Prescription vaccines SIV

Canadian Food Inspection Agency Canadian Centre for Veterinary Biologics Importation of Prescription Product SIV vaccine (CCVB: 920PL/S1.0/I6.2) from Jan 1, 2019 - May 11, 2023		
Number	Number of Permits	Date Permit issued

s.20(1)(b)
s.20(1)(c)

Prescription vaccines SIV

Number	Number of Permits	Date Permit issued

Prescription vaccines SIV

Number	Number of Permits	Date Permit issued

s.20(1)(b)

s.20(1)(c)

Prescription vaccines SIV

Number	Number of Permits	Date Permit issued

s.20(1)(b)
s.20(1)(c)

Prescription vaccines SIV

	Number	Number of Permits	Date Permit issued

s.20(1)(b)
s.20(1)(c)

Prescription vaccines SIV

Number	Number of Permits	Date Permit issued

Prescription vaccines SIV

Number	Number of Permits	Date Permit issued
Total number of import permits		

Prescription vaccines RV

Canadian Food Inspection Agency Canadian Centre for Veterinary Biologics Importation of Prescription Product RV vaccine (CCVB: 920PL/S1.01/I6.2) from Jan 1, 2019 - May 11, 2023		
Number	**Number of Permits**	**Date Permit issued**

Prescription vaccines RV

Number	Number of Permits	Date Permit issued

Prescription vaccines RV

Number	Number of Permits	Date Permit issued

Prescription vaccines RV

Number	Number of Permits	Date Permit issued

Prescription vaccines RV

Number	Number of Permits	Date Permit issued
Total number of import permits		

s.20(1)(b)
s.20(1)(c)

Prescription vaccines PCV3

Canadian Food Inspection Agency Canadian Centre for Veterinary Biologics Importation of Prescription Product PCV3 vaccine (CCVB: 920PL/S1.02/I6.2) from Jan 1, 2019 - May 11, 2023		
Number	Number of Permits	Date Permit issued

s.20(1)(b)
s.20(1)(c)

Prescription vaccines PCV3

Number	Number of Permits	Date Permit issued

s.20(1)(b)
s.20(1)(c)

Prescription vaccines PCV3

Number	Number of Permits	Date Permit issued
Total number of import permits		

s.19(1)

s.20(1)(b)

s.20(1)(c)

CFIA_ACIA-#19244536-v1-#A-2023-00036 (ATIP) Prescription Product_ RNA Particle Adverse Event Reports.XLSX

CASE REFNO	USER PROBLEM TYPES	BRAND	GENERIC	BATCH NUMBERS	USED CORRECTLY	MISUSE TYPES	OTHER PRODUCTS	SPECIES	PATIENT AGE
	Susp adverse reaction	RNA Particle Swine Influenza Virus Vaccine 250ml	Swine Influenza Vaccine		Unknown		Unknown vaccine ()	Porcine	6 Month(s)

NARRATIVE	PT TERMS
Suspected Adverse Reaction reported by the veterinarian on 15 Aug 2019. A producer boostered 800 gilts, 6 month of age in Aug 2019 with RNA Particle Swine Influenza Virus vaccine around 01 Aug 2019. They had received first one 3 weeks prior without issue. A farm technician has seen approximately 12-14 gilts with abscess but some of them may be only swelling (limited information), golf ball size, around 12 Aug 2019, 1-2 weeks following second vaccination with RNA Particle. Some of them may be only lump/swelling. Other vaccines were part of vaccination protocol (information is unknown, product, date and site given). The veterinarian will visit the gilt developer site and provide complementary information. Follow-up pending. Follow-up, 28 Aug 2019. The farm veterinarian mentioned she has visited another farm with similar management and genetic and did not see any local reaction. After further discussion with herd supervisor (from this case), he said he does not think the vaccine is responsible for the local reactions as there were many flaws in the vaccination technique that needed to be reviewed with employees. It was reported as approximately 13 abscess. No more information is expected.	Injection site infection

OUTCOME	CAUSALITY CODE	CAUSALITY COMMENT	COMPANY SERIOUS	NO TREATED	NO REACTED	NO EUTHANISED	NO DIED	NO RECOVERED
Remains under treatment				800	13	0	0	0

	Susp adverse reaction	RNA Particle Swine Influenza Virus Vaccine 250ml	Swine Influenza Vaccine					Porcine	Age: unknown	\ p

Suspected adverse reaction reported by the veterinarian on 10 Dec 2019. Limited information received for this case. A swine producer mentioned to the veterinarian that 30-40% of pigs are eating less since vaccination with RNA Particle Swine Influenza Virus Vaccine given on 30 Nov 2019. It is mostly the lactating and pregnant sows. One sow had generalized red spots on skin (see photo). Follow-up 18 Dec 2019: The veterinarian reported that 530 sows were vaccinated. The herd has a high health status (PRRS negative). He has not done a follow up with the producer but is convinced that the clinical signs resolved quickly otherwise the producer would have called him back. The sow herd will receive a booster dose shortly; he will let us know if a reaction occurs. No more information is expected .	Anorexia;Dermatitis and eczema

Remains under treatment		530	213	0	0	0	

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2021-01-03		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Lack of efficacy;	Lack of efficacy;	
	2022-05-18		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;	Animal event	Lack of efficacy; Death;	Lack of efficacy;	
	2023-03-21		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Lack of efficacy;	Lack of efficacy;	

s.19(1)

s.20(1)(b)

s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2021-02-08 14:00	Remains under treatment		0	0
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2022-06-03 11:00	Euthanasia	4 Day(s)	0	4
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2023-03-24 15:59	Remains under treatment		0	0

s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
2	2	0		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		unknown		Canada
12000	240	0		PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;		unknown		Canada
1200	120	0		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		unknown		Canada

s.19(1)
s.20(1)(b)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case narrative (Long)
Suspected Lack of Expected Efficacy reported the farm veterinarian on 03 Jan 2021. A Canadian farm is vaccinating their sows with Sequivity RNA particle Swine Influenza vaccine. They did a whole herd vaccination blitz (2 injection) with Sequivity RNA particle Swine Influenza vaccine in winter 2020 and has been vaccinating pre-farrow since then (approximately 320 sows per week). Approximately 3000 piglets were moved to a farm in the US. Approximately 10 % of the exported piglets (300) are showing influenza clinical signs (see case . Nasal swabs were taken from 2 piglets in the nursery (farm in Canada) and were positive for Swine Influenza Virus A (SIV A). SIV Sub-typing results are awaited. Further follow-up pending. Follow-up, 28 Jan 2021. The farm veterinarian reported that no sub-typing was performed. The farm is still dealing with SIV in the sow herd and nursery, but the producer didn't want to wait on more results before re-ordering another batch of Sequivity vaccines, to speed up the process. No further information is expected.
Suspected Lack of Expected Efficacy (SLEE) reported by the farm veterinarian on 18 May 2022. A swine producer has a 3000 sows herd in 4 week batch farrowing system (600 sow per batch). He started to use Sequivity rotavirus vaccine a few weeks ago (calculated to be approximately 07 Apr 2022) since they have a history of Rotavirus in 3-4 days old piglets. Sows are vaccinated twice at 4 and 1 week pre-farrow. In the first batch, the producer noticed a good improvement with diarrhea prevalence in piglets compared to previous batches but there were still some diarrhea, now around 4-5 days of age. Four piglets were sent to the diagnostic lab on 25 Apr 2022. At necropsy, all piglets had lesions compatible with Rotavirus. PCR was done on 2 pooled samples of intestines (2 intestines per pool). PCR was positive for Rotavirus A (CT 17.25) for one pool and positive for Rotavirus A (CT 17.22) and Rotavirus C (CT 35.12) for the other pool. Intestine content was positive for Clostridium difficile in 3 of the 4 piglets. PCRs were negative for porcine E.coli, Porcine epidemic diarrhea (PED), Porcine reproductive and respiratory syndrome (PRRS), Deltacoronavirus. The samples are to be sequenced and compared to sequences in vaccine. The second vaccinated batch has farrowed few days ago and producer mentioned to the vet that the prevalence of diarrhea is even lower, so improving. The number of piglets are estimated as a total of 12000, with a morbidity rate of 1-2 % = 240. The veterinarian did not want to report a SLEE but wanted to discuss the case and have positive Rota PCR from first batch sequenced. Follow-up pending. 27 May 2022: Rotavirus A found on the farm was sequenced and showed 99.39% homology with the replicon in the Sequivity vaccine that was used. The veterinarian will evaluate if there is any management issues at this farm. No more information is expected.
Suspected lack of expected efficacy reported by the herd vet on 21 March 2023. A producer vaccinated his 1200 sows in 2022 with Sequivity Swine Influenza Virus (SIV). At present time (estimated since week of 13 March 2023 for reporting purposes) it is reported that 10% of the piglets are experiencing flu like symptoms, sneezing and coughing, and no mortality. An unknown number of piglets tested positive for SIV, the result indicated the virus is 98.94 % homologous with the vaccine. The farm produces weekly 1200 piglets (estimated as 120 affected). A investigation is pending into the situation. Further details are expected.

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2020-12-15		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Lack of efficacy; Death;	Lack of efficacy;	
	2023-02-23		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Infertility NOS;	Adverse reaction;	

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2020-12-23 17:00	Euthanasia	6 Week(s)	0	5
Biologic / vaccine	Bio.(1);		Adverse reaction		Attending veterinarian		2023-03-07 13:00	Unknown		0	0

s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
200	25	0	F	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		unknown		Canada
500	10	0	I	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		intramuscular		Canada

s.19(1)
s.20(1)(b)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case narrative (Long)
Suspected Lack of Efficacy reported by the veterinarian on 15 Dec 2020. This swine colony was diagnosed with influenza H1N2 in 2018 after decreased nursery growth and increased mortality was observed. Overtime, the herd has not stabilized (continued to see clinical disease in weaned pigs (decreased growth and increased mortality as well as secondary infections from chronic influenza infections) and influenza continued to be identified through diagnostics. The herd (715 animals- sows, gilts and boars) was then mass vaccinated with RNA Particle Swine influenza vaccine in May 2020. They were also boostered according to label 4 weeks later (Jun 2020). On 05 Oct 2020, 34 oral fluids sample from nursery pigs were collected and sent for PCR. Results showed increased presence of virus (2 pools of 4 piglets and 6 individually tested piglets were positive, 20 were negative). The vet commented that the farm was also starting to see decreased quality of pigs in the nursery (increased poor doers, pigs needing to be euthanized) and there was some sneezing during her visit (numbers were not specified- estimated as 20 poor doers/sneezing and 5 euthanised). The clinical signs are found around 6-8 weeks of age which could be the time to maternal antibodies are wearing out. The whole herd was re-vaccinated with RNA Particle Swine influenza vaccine at the end of October 2020. They have not seen any improvement, the situation even seems to be worse according to the vet (see SLEE for vaccine given in Oct 2020 in case This present case will be closed and follow-up will continue in the case No more information is expected. Follow up information received on 6/22/2021 2:58:40 PM Suspected Lack of Efficacy reported by the veterinarian on 15 Dec 2020. This swine colony was diagnosed with influenza H1N2 in 2018 after decreased nursery growth and increased mortality was observed. Overtime, the herd has not stabilized (continued to see clinical disease in weaned pigs (decreased growth and increased mortality as well as secondary infections from chronic influenza infections) and influenza continued to be identified through diagnostics. The herd (715 animals- sows, gilts and boars) was then mass vaccinated with RNA Particle Swine influenza vaccine in May 2020. They were also boostered according to label 4 weeks later (Jun 2020). On 05 Oct 2020, 34 oral fluids sample from nursery pigs were collected and sent for PCR. Results showed increased presence of virus (2 pools of 4 piglets and 6 individually tested piglets were positive, 20 were negative). The vet commented that the farm was also starting to see decreased quality of pigs in the nursery (increased poor doers, pigs needing to be euthanized) and there was some sneezing during her visit (numbers were not specified- estimated as 20 poor doers/sneezing and 5 euthanised). The clinical signs are found around 6-8 weeks of age which could be the time to maternal antibodies are wearing out. The whole herd was re-vaccinated with RNA Particle Swine influenza vaccine at the end of October 2020. They have not seen any improvement, the situation even seems to be worse according to the vet (see SLEE for vaccine given in Oct 2020 in case . This present case will be closed and follow-up will continue in the case No more information is expected.
Suspected Adverse Reaction reported by the swine production site veterinarian on 23 Feb 2023. They have noticed that their conception rate went down a bit after the whole herd was vaccinated with Sequivity Influenza (unspecified number of non-pregnant females- estimated as 10 out of 500). The veterinarian agrees that management and stress of handling during vaccination is likely a factor. They will review their procedures in order to reduce stress and will also move Sequivity vaccination to pre-farrow (3 weeks apart between doses) instead of whole herd, to decrease the stress at early pregnancy. No more information is expected.

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2020-12-15		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Lack of efficacy; Lameness;	Adverse reaction; Lack of efficacy;	
	2020-11-20		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Lack of efficacy;	Lack of efficacy;	

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Adverse reaction		Attending veterinarian		2020-12-23 17:00	Remains under treatment	6 Week(s)	0	0
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2021-02-08 14:00	Remains under treatment		0	0

s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
200	40	0		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		unknown		Canada
500	10	0		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		intramuscular		Canada

s.19(1)
s.20(1)(b)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case narrative (Long)
Suspected Lack of Expected Efficacy reported by the veterinarian on 15 Dec 2020. This swine colony has a history of influenza H1N2 since 2018. Since the issue was not resolving, the herd (715 animals- sows, gilts and boars) was mass vaccinated with RNA Particle Swine influenza vaccine in May 2020. They were also boostered according to label 4 weeks later (Jun 2020). In October 2020, the farm was starting to see decreased quality in 6-8 week old pigs in the nursery (increased poor doers, pigs needing to be euthanized, and some sneezing). Some PCR were positive for Influenza (see SLEE . The whole herd was re-vaccinated with RNA Particle Swine influenza vaccine at the end of October 2020. They have not seen any improvement, the situation even seems to be worse according to the vet (entered as 30 sick pigs approximately). Samples will be taken again in January 2021 to rule out PCV2 and a new SIV strain circulating. Follow-up pending. Follow up information received on 6/22/2021 2:40:35 PM Suspected Lack of Expected Efficacy reported by the veterinarian on 15 Dec 2020. This swine colony has a history of influenza H1N2 since 2018. Since the issue was not resolving, the herd (715 animals- sows, gilts and boars) was mass vaccinated with RNA Particle Swine influenza vaccine in May 2020. They were also boostered according to label 4 weeks later (Jun 2020). In October 2020, the farm was starting to see decreased quality in 6-8 week old pigs in the nursery (increased poor doers, pigs needing to be euthanized, and some sneezing). Some PCR were positive for Influenza (see SLEE . The whole herd was re-vaccinated with RNA Particle Swine influenza vaccine at the end of October 2020. They have not seen any improvement, the situation even seems to be worse according to the vet (entered as 30 sick pigs approximately). Samples will be taken again in January 2021 to rule out PCV2 and a new SIV strain circulating. Follow-up pending. Follow-up, 26 Jan 2021: Suspected Adverse Reaction (SAR) added to the case. The veterinarian was contacted. She provided the last vaccination dates for RNA particles, swine Influenza virus vaccine: 29 Jun 2020 and 21 Oct 2020. During her visit last week, she saw disease challenges that might be impacting the vaccine response. The herd is dealing with a feed quality issue for the sows and is causing an ongoing lameness problem (SAR)(unknown number of animals: 10 entered arbitrarily). The second vaccination with RNA particle swine influenza virus vaccine was performed on 25 Jan 2021. The veterinarian stated that the herd was first diagnosed with influenza in 2016 with increased issues in 2018. She believes the vaccine did actually help with this farm. The case will be closed as it is thought that the sows have ongoing health issues and are not in the best shape to have an optimal response to the vaccine. No more information is expected.
Suspected Lack of Expected Efficacy reported by the veterinarian on 20 Nov 2020. A farmer with a herd of 5500 sows reported clinical respiratory signs on nursery pigs. They are vaccinated with RNA Particle, Swine Influenza Virus (SIV) vaccine, number is unknown entered 500 arbitrarily. He has 310 sows vaccinated weekly plus replacements for a total of almost 500 per week. Some pigs are coughing and sneezing (number is unknown, entered 10 arbitrarily). No mortalities was reported. The veterinarian wants to ruled out swine influenza virus and suspects that the farm got hit by a new strain. The veterinarian will take samples for PRRS, Mycovirus and SIV. Follow-up pending. Follow-up 05 Jan 2021: PCR came back weakly positive for Mycoplasma hyopneumoniae in few animals and weakly positive Porcine Circovirus 3 (PCV/) in most tested pigs and swab from skin udder PCR weak positive for Swine Influenza A virus subtype H3N2. They will not perform the sequence for SIV of the vaccine since it was weak positive in 1 skin udder sample and larynx swab PCR negative for Swine Influenza A in all pigs. PCR was negative for PCV2 and Leptospira. The veterinarian is suspecting PCV3 issue and will vaccine for PCV3. No more information is expected.

Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2022-03-11		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Abortion;	Adverse reaction;	
	2020-10-01		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Death; Cough; Weight loss; Dyspnoea; Respiratory tract disorder NOS; Digestive tract disorder NOS;	Adverse reaction;	

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Adverse reaction		Attending veterinarian		2022-03-23 15:00	Unknown	1 Year(s)	0	0
Biologic / vaccine	Bio.(1);		Adverse reaction		Attending veterinarian		2020-10-13 18:00	Natural Death		3	0

s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
530	5	0		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		intramuscular		Canada
600	10	7		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Product expired;	intramuscular		Canada

s.19(1)
s.20(1)(b)

Case narrative (Long)
Suspected Adverse Reaction reported by the farm veterinarian on 11 Mar 2022. This swine farm has a total of 530 sows and works on a 4 weeks batch farrowing system. The herd is PRRS (porcine reproductive and respiratory syndrome) negative and has a high health status. The herd was mass vaccinated with Sequivity (for Influenza) on 08 Dec 2021. A batch of 100 sows and 22 gilts were inseminated between 08 -13 Nov 2021 (before vaccination). The producer told the veterinarian that 5 sows were found negative on second pregnancy test 42 days following insemination (20-25 Dec 2021). The producer thinks they have possibly aborted. Further suspected adverse reactions that occurred following booster vaccination given on 08 Jan 2022 are reported in case (some mummified foetuses, 7-8 gilts with reddish vulvar secretions 10-11 days after insemination. The producer wonder if those observations could be vaccine-related. The veterinarian has not yet visited the farm. Some mummified foetus will be brought to the lab for diagnostic work to try to identify the cause. This farm has reported a SLEE to Sequivity in 2020 signs of flu after vaccination). Follow-up pending. Follow up information received on 10/31/2022 10:59:49 AM. Suspected Adverse Reaction reported by the farm veterinarian on 11 Mar 2022. This swine farm has a total of 530 sows and works on a 4 weeks batch farrowing system. The herd is PRRS (porcine reproductive and respiratory syndrome) negative and has a high health status. The herd was mass vaccinated with Sequivity (for Influenza) on 08 Dec 2021. A batch of 100 sows and 22 gilts were inseminated between 08 -13 Nov 2021 (before vaccination). The producer told the veterinarian that 5 sows were found negative on second pregnancy test 42 days following insemination (20-25 Dec 2021). The producer thinks they have possibly aborted. Further suspected adverse reactions that occurred following booster vaccination given on 08 Jan 2022 are reported in case some mummified foetuses, 7-8 gilts with reddish vulvar secretions 10-11 days after insemination. The producer wonder if those observations could be vaccine-related. The veterinarian has not yet visited the farm. Some mummified foetus will be brought to the lab for diagnostic work to try to identify the cause. This farm has reported a SLEE to Sequivity in 2020 (; signs of flu after vaccination). Follow-up pending. 23 Mar 2022: Laboratory tests done on two mummified foetuses (reported in case did not reveal a pathogen or lesions that would explain increase in fetal mummification (PCR negative for Circovirus 2, Leptospira, Parvovirus and PRRS (porcine reproductive and respiratory syndrome). No other testing was done. 01 Apr 2022: Further tests results done on the mummified foetus were provided. Circovirus 3 and herpesvirus were both negative on PCR. Further information is expected.
Suspected Adverse Reaction- reported by the farm veterinarian on 01 Oct 2020. The swine producer told him that, following RNA Particle Swine Influenza Virus vaccine, he saw clinical signs of flu on some sows; 1 gilt was found dead and one other is coughing and losing weight. Further details were received on 06 Oct 2020: The swine producer has a PRRS negative herd that should be of high health although they have had influenza issues in the past in this farm. He vaccinated 600 sows and gilts with RNA Particle Swine Influenza Virus vaccine mostly on 25 Sep 2020, a few gilts on 02 Oct 2020 (ELU- product was expired since 23 Sep 2020). In the days following vaccination (approx. 27 Sep 2020), the producer saw Swine Influenza virus (SIV)- like symptoms (coughing, dyspnea, nose secretion) on a few sows (unknown number- estimated as 10) and reported this to his vet on 30 Sep 2020. Two gilts died on 30 Sep 2020 and one died on 04 Oct 2020 (this one was vaccinated on 02 Oct 2020). The gilts that died were vaccinated for the first time. The swine company technician visited the herd on 01 Oct 2020 and did not see any of the clinical signs reported by the producer. The event is reported more as a SAR (Suspected Adverse Reaction) and not a SLEE (lack of expected efficacy). The gilt that died on 04 Oct 2020 was sent to the lab for testing. This farm also reported a SAR in Dec 2019 for decreased appetite and red spots on skin after this vaccine was administered (Follow-up pending. Follow up information received on 8/23/2021 4:27:08 PM Suspected Adverse Reaction- reported by the farm veterinarian on 01 Oct 2020. The swine producer told him that, following RNA Particle Swine Influenza Virus vaccine, he saw clinical signs of flu on some sows; 1 gilt was found dead and one other is coughing and losing weight. Further details were received on 06 Oct 2020: The swine producer has a PRRS negative herd that should be of high health although they have had influenza issues in the past in this farm. He vaccinated 600 sows and gilts with RNA Particle Swine Influenza Virus vaccine mostly on 25 Sep 2020, a few gilts on 02 Oct 2020 (ELU- product was expired since 23 Sep 2020). In the days following vaccination (approx. 27 Sep 2020), the producer saw Swine Influenza virus (SIV)- like symptoms (coughing, dyspnea, nose secretion) on a few sows (unknown number- estimated as 10) and reported this to his vet on 30 Sep 2020. Two gilts died on 30 Sep 2020 and one died on 04 Oct 2020 (this one was vaccinated on 02 Oct 2020). The gilts that died were vaccinated for the first time. The swine company technician visited the herd on 01 Oct 2020 and did not see any of the clinical signs reported by the producer. The event is reported more as a SAR (Suspected Adverse Reaction) and not a SLEE (lack of expected efficacy). The gilt that died on 04 Oct 2020 was sent to the lab for testing. This farm also reported a SAR in Dec 2019 for decreased appetite and red spots on skin after this vaccine was administered . Follow-up pending. Follow-up, 20 Oct 2020: The veterinarian reported that, according to the lab report, the gilt that was sent to the laboratory died of digestive issue. There is no more health issue at the farm. They will give the booster vaccination in the next days and will communicate with us if there is further abnormal findings. No more information is expected.

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2022-01-05		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;	Animal event	Lack of efficacy; Death;	Lack of efficacy;	

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2022-01-18 20:00	Natural Death	3 Week(s)	300	0

s.20(1)(b)
s.20(1)(c)

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# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
10000	4000	0		PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;		unknown		Canada

s.19(1)
s.20(1)(b)

Case narrative (Long)
Suspected Lack of Expected Efficacy reported by the farm veterinarian on 05 Jan 2022. A swine producer vaccinates his 2500 sows (DNA genetics multiplier) with Sequivity Rotavirus (Date of vaccination entered as 2021). Since at least end of November 2021, they are having approximately 40% of the litters scouring, which is causing an increase in pre-weaning mortality of about 3% (50 piglets per week). Total number of piglets over 6 weeks is estimated as 10000; 4000 scouring, 300 mortalities. One fecal swab was collected on 24 Nov 2021 and sent to lab. PCR was positive for Rotavirus A and Rotavirus C (negative for Rotavirus B). Sequencing found a multiple strain infection, some other results showed the same strain that was in the vaccine. This farm exports 500 piglets per week to a farm in USA. During Christmas Holidays, the USA farm has had a higher incidence in scours- reported in case Follow-up pending. Follow up information received on 10/26/2022 1:47:34 PM Suspected Lack of Expected Efficacy reported by the farm veterinarian on 05 Jan 2022. A swine producer vaccinates his 2500 sows (DNA genetics multiplier) with Sequivity Rotavirus (Date of vaccination entered as 2021). Since at least end of November 2021, they are having approximately 40% of the litters scouring, which is causing an increase in pre-weaning mortality of about 3% (50 piglets per week). Total number of piglets over 6 weeks is estimated as 10000; 4000 scouring, 300 mortalities. One fecal swab was collected on 24 Nov 2021 and sent to lab. PCR was positive for Rotavirus A and Rotavirus C (negative for Rotavirus B). Sequencing found a multiple strain infection, some other results showed the same strain that was in the vaccine. This farm exports 500 piglets per week to a farm in USA. During Christmas Holidays, the USA farm has had a higher incidence in scours- reported in case Follow-up pending. 20 Jan 2022 follow-up: Some testing was done in tissues from 4 piglets exported in USA (case Overall, findings were consistent with acute rotaviral enteritis (mild lesions). Rotavirus PCR was positive in 3 of the 4 piglets (two positive for group A and B and one positive for group B only). A mild colitis was observed in one colon section, which may indicate bacterial proliferation. Culture did identified Clostridium perfringens and E.coli in 2 piglets. 27 Jan 2022: The RNA sequencing was provided for this case. It showed that the identified Rotavirus A was a Rotavirus A (G9). The Sequivity vaccine administered at this farm was protective against rotavirus A and B strains, however the homology report showed a low homology of 83.13% to the Sequivity strain used in the farm. No more information is expected.

s.19(1)
s.20(1)(b)
s.20(1)(c)

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Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2022-03-11		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;	Animal event	Vulvovaginitis; Foetal mummification;	Adverse reaction;	

s.19(1)
s.20(1)(b)
s.20(1)(c)

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Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Adverse reaction		Attending veterinarian		2022-03-23 15:00	Natural Death	1 Year(s)	67	0

s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
530	75	8		PRESCRIPTION PRODUCT, RNA PARTICLE, SWINE INFLUENZA VACCINE;		intramuscular		Canada

s.19(1)
s.20(1)(b)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case narrative (Long)
Suspected Adverse Reaction reported by the farm veterinarian on 11 Mar 2022. This swine farm has a total of 530 sows and works on a 4 weeks batch farrowing system. The herd is PRRS (porcine reproductive and respiratory syndrome) negative and has a high health status. The herd was mass vaccinated with Sequivity (for Influenza) on 08 Dec 2021 and boostered on 08 Jan 2022. A batch of 100 sows and 22 gilts were inseminated between 08 -13 Nov 2021 (before vaccination). This batch is now farrowing and the producer reported to the veterinarian that he has seen 5 or 6 mummified foetuses. In another batch, 7-8 gilts inseminated on 04 Jan 2022 (received their booster 4 days later- on 08 Jan 2022), had some reddish vulvar secretions on 14 and 15 Jan 2022 and were back in heat on 20 Jan 2022. The producer wonder if those observations could be vaccine-related. The veterinarian has not yet visited the farm. Some mummified foetus will be brought to the lab for diagnostic work, and try to identify the cause. From the first mentioned batch, 5 sows were found negative on second pregnancy test (42 days following insemination). The producer suspects abortion. This is reported in case since the pregnancy tests were done prior to booster vaccination. This farm has reported a SLEE to Sequivity in 2020 ; signs of flu after vaccination) Follow-up pending. Follow up information received on 10/31/2022 10:57:15 AM Suspected Adverse Reaction reported by the farm veterinarian on 11 Mar 2022. This swine farm has a total of 530 sows and works on a 4 weeks batch farrowing system. The herd is PRRS (porcine reproductive and respiratory syndrome) negative and has a high health status. The herd was mass vaccinated with Sequivity (for Influenza) on 08 Dec 2021 and boostered on 08 Jan 2022. A batch of 100 sows and 22 gilts were inseminated between 08 -13 Nov 2021 (before vaccination). This batch is now farrowing and the producer reported to the veterinarian that he has seen 5 or 6 mummified foetuses. In another batch, 7-8 gilts inseminated on 04 Jan 2022 (received their booster 4 days later- on 08 Jan 2022), had some reddish vulvar secretions on 14 and 15 Jan 2022 and were back in heat on 20 Jan 2022. The producer wonder if those observations could be vaccine-related. The veterinarian has not yet visited the farm. Some mummified foetus will be brought to the lab for diagnostic work, and try to identify the cause. From the first mentioned batch, 5 sows were found negative on second pregnancy test (42 days following insemination). The producer suspects abortion. This is reported in case since the pregnancy tests were done prior to booster vaccination. This farm has reported a SLEE to Sequivity in 2020 . signs of flu after vaccination) Follow-up pending. 23 Mar 2022. Lab results from the 2 mummified foetus was received. Laboratory tests did not reveal a pathogen to explain the increase in fetal mummification (PCR negative for Circovirus 2, Leptospira, Parvovirus and PRRS (porcine reproductive and respiratory syndrome). Histopathology did not reveal any lesion specific to a cause of mummification but the changes postmortem (poor conservation state) have severely limited the detection and interpretation of histological changes. 01 Apr 2022: Further tests results done on the mummified foetus were provided. Circovirus 3 and herpesvirus were both negative on PCR. Further information is expected. Follow up information received on 10/31/2022 10:57:24 AM Suspected Adverse Reaction reported by the farm veterinarian on 11 Mar 2022. This swine farm has a total of 530 sows and works on a 4 weeks batch farrowing system. The herd is PRRS (porcine reproductive and respiratory syndrome) negative and has a high health status. The herd was mass vaccinated with Sequivity (for Influenza) on 08 Dec 2021 and boostered on 08 Jan 2022. A batch of 100 sows and 22 gilts were inseminated between 08 -13 Nov 2021 (before vaccination). This batch is now farrowing and the producer reported to the veterinarian that he has seen 5 or 6 mummified foetuses. In another batch, 7-8 gilts inseminated on 04 Jan 2022 (received their booster 4 days later- on 08 Jan 2022), had some reddish vulvar secretions on 14 and 15 Jan 2022 and were back in heat on 20 Jan 2022. The producer wonder if those observations could be vaccine-related. The veterinarian has not yet visited the farm. Some mummified foetus will be brought to the lab for diagnostic work, and try to identify the cause. From the first mentioned batch, 5 sows were found negative on second pregnancy test (42 days following insemination). The producer suspects abortion. This is reported in case since the pregnancy tests were done prior to booster vaccination. This farm has reported a SLEE to Sequivity in 2020 ; signs of flu after vaccination) Follow-up pending. 23 Mar 2022. Lab results from the 2 mummified foetus was received. Laboratory tests did not reveal a pathogen to explain the increase in fetal mummification (PCR negative for Circovirus 2, Leptospira, Parvovirus and PRRS (porcine reproductive and respiratory syndrome). Histopathology did not reveal any lesion specific to a cause of mummification but the changes postmortem (poor conservation state) have severely limited the detection and interpretation of histological changes. 01 Apr 2022: Further tests results done on the mummified foetus were provided. Circovirus 3 and herpesvirus were both negative on PCR. Further information is expected. 07 Apr 2022: Further information was received. The initial dose of Sequivity was given on 10 Dec 2022 rather than 08 Dec 2022. As per protocol, the sows are also vaccinated with non-company Farrowsure 42 days post breeding (approx. 22 Dec 2021) and with non-company Circoflex 3-4 weeks before parturition (approx. 18 Feb 2022). The farm data was provided and it was found that for that particular batch they had a % of mummified foetus of 4.0% which would represent approximately 67 mummified foetus. They would usually get approximately 2% of mummified foetus in previous batches. The food consumption of the sows during gestation was analysed and did not show any decrease in consumption. The cause of the mummified foetus will remain unknown. No more information is expected.

s.19(1)
s.20(1)(b)
s.20(1)(c)

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Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2022-01-05		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;	Animal event	Lack of efficacy; Death;	Lack of efficacy;	
	2022-08-11		Pig	PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;	Animal event	Lack of efficacy;	Lack of efficacy;	

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2023-03-10 15:00	Euthanasia		0	4
Biologic / vaccine	Bio.(1);		Lack of efficacy		Attending veterinarian		2022-08-19 15:00	Unknown		0	0

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
1000	100	0		PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;		unknown		Canada
100	10	0		PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;		unknown		Canada

s.19(1)
s.20(1)(b)

Case narrative (Long)
Suspected Lack of Expected Efficacy: Reported by the Canadian farm veterinarian on 05 Jan 2022. A Canadian swine producer vaccinates his 2500 sows (DNA genetics multiplier) with Sequivity Rotavirus (Date of vaccination entered as 2021). Since at least end of November 2021, they are having approximately 40% of the litters scouring, which is causing an increase in pre-weaning mortality of about 3% (reported in case . One fecal swab was collected on 24 Nov 2021 and sent to lab. PCR was positive for Rotavirus A and Rotavirus C (negative for Rotavirus B). Sequencing found a multiple strain infection, some other results showed the same strain that was in the vaccine. This farm exports 500 piglets per week to a farm in USA. During Christmas Holidays (approximately 22 Dec 2021), the USA farm has had a higher incidence in scours than before (total amount of pigs estimated as 1000 with 10% morbidity= 100 sick piglets). Some testing will be performed in the USA. Follow-up pending. Follow-up, 20 Jan 2022: Preliminary lab report was received. Tissues from 4 piglets were sent to lab on 03 Jan 2022 (4 euthanised piglets added to the case). Culture was positive for Clostridium perfringens in 2 piglets. Genotyping showed Genotype A- Alpha and enterotoxin. Culture was positive for E. coli haemolytic and E.coli smooth/mucoid on the same two piglets. E. coli was genotyped in one piglet showing EAST1 toxin, STb toxin, K88 pilus, EAEA adhesin. Rotavirus PCR was positive in 3 of the 4 piglets (two positive for group A and B and one positive for group B only). PCR for C. difficile were negative for all. Pathologist diagnostic was:1. Rotaviral enteritis villous atrophy with enterocyte vacuolation, acute, multifocal, mild. 2. Colitis with suppurative exudate, acute, multifocal, mild. He commented that findings were diagnostic for acute rotaviral enteritis. Overall, these lesions were considered very mild. Sapovirus was detected in one piglet with a relatively high Ct of 31.1 and may indicate transmission within some litters; however, the overall clinical significance of this virus within the herd is unknown. Typically a lower Ct value would be observed in litters with sapovirus disease. A mild colitis was observed in one colon section, which may indicate bacterial proliferation. Further follow-up expected. 27 Jan 2022: The RNA sequencing was provided for this case. It showed that the identified Rotavirus A was a Rotavirus A (G9). The Sequivity vaccine administered at this farm was protective against rotavirus A and B strains, however the homology report showed a low homology of 83.13% to the Sequivity strain used in the farm. Clarification to previous report, the piglets were euthanised for diagnostic purposes. No more information is expected.
Suspected lack of expected efficacy reported by the herd veterinarian on 11 Aug 2022. It was reported that there is an increased scour occurrence on first parity litters despite vaccination with Sequivity. Information is pending on how many sows were vaccinated (estimated as 100), when vaccinated, how many sick piglets (estimated as 10) and the onset. The mortality and morbidity rates are currently unknown for this farm. The herd vet has reviewed vaccine handling techniques at this farm. Four pooled fecal samples were collected for PCR analysis on 25 July 2022. The results are as follows: all 4 pools were positive for Rotavirus A, 1-CT 24.67, 2-CT 19.54, 3-CT 19.12, 4-CT 30.26, all 4 pools were negative for Rotavirus B, only pool 1 was positive for Rotavirus C CT 32.88. Rotavirus A sequencing was done: pools 1 to 3 were at 99.08 to 100% homology with the replicon in the Sequivity vaccine that was used. Pool 4 was too weak to type. Rotavirus C sequencing was done on pool 1, was too weak to type. Complete details are pending. Follow up information received on 5/9/2023 3:43:28 PM Suspected lack of expected efficacy reported by the herd veterinarian on 11 Aug 2022. It was reported that there is an increased scour occurrence on first parity litters despite vaccination with Sequivity. Information is pending on how many sows were vaccinated (estimated as 100), when vaccinated, how many sick piglets (estimated as 10) and the onset. The mortality and morbidity rates are currently unknown for this farm. The herd vet has reviewed vaccine handling techniques at this farm. Four pooled fecal samples were collected for PCR analysis on 25 July 2022. The results are as follows: all 4 pools were positive for Rotavirus A, 1-CT 24.67, 2-CT 19.54, 3-CT 19.12, 4-CT 30.26, all 4 pools were negative for Rotavirus B, only pool 1 was positive for Rotavirus C CT 32.88. Rotavirus A sequencing was done: pools 1 to 3 were at 99.08 to 100% homology with the replicon in the Sequivity vaccine that was used. Pool 4 was too weak to type. Rotavirus C sequencing was done on pool 1, was too weak to type. Complete details are pending. 03 Oct 2022: the herd veterinarian reported he is not pursuing any further investigation with this case as they have not seen any pigs that exhibit symptoms typical of the issue anymore. Nothing further is expected.

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Case number - Version	Date first received	Date latest follow up	Species	Brand name (all suspect)	Case type	VedDRA PREF (all)	Product problem type (all suspect)	Case serious
	2022-11-16		Pig	PROSYSTEM RCE; PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;	Animal event	Lack of efficacy;	Lack of efficacy; Lack of efficacy;	
	2022-01-21		Pig	PROSYSTEM RCE; PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;	Animal event	Lack of efficacy; Death;	Lack of efficacy; Lack of efficacy;	

s.19(1)
s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

Product type	Product type (all suspect)	Industry case number	Problem type	Case reportability	Source	Causality (all suspect)	Case created date	Outcome	Age	# died	# euthanized
Biologic / vaccine	Bio.(2);		Lack of efficacy		Attending veterinarian		2022-11-25 15:00	Remains under treatment		0	0
Biologic / vaccine	Bio.(2);		Lack of efficacy		Attending veterinarian		2022-01-28 14:07	Natural Death		2	0

s.20(1)(b)
s.20(1)(c)

CFIA_ACIA - #19252172 - v1 - #A-2023-00036 (ATIP) Prescription Product, RNA Particle Adverse Event Reports .XLS

# exposed	# reacted	# recovered	Batch no (all suspect)	Generic (all suspect)	Misuse type (all)	Route (primary)	Assessment reason	Country of occurrence
100	10	0		PORCINE ROTAVIRUS VACCINE, MLV, CLOSTRIDIUM PERFRINGENS TYPE C-ESCHERICHIA COLI BACTERIN-TOXOID; PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS		unknown		Canada
1100	55	0		PORCINE ROTAVIRUS VACCINE, MLV, CLOSTRIDIUM PERFRINGENS TYPE C-ESCHERICHIA COLI BACTERIN-TOXOID; PRESCRIPTION PRODUCT, RNA PARTICLE, ROTAVIRUS VACCINE;		unknown		Canada

Case narrative (Long)
Suspected Lack of Expected Efficacy reported by the farm veterinarian on 16 November 2022. Very minimal information was provided. A swine producer has been using both Sequivity (for Rotavirus) and ProSystem RCE and continues to have diarrhea problems in his piglets (unknown number of animals, estimated at 10 out of 100 affected). Rotavirus Immunohistochemistry (IHC) on intestinal samples and sequencing of the rotavirus detected will be performed. They may also test for Porcine Circovirus 3 and Sapovirus. A follow-up is pending.Follow up information received on 5/15/2023 11:20:27 AM Suspected Lack of Expected Efficacy reported by the farm veterinarian on 16 November 2022. Very minimal information was provided. A swine producer has been using both Sequivity (for Rotavirus) and ProSystem RCE and continues to have diarrhea problems in his piglets (unknown number of animals, estimated at 10 out of 100 affected). Rotavirus Immunohistochemistry (IHC) on intestinal samples and sequencing of the rotavirus detected will be performed. They may also test for Porcine Circovirus 3 and Sapovirus. A follow-up is pending. 19 December 2022: After several attempts to contact the farm veterinarian for further information, they did not comply. No further details are expected.
Suspected Lack of Expected Efficacy reported by the farm veterinarian on 21 Jan 2022. A swine producer has a 2600 Sow Farm and is using both Sequivity (for Rotavirus C) and ProSystem RCE and continues to have scours due to Rotavirus. The farm is experiencing 5 % diarrhea in piglets, the farm produces 1100 piglets per week (entered as 55 sick out of 1100). Small intestines collected on 2 piglets (entered as dead piglets) were submitted to the laboratory on 17 Jan 2022. PCR was positive for Rotavirus A for both of them (CT of 36.94 and 14.34) and negative for Rotavirus B and C. PCR was negative for Coronavirus. The Sequivity portion is working well since it was made for Rotavirus type C. A sequence of the virus was requested to rule out a lack of efficacy of Prosystem RCE. Follow-up pending.Follow up information received on 5/15/2023 11:27:23 AM Suspected Lack of Expected Efficacy reported by the farm veterinarian on 21 Jan 2022. A swine producer has a 2600 Sow Farm and is using both Sequivity (for Rotavirus C) and ProSystem RCE and continues to have scours due to Rotavirus. The farm is experiencing 5 % diarrhea in piglets, the farm produces 1100 piglets per week (entered as 55 sick out of 1100). Small intestines collected on 2 piglets (entered as dead piglets) were submitted to the laboratory on 17 Jan 2022. PCR was positive for Rotavirus A for both of them (CT of 36.94 and 14.34) and negative for Rotavirus B and C. PCR was negative for Coronavirus. The Sequivity portion is working well since it was made for Rotavirus type C. A sequence of the virus was requested to rule out a lack of efficacy of Prosystem RCE. Follow-up pending. 08 Feb 2022: Sequencing results were received. The sequences from both submitted samples were 100% identical and showed 96.9% homology with the Prosystem RCE strain, therefore it is unsure if cross-protection against the strain found on the farm can be expected. No further information is expected.