



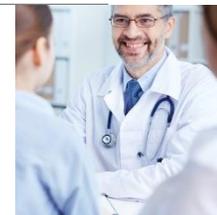
European Federation of Pharmaceutical
Industries and Associations



Insights to Industry Led CMC Post Approval Change (PAC) Pilots



January 2026





EFPIA CMC PAC RELIANCE OBJECTIVES

Objective:

Produce Industry Best Practice Guidance document for CMC PAC Reliance to support companies and Regulatory Authorities to adopt reliance.

Collect and share company metrics from Industry led CMC PAC reliance pilots, identifying success factors and challenges.

- Gather learnings from completed and ongoing industry led CMC PAC reliance pilots to ensure Industry alignment and foster a harmonized approach for CMC PAC reliance practices;
- Facilitate Industry / Regulatory Authority Engagement;
- Build on and incorporate Regulatory Authority feedback;
- Support the continued evolution of the Industry Best Practice Guidance;
- Further facilitate Industry / Regulatory Authority engagement and collaboration.

Collaboration and transparency are key drivers – both within / between Industry and Health Authorities

EFPIA CMC PAC RELIANCE Process



Observed differences in approach to reliance pilots:

1. One Company submitted CMC PAC to all Regulatory Authorities (reference & reliance) simultaneously .
2. Many companies invited Regulatory Authorities to use an online platform, albeit all Regulatory Authorities also received the CMC PAC through standard submission routes. Differences in use of platform are captured below:
 - Some Companies included a Product Sameness document on the platform;
 - Some Companies included the complete reliance package e.g. Reference Regulatory Authority questions and company responses; final Assessment Report;
 - Some Companies also included the variation dossier.

Collaboration and transparency are key drivers – both within / between Industry and Health Authorities



REGULATORY AUTHORITY PARTICIPATION

(Data from all Pilots – Completed / Ongoing / To be initiated)

113	Total Number of Regulatory Authorities invited to join a pilot
77	Regulatory Authorities that joined 1 or more pilots
36	Regulatory Authorities that never accepted a pilot

	Number of Invitations sent to Regulatory Authorities requesting participation in a Pilot	Number of Invitations resulting in a Regulatory Authority participating in a Pilot	Number of Invitations that did <u>not</u> result in a Regulatory Authority participating in a pilot	% Accepted Invitations
2023	36	20	16	56%
2024	173	97	76	56%
2025	281	163	118	58%

SUMMARY OF PILOTS THAT HAVE REACHED THE END OF THEIR RELIANCE PROCEDURE

Pilot Number	Reference Authority	Company	Product Type	Variation Category ²	Type of Change	Regulatory Authorities Invited to join pilot as Reliance Authorities	Regulatory Authorities Participated in pilot as Reliance Authorities	Reliance Authority Percentage Participation ³
1	Health Canada	Sanofi	Vaccine	Type II	New Drug Product Manufacturing Site	36	20	56
2	EMA	Roche	Biologic	Type II	Drug Substance Process Changes	83	48	58
3	EMA	GSK	Vaccine	Type II	New Drug Product Manufacturing Site	13	5	38
4	EMA	AZ	Biologic	Type IB / IA PACMP Part 2	Drug Substance Process Changes	21	13	62
5	EMA ¹	Amgen	Biologic	Type II	Drug Substance Process Optimisation	37	26	70
6	EMA	Pfizer	Small Molecule	Type II	New Manufacturing Site (Drug Product)	12	6	50
7	EMA	Sanofi	Biologic	Type II	Analytical change (3 products)	31	14	45
8	EMA	AZ	Biologic	Type II	New Site (Drug Substance)	8	4	50
9	EMA	Roche	Biologic	Type II / IB PACMP Part 1&2	New DS & DP Manufacturing Site	25	17	68

¹Collaborative process/reliance. Concurrent submission of identical dossier to Reference Authority & Relying Authorities.

²Based on EU Variation Classification Framework

³For consistency across pilots, participation refers to Relying Authorities only and does not include Reference Authority.

SUMMARY OF PILOTS ONGOING OR TO BE INITIATED

Pilot Number	Reference Authority	Company	Product Type	Variation Category ¹	Type of Change	Regulatory Authorities Invited to join pilot as Reliance Authorities	Regulatory Authorities Participated in pilot as Reliance Authorities	Reliance Authority Percentage Participation ²
11	EMA	Roche	Biologic	Type II	New Manufacturing Site	85	35	41
12	EMA	AstraZeneca/ Alexion	Biologic	Type II	Addition of alternative test methods	14	8	57
13	EMA	AstraZeneca	Biologic	Type IB	Alternative sterilization method	10	7	70
14	MHRA ³	Amgen	Biologic	Type II ⁴	DS manufacturing process changes	29	17	59
15	EMA	AstraZeneca / Daiichi Sankyo	Biologic	Type II	New Site (Drug Substance)	26	15	58
16	EMA/ Swissmedic	Merck KGaA	Biologic	Type II	New Manufacturing Site (Drug Product)	71 ⁵	45	63

¹ Based on EU Variation Classification Framework

² For consistency across pilots, participation refers to Relying Authorities only and does not include Reference Authority.

³ Collaborative process/reliance. Concurrent submission of identical dossier to Reference Authority & Relying Authorities .

⁴ EMA downgraded to a Type IB.

⁵ 11 NRAs yet to confirm participation (Interactions planned with remaining HAs)

COUNTRIES THAT NEVER ACCEPTED TO JOIN A PILOT¹

36 Countries out of 113 (32%)

Country	Invited to Join pilot	Agreed to Join Pilot	% Accepted
Armenia	1	-	0%
Aruba	2	-	0%
Azerbaijan	1	-	0%
Bangladesh	1	-	0%
Belarus	2	-	0%
Curacao	3	-	0%
Eurasia Economic Union	1	-	0%
EU	1	-	0%
Guinea	1	-	0%
Guyana	1	-	0%
Hong Kong	6	-	0%
Iraq	3	-	0%
Ivory Coast	2	-	0%
Kyrgyzstan	1	-	0%
Lebanon	5	-	0%
Libya	2	-	0%
Macao	1	-	0%

Country	Invited to Join pilot	Agreed to Join Pilot	% Accepted
Malawi	1	-	0%
Maldives	1	-	0%
Mauritania	1	-	0%
Mongolia	1	-	0%
Myanmar	2	-	0%
Nepal	1	-	0%
Niger	1	-	0%
Pakistan	2	-	0%
Palestine	2	-	0%
Russia	2	-	0%
Rwanda	1	-	0%
Sint Maarten	2	-	0%
South Korea	6	-	0%
Sudan	2	-	0%
Syria	3	-	0%
Turkmenistan	1	-	0%
US	2	-	0%
Uzbekistan	3	-	0%
Venezuela	2	-	0%

¹Data from all Pilots – Completed / Ongoing / To be initiated

COUNTRIES WITH 100% ACCEPTANCE RATE¹

24 Countries out of 113 (21%)

Country	Invited to Join pilot	Agreed to Join Pilot	% Accepted
Argentina	9	9	100%
Botswana	2	2	100%
Chile	7	7	100%
Colombia	9	9	100%
Dem. Rep. of Congo	3	3	100%
El Salvador	6	6	100%
Ethiopia	1	1	100%
Gabon	1	1	100%
Germany	1	1	100%
Kenya	5	5	100%
Montenegro	11	11	100%
Namibia	3	3	100%
Netherlands	1	1	100%
Nigeria	3	3	100%
Senegal	1	1	100%
Serbia	12	12	100%
Sierra Leone	1	1	100%
Sri Lanka	3	3	100%

Country	Invited to Join pilot	Agreed to Join Pilot	% Accepted
Taiwan	9	9	100%
Tunisia	3	3	100%
Turkey	7	7	100%
Uganda	2	2	100%
WHO	1	1	100%
Zimbabwe	3	3	100%

¹Data from all Pilots – Completed / Ongoing / To be initiated

COUNTRIES WITH VARIABLE ACCEPTANCE RATE¹

53 Countries out of 113 (47%)

Country	Invited to Join pilot	Agreed to Join Pilot	% Accepted
Costa Rica	8	1	13%
Vietnam	6	1	17%
India	4	1	25%
Kosovo	4	1	25%
United Arab Emirates	8	2	25%
Bosnia & Herzegovina	7	2	29%
Albania	6	2	33%
Cameroon	3	1	33%
Kazakhstan	3	1	33%
Nicaragua	3	1	33%
Ecuador	8	3	38%
Algeria	5	2	40%
Guatemala	7	3	43%
Morocco	7	3	43%
Indonesia	9	4	44%
Bahrain	10	5	50%
Canada	2	1	50%
Ghana	2	1	50%
Jamaica	2	1	50%

Country	Invited to Join Pilot	Agreed to Join Pilot	% Accepted
Madagascar	2	1	50%
Mauritius	2	1	50%
Moldova	4	2	50%
Philippines	8	4	50%
Saudi Arabia	6	3	50%
South Africa	8	4	50%
Tanzania	4	2	50%
Trinidad & Tobago	2	1	50%
Zambia	2	1	50%
Brazil	7	4	57%
Mexico	7	4	57%
North Macedonia	7	4	57%
Qatar	7	4	57%
Australia	5	3	60%
Bolivia	5	3	60%
Kuwait	10	6	60%
Oman	10	6	60%
Uruguay	5	3	60%
Egypt	8	5	63%
Singapore	11	7	64%
Dominican Republic	6	4	67%

¹Data from all Pilots – Completed / Ongoing / To be initiated

COUNTRIES WITH VARIABLE ACCEPTANCE RATE¹

53 Countries out of 113 (47%)

Country	Invited to Join Pilot	Agreed to Join Pilot	% Accepted
New Zealand	6	4	67%
United Kingdom	3	2	67%
Georgia	4	3	75%
Honduras	4	3	75%
Israel	9	7	78%
Peru	9	7	78%
Thailand	9	7	78%
Brunei Darussalam	5	4	80%
Malaysia	10	8	80%
Panama	5	4	80%
Paraguay	6	5	83%
Ukraine	7	6	86%
Jordan	9	8	89%

¹Data from all Pilots – Completed / Ongoing / To be initiated

NEXT STEPS

* Continue to collect data.

Change Information	Regulatory Authority Information	Procedural Information
<ul style="list-style-type: none">• Sponsor Company• Product Type• Change Type• Dossier Sameness	<ul style="list-style-type: none">• Reference Regulatory Authority• Regulatory Authorities that agreed to participate• Regulatory Authorities that did not agree to participate• Reason for Regulatory Authorities not participating	<ul style="list-style-type: none">• Submission Date (Relying Regulatory Authorities)• Use of Online Platform• Target Approval timeline• Actual Approval timeline• Reason for Non-Approval

* Analyse available data.

* Continuous. 9 Pilots have reached the end of their reliance procedure deadline.

* Engage with stakeholders to drive wider participation.

* Including EMA workshop (January 2026)





Acknowledgements

- ❖ Participating Reference Authorities:
 - ✓ **EMA / WHO: 12 pilots**
 - ❖ [Reliance for post-authorisation changes: pilots for the pharmaceutical industry | European Medicines Agency \(EMA\)](#)
 - ✓ **EMA / Swissmedic: 1 pilot**
 - ✓ **Health Canada: 1 pilot**
 - ✓ **MHRA: 1 pilot**

- ❖ All 77 Participating Relying Authorities

- ❖ Companies sharing pilot learnings / data through EFPIA CMC LCM PAC Reliance Sub-Team:
 - ✓ **Amgen, AstraZeneca, GSK, Merck KGaA, Pfizer, Roche, Sanofi**