Press Release March 11 2026

To: Mr. Kenichiro Ueno Minister of Health, Labour and Welfare

Petition to Stop Plans for Routine Vaccination with Abrysvo®

Japan Institute of Pharmacovigilance (MedCheck), General Incorporated Association

Director HAMA, Rokuro

Chiyoda Building North wing, 3rd Floor Room I, 13-38 Naniwacho, Kita-ku, Osaka 530-0022, Japan

TEL.06-6147-5639 FAX.06-6147-5649 npojip@nifty.com http://www.medcheckjp.org

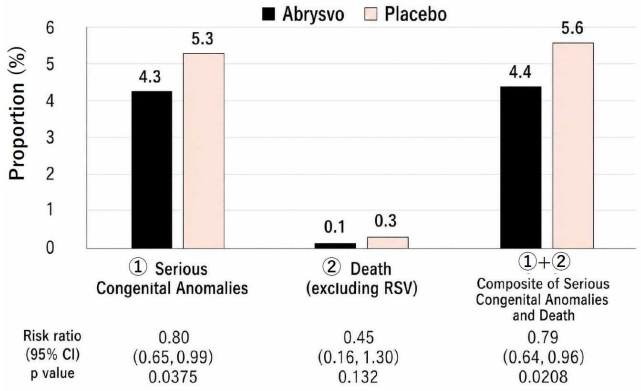
【1】Request: Stop Plans for Routine Vaccination with Abrysvo untill

1. Disclosure of maternal medication/substance use histories, strongly suspected as a possible cause of the bias favoring Abrysvo in the reported rates of congenital anomalies and neonatal deaths.
2. Re-analysis and re-evaluation of efficacy outcomes (including hospitalized respiratory tract infections and hospitalized RSV infections) and adverse-event outcomes, with appropriate statistical adjustment using those data.
3. Assessment of efficacy using all lower respiratory tract infections, including RSV-negative as well as RSV-positive cases, with particular emphasis on one-year data for hospitalized respiratory tract infections.
4. Use of absolute risk reduction (ARR), not only relative risk reduction (RRR) or vaccine efficacy (VE), when comparing benefits and harms, and comparison with the risk difference (RD; absolute risk increase) for serious adverse events, to determine whether benefits truly outweigh harms.
5. Routine vaccination should not begin unless and until re-evaluation confirms that benefits exceed harms.

1. GSK stopped after +40% preterm birth and doubled infant deaths. Is Abrysvo safe despite +20% preterm birth?

2. Suspected allocation imbalance favoring Abrysvo

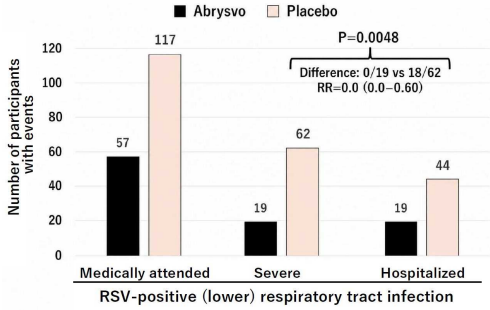
Fig. 1: Imbalances in congenital anomalies and deaths raise suspicion of allocation bias



3. Unusually favourable outcomes for Abrysvo

"Severe cases" as a prioritised primary outcome are inappropriate for primary outcome.

Fig. 2: The extreme difference in severe cases suggests possible unmasking

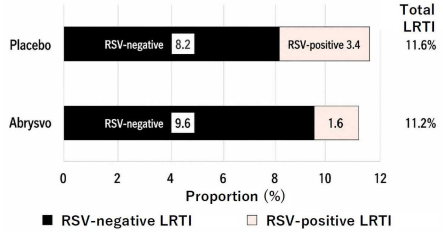


4. Overlooked rise in RSV-negative LRTIs (lower respiratory tract infections)

Fig. 3: Comparison of RSV-positive, RSV-negative, and total LRTI cases

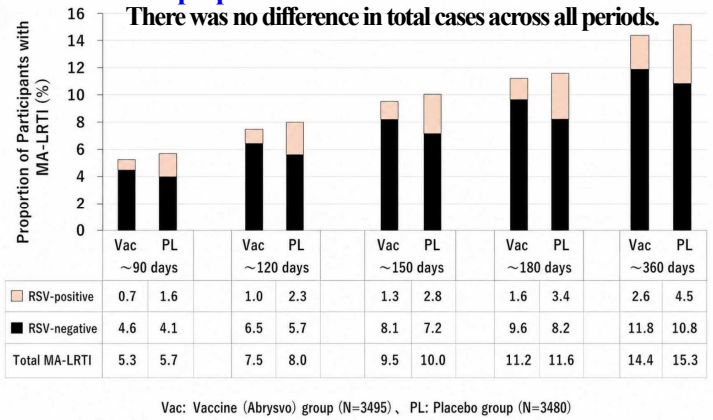
A: through 180 days

RSV-positive cases decreased by 1.8%, from 3.4% to 1.6%; however, RSV-negative cases increased by 1.4%, from 8.2% to 9.6%, and the total changed only from 11.6% to 11.2%, indicating virtually no overall reduction.



B. Trends of cumulative proportions

There was no difference in total cases across all periods.



	Vac ~90 days	PL ~90 days	Vac ~120 days	PL ~120 days	Vac ~150 days	PL ~150 days	Vac ~180 days	PL ~180 days	Vac ~360 days	PL ~360 days
RSV-positive	0.7	1.6	1.0	2.3	1.3	2.8	1.6	3.4	2.6	4.5
RSV-negative	4.6	4.1	6.5	5.7	8.1	7.2	9.6	8.2	11.8	10.8
Total MA-LRTI	5.3	5.7	7.5	8.0	9.5	10.0	11.2	11.6	14.4	15.3

Vac: Vaccine (Abrysvo) group (N=3495)、PL: Placebo group (N=3480)

5. Absolute risk reduction (ARR) for benefit-harm comparison
6. Statistical interpretation should be applied appropriately
7-1. Appropriate indicator for efficacy and harm

7-2,3. Induced preterm delivery risk due to HDP ("pregnancy toxemia": 0.65%) exceeds infant benefit (0.46-0.55%)

Fig. 4: Proportion of RSV-positive hospitalised RTI cases (~ 1 year)

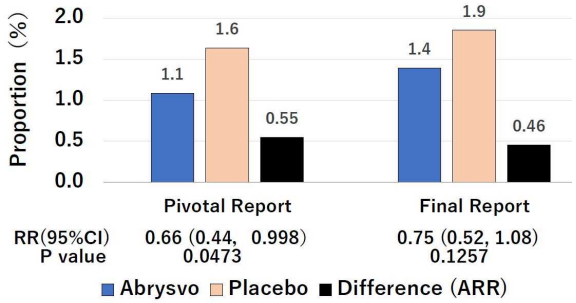
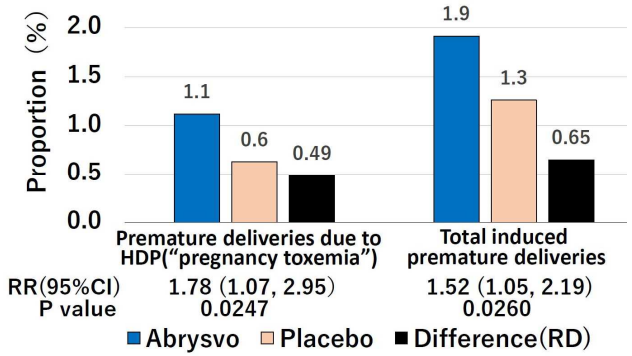


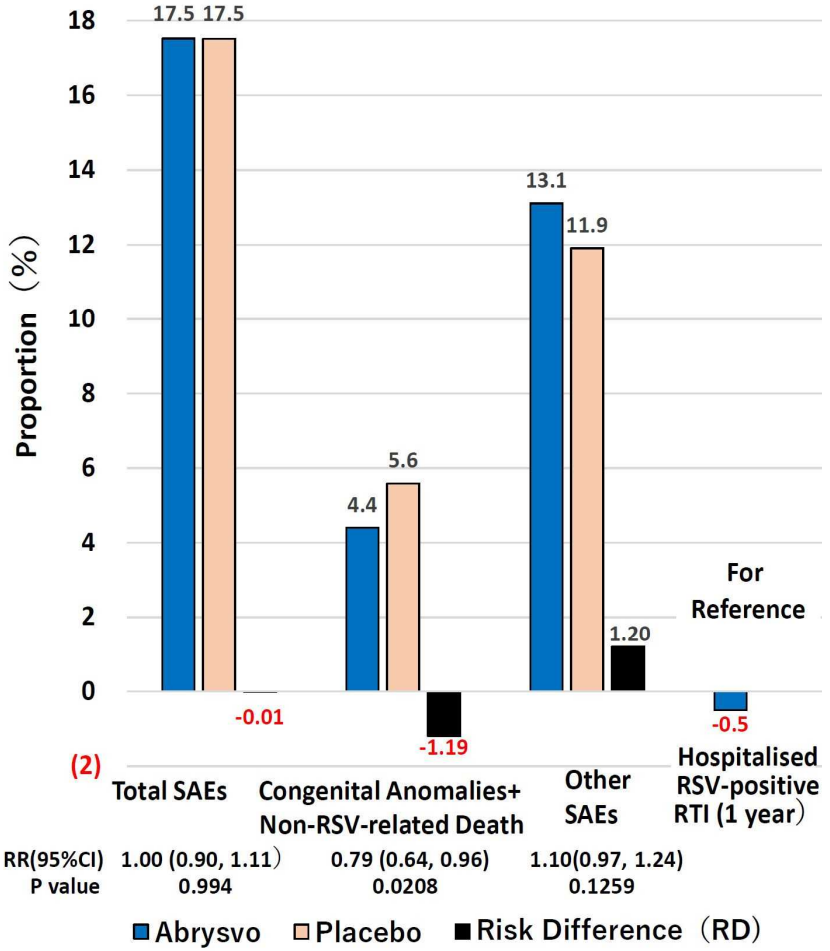
Fig. 5: Proportion of induced preterm deliveries due to complications (final report)



The risk of induced preterm delivery due to hypertensive disorders of pregnancy (HDP, formerly known as pregnancy toxemia; 0.65%) (Fig. 5) exceeds infant benefit (0.46–0.55%) (Fig. 4). Moreover, the final report shows that the benefit is not statistically significant, whereas the harm is statistically significant. The term "pregnancy toxemia" was historically used for serious hypertensive disorders of pregnancy (HDP). HDP includes gestational hypertension without proteinuria, preeclampsia (hypertension with proteinuria), and eclampsia, in which seizures occur.

7-4 Infant harms exceed benefit by more than twofold

Fig. 6: Comparison by category of serious adverse events occurring in infants (up to age 1–2 years: primary report)



The 1.20% increase in harm is more than twice the 0.5% increase in benefit to children.

Table 2: Comprehensive evaluation of serious events in mothers and infants from maternal Abrysvo vaccination (summary of Phase III trial)

Outcomes [Reference]	Abrysvo (a)			Placebo (p)			RD (%) (−ARR:%)	NNTB (H)	Risk Ratio (RR)		P value
	Na	Ea	a%	Np	Ep	p%			RR	95%CI	
①a RSV-confirmed hospitalised LRTI (1 year) [8]	3,495	38	1.1	3,480	57	1.6	−0.55	182	0.66	(0.44,1.00)	0.0473
①b RSV-confirmed hospitalised LRTI (1 year) [9]	3,585	50	1.4	3,563	66	1.9	−0.46	218	0.75	(0.52, 1.08)	0.1257
②a Maternal: Induced preterm deliveries due to HDP [9]	3,659	41	1.1	3,646	23	0.6	0.49	204	1.78	(1.07, 2.95)	0.0247
②b Maternal: All induced preterm deliveries [9]	3,659	70	1.9	3,646	46	1.3	0.65	154	1.52	(1.05、2.19)	0.0260
②c Maternal: All SAEs (～ postpartum 6M) [20]	3,682	598	16.2	3,675	558	15.2	1.06	−95	1.08	(0.96, 1.23)	0.2127
③ Infant: All SAEs (full study period; 1 or 2 years) [20]	3,568	625	17.5	3,558	623	17.5	0.01	—	1.00	(0.89, 1.13)	0.9938
④ Infant: Serious congenital anomalies [8]	3,568	152	4.3	3,558	189	5.3	−1.05	—	0.80	(0.65, 0.99)	0.0375
⑤ Infant: Non-RSV-related deaths [8]	3,568	5	0.1	3,558	11	0.3	−0.17	—	0.45	(0.16, 1.30)	0.1317
⑥ Infant: ④ + ⑤	3,568	157	4.4	3,558	199	5.6	−1.19	—	0.79	(0.64, 0.96)	0.0208
⑦ Infant: Other SAEs (③ excluding ⑥)	3,568	468	13.1	3,558	424	11.9	1.20	−83	1.10	(0.97, 1.24)	0.1259

Summary of Section 7.

If 200 pregnant women receive Abrysvo, one infant RSV respiratory tract infection hospitalisation can be prevented, but in exchange two mothers will suffer harm equivalent to hospitalisation or worse: including more than one significant increase of induced preterm delivery due to pregnancy complications including so called "pregnancy toxemia". Furthermore, there was an increase in RSV-negative infections in infants, and the overall number of respiratory infections occurring in hospitals did not decrease. There is concern that two or more infants may suffer harm equivalent to hospitalisation or worse over one to two years. Harms must not be overlooked.

8. Routine vaccination may benefit about 2,500 people but harm more than 10,000 annually

There were just over 680,000 births in Japan in 2024. If 80% of pregnant women receive vaccination under routine immunisation, approximately 500,000 mothers would be vaccinated and nearly the same number of newborns would be born.

Although these figures are not statistically significant except significant increase of induced preterm delivery due to pregnancy complications at the alpha-error 0.05 level, we estimated the potential scale of harm under routine vaccination in order to avoid overlooking harms and to take potential imbalance in baseline characteristics into account.

As a result, approximately 2,500 infants would avoid RSV infection severe enough to require hospitalisation during the first year after birth. On the other hand, approximately 5,000 mothers would suffer harm severe enough to require hospitalisation within six months postpartum, of whom half would have preterm delivery indicated because of so-called toxemia of pregnancy (serious hypertensive disorders of pregnancy), and induced preterm delivery with some complications would be expected to occur even more frequently. In addition, approximately 6,000 infants would be estimated to suffer harm severe enough to require hospitalisation during the first or second year after birth.

We request suspension of plans for routine vaccination with Abrysvo®

We conclude that routine maternal vaccination with Abrysvo may cause substantial harm to both mothers and infants and may result in new large-scale drug-induced sufferings.

We request that the government review the possibility of imbalance in baseline characteristics at allocation and re-evaluate harms, and that, until such a review is completed—and unless the review still concludes that benefits outweigh harms—routine maternal vaccination with Abrysvo should be suspended, and routine vaccination plans not be initiated.