20241108854	2024/05/05	Resolution Latin America	PI-MPI-1471 PI-MPI-1472 PI-MPI-1473
20241108857	2024/05/05	Resolution Latin America	PI-MPI-1471
20241108862	2024/05/05	Sanofi Pasteur S.A.	PI-SAP-1513
20241112356	2024/05/08	Sanofi Pasteur S.A.	PI-SAP-1513
20241113273	2024/05/09	Janssen Cilag S.A.	PI-JR-1712
20241112370	2024/05/08	Janssen Cilag S.A.	PI-JR-1712
20241113308	2024/05/09	Bristol Myers Squibb Company	PI-BM-745
20241112769	2024/05/08	Novo Nordisk S.A.	PI-NN-1309 PI-NN-1436 PI-NN-1671 PI-NN-1715
20241112962	2024/05/08	Parexel International Colombia S.A.S.	EO-PA-230
20241112985	2024/05/08	Bayer S.A.	PI-BH-1408
20241113536	2024/05/09	Bayer S.A.	PI-BH-1408
20241112988	2024/05/08	Bayer S.A.	PI-BH-1408

20241113595	2024/05/09	Bayer S.A.	PI-BH-1408
20241112991	2024/05/08	Bayer S.A.	PI-BH-1663
20241112994	2024/05/08	Bayer S.A.	PI-BH-1663
20241113809	2024/05/09	Astrazeneca Colombia S.A.S.	PI-AZ-1576
20241113823	2024/05/09	Sanofi Pasteur S.A.	PI-SAP-1513
20241113897	2024/05/09	Bristol Myers Squibb Company	PI-BM-1673
20241114718	2024/05/10	Janssen Cilag S.A.	PI-JR-1712
20241114299	2024/05/09	Janssen Cilag S.A.	PI-JR-1712
20241114724	2024/05/10	Janssen Cilag S.A.	PI-JR-1712
20241116376	2024-05-14	Amgen Biotecnológica S.A.S.	PI-AG-1580

Eventos Adversos Serios Internacionales

RADICADO	FECHA	PATROCINADOR	CÓDIGO INVIMA
20241087318	2024/04/12	UCB Biopharma SRL	PI-UCB-1614
20261324742	2026-09-25	EYEBIOTHEC LTD	PI-RE-1848
20241087591	2024-04-12	Bristol Myers Squibb Company	PI-BM-1325
20241087330	2024-04-12	Bristol Myers Squibb Company	PI-BM-1325
20241087341	2024-04-12	AstraZeneca AB	PI-AZ-1667
20241089556	2024-04-15	Bristol Myers Squibb Company	PI-BM-1325
20241089613	2024-04-15	SK bioscience Co., Ltd	PI-SB-1641
20241091948	2024-04-17	Shionogi Inc	PI-SG-1645
20241091979	2024-04-17	Actelion Pharmaceuticals Ltd.	PI-AC-1447
20241089646	2024-04-15	SK bioscience Co., Ltd	PI-SB-1641
20241089587	2024-04-15	Bristol Myers Squibb de Colombia S.A.	PI-BM-1282
20241091193	2024-04-16	Bristol Myers Squibb Company	PI-BM-1325
20241091203	2024-04-16	BAYER S.A.	PI-BH-1408
20241091562	2024-04-17	Janssen Research & Development	PI-JC-1559
20241091565	2024-04-17	Amgen Inc.	PI-AG-1580
20241091568	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091574	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091202	2024-04-16	GlaxoSmithKline Colombia S.A	PI-GS-1451
20241091595	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091197	2024-04-16	Bristol Myers Squibb Company	PI-BM-1325
20241091676	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091689	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091198	2024-04-16	Bristol Myers Squibb Company	PI-BM-1325

20241091755	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091779	2024-04-17	Bristol Myers Squibb Company	PI-BM-1325
20241091876	2024-04-17	JANSSEN RESEARCH& DEVELOPMENT, LLC	PI-JC-1455
20241091557	2024-04-17	Amgen Inc.	PI-AG-1580
20241092981	2024-04-18	Global Blood Therapeutics, Inc.	PI-GB-1551
20241093350	2024-04-18	Janssen Research & Development	PI-NO-1607
20241092984	2024-04-18	Global Blood Therapeutics, Inc.	PI-GB-1521
20241093312	2024-04-18	Novo Nordisk A/S	PI-NN-1309
20241093364	2024-04-18	Fundación Valle de Lili	PI-FV-1375
20241094963	2024-04-20	Mirum Pharmaceuticals Inc.	PI-MPI-1471
20241094978	2024-04-20	Vaxart, Inc.	PI-VI-1472
20241094983	2024-04-20	Global Blood Therapeutics, Inc.	PI-GB-1551
20241094987	2024-04-20	Global Blood Therapeutics, Inc.	PI-GB-1521
20241095002	2024-04-21	AstraZeneca AB	PI-AZ-1667
20241095051	2024-04-22	BAYER S.A.	PI-BH-1408
20241095059	2024-04-22	BAYER S.A.	PI-BH-1408
20241095071	2024-04-22	BAYER S.A.	PI-BH-1408
20241086423	2024-04-11	Actelion Pharmaceuticals Ltd.	PI-AC-1447
20241095090	2024-04-22	Bayer S.A.	PI-BH-1663
20241095065	2024-04-22	Janssen Research & Development	PI-NO-1607
20241096886	2024-04-23	Novartis Pharma AG	PI-CHT-1571
20241097316	2024-04-23	Amgen Inc.	PI-AG-1580
20241113279	2024/05/09	IQVIA RDS Colombia S.A.S.	PI-AE-1704
20261331514	2026-10-05	REGENERON PHARMACEUTICALS, INC	PI-RPH-1885
20261336773	2026-10-13	Bristol Myers Squibb	PI-BM-1759

Atentamente,

ANGELA STELLA CAUSIL DURANTE
Coordinadora Grupo de Investigación Clínica
Dirección de Medicamentos y Productos Biológicos (DMPB)

Proyectó: Grupo de Investigación Clínica