EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 September 2026
European Medicines Agency
EMA/202541/2026

Report on the International Active Pharmaceutical Ingredient Inspection Programme 2017 – 2024

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1. Executive summary

The International Active Pharmaceutical Ingredient (API) Inspection Programme aims to strengthen global collaboration and information sharing on Good Manufacturing Practice (GMP) inspections of API manufacturers. By promoting reliance and reducing duplication, the programme seeks to optimize inspection resources and enhances regulatory oversight across participating authorities.

This report covers the period from 2017 to 2024, during which the programme expanded from 10 to 13 authorities, including Health Canada, PMDA Japan, and ANVISA Brazil. The COVID-19 pandemic significantly disrupted on-site inspections activities but also accelerated the adoption of remote inspections and reinforced reliance-based approaches.

Key achievements include:

- **Inspection Activity**: information shared regarding 936 sites inspected, with total inspections increasing by ~50% compared to the previous period.
- **Collaboration and reliance**: a high level of convergence was observed, with 69% of sites identified as being of shared interest among participating authorities; 107 sites benefited from inspection reliance.
- **Innovation**: Remote inspections were introduced (91 conducted).

Key challenges remain:

- Joint inspections decreased, representing only 4.2% of sites of shared interest, reflecting operational and resource constraints.
- Duplication of inspections persists, particularly for sites with non-compliance outcomes.
- Legal, confidentiality, and language barriers continue to limit the effective sharing and use of inspection reports.
- Progress in establishing a centralised data-sharing platform has been limited due to technical and regulatory constraints.

Overall, the programme has demonstrated clear benefits in improving information sharing and enabling reliance practices, contributing to more efficient use of regulatory resources, reduced burden on stakeholders, and improved environmental sustainability. However, further efforts are required to address structural and operational barriers.

Moving forward, priorities include:

- Enhancing active participation and ensuring timely information exchange among authorities.

- Improving the usability and accessibility of inspection reports to facilitate reliance.
- Expanding the use of reliance practices to reduce duplication of inspections.
- Developing practical guidance and training to support joint inspections.
- Establishing a secure and centralised repository for inspection data and reports.

2. Objective of this report

The objective of this report is to provide an overview of the functioning and outputs of the International API Inspection Programme for the period between 2017 and 2024. The extended review period covered, reflects the impact of the COVID-19 pandemic, which significantly reduced inspection activities.
The report assesses the extent to which recommendations from the previous reporting period have been implemented, reviews key deliverables and performance indicators, and identifies areas for further improvement, based on the findings. It also proposes future directions for the programme's objectives and operations.

3. Goals of the initiative

The International Active Pharmaceutical Ingredient (API) Inspection Programme was established in 2008, first as a pilot in late 2008 to late 2010, and as a full programme since January 2011 with the aim to strengthen global collaboration and information sharing on Good Manufacturing Practice (GMP) inspections of API manufacturers, to reduce duplication and to optimise inspection resources.

Participating authorities agreed that, for sites of common interest, they would:

- Consider inspections conducted or planned by other authorities when scheduling or prioritising their own inspection.
- Request, where appropriate, that other authorities expand the scope of a planned inspection to cover their areas of interest instead of conducting separate inspections
- Conduct joint inspections with one or more participating authorities

Activity reports were issued at the end of the pilot phase and the period 2011-2016. These reports recommended regular assessment of the programme and, where necessary, revision of the Terms of Reference. They also identified remaining challenges, including the need for more active

participation by all members and the establishment of a formal electronic information-sharing platform.

4. History and membership

The International API Inspection Programme comprises 13 participating authorities, including 10 national authorities and 3 transnational organisations. The programme was initially established in 2008 with a core group of authorities, with additional members joining over time as outlined below.

Founding members (since 2008):

- Australia (Therapeutic Goods Administration/TGA)
- France (Agence Nationale de Sécurité du Médicament et des Produits de Santé/ANSM)
- Italy (Agenzia Italiana del Farmaco/AIFA)
- Ireland (Health Products Regulatory Authority/HPRA)
- United Kingdom (Medicines and Healthcare products Regulatory Agency/MHRA)
- Council of Europe, European Directorate for the Quality of Medicines and Healthcare/EDQM
- European Union, European Medicines Agency/EMA
- United States of America Food and Drug Administration (US FDA)
- Germany - Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG), till the end of the pilot programme

Subsequent members

- Denmark - Danish Medicines Agency (DKMA), since 2011
- World Health Organization (WHO), since 2017 but provided data since their observership in 2012 and was therefore counted as a member in the metrics of the previous report
- Canada - Health Canada (HC), since the end of 2016, therefore fully effective in 2017
- Japan - Pharmaceuticals and Medical Devices Agency (PMDA) Japan, since the end of 2016, therefore fully effective in 2017
- Brazil - Agência Nacional de Vigilância Sanitária (ANVISA), since 2021.

5. Tools of the programme

The programme relies primarily on the Master List, complemented by additional platforms and mechanisms for information exchange among participating authorities.

5.1. Master List and other platforms for exchange

The Master List (spreadsheet) has been the central tool of the programme since its inception. It serves as the primary mechanism for communication and information sharing among participating authorities and supports inspection planning and decision-making.
The Master List

- Includes API manufacturing sites of interest to participating authorities, located outside their jurisdictions
- Captures key information on the inspection history and planned inspections across authorities.

Historically, the Master List was periodically published in the protected module of EudraGMDP for reference by participants and maintained by the acting secretariat based on information provided by the authorities. In addition, some authorities recorded inspection data in the EudraGMDP planning module

During the 2017-2024 period, the Master List was no longer uploaded to EudraGMDP. However, it was further developed and enriched to improve monitoring and coordination, including:

- Site identification codes (e.g. USFDA FEI, ANVISA id, TGA id, DUNS, SPOR LOC id, GEO),
- Additional data field to support monitoring of key performance indicators (KPIs), such as duplication, reliance, specific risks (e.g. nitrosamines), and sites of common interest

In addition to the Master List, inspection-related information is also accessible through specific authority systems, such as Eudra GMDP (EU), the COMSTAT/FACTS platform (US FDA), and WHOPIRS (WHO), which complement the programme's internal information exchange mechanisms.

5.2. Non-compliance Alerting and Regulatory action

The programme includes mechanisms for the early exchange on sites identified as being non-compliant with GMP.
Within the scope of existing confidentiality agreements, some of the participating authorities regularly exchanged information on GMP non-compliant sites prior to such information being made publicly available by the

relevant authority (e.g. through Warning Letters or draft Statements of GMP Non-Compliance).
Future inspection plans related to GMP non-compliance have also been shared and, where deemed necessary, other participating authorities may follow up by proposing a joint re-inspection.
In addition to inspection outcomes, some participating authorities have also shared early notification of regulatory actions, including license suspensions and other national enforcement measures taken against non-compliant manufacturers.

5.3. Secretariat of the group, monthly meetings, bi/multilateral meetings

The authority/agency responsible for the secretariat organizes the monthly teleconferences and manages key documentation, including meeting minutes and Master List. These teleconferences are intended to facilitate the exchange of information on upcoming inspections, inspection outcomes and, where applicable, the follow-up of inspections performed. The information shared during these teleconferences forms the basis for subsequent bi-or multilateral exchange of documents and/or the organization of joint inspections.

After a prolonged period during which EMA and USFDA jointly held the secretariat, a rotation system has been introduced to prevent the concentration of secretariat responsibilities on a limited number of authorities and to distribute the workload more evenly, as shown in Table 1 below.

Table 1: The rotation schedule for the secretariat function of the API Programme from 2008 – 2024, including which participating authority was secretariat during each rotation.

Time Period	API Programme Secretariat
Until January 2020	USFDA-EMA
January 2020 – March 2020	HC
April 2020 – September 2020	EMA
October 2020 – March 2021	WHO
April 2021 – October 2021	ANSM
November 2021 – April 2022	PMDA
May 2022 – October 2022	DKMA
November 2022 – April 2023	HPRA
May 2023 – December 2024	EDQM

In addition to the monthly meetings, numerous bilateral or multilateral exchanges took place to address specific needs such as cross-checking information, exchanging reports, planning joint inspections, and coordinating reliance activities.

Participation in the monthly meetings varied due to resource constraints, staff turnover, and evolving priorities among the participating authorities.

6. Deliverables

For the period 2017-2024, the Master List served as the primary source for compiling the various deliverables, as it is the main document used for information sharing within the group.

Deliverables are presented and assessed in a manner consistent with the previous report.

To the extent possible, data from the reviewed period are presented alongside data from the previous period.

In the data presented below, the term "Europe" refers to sites and inspections associated with EDQM's Certification of Suitability (CEP) scheme, inspections requested in the context of centrally authorised products in EU (EMA/European Commission), EU inspectorates participating in this programme, and the MHRA.

6.1. Number of sites inspected and number of inspections

Based on the Master List, the number and distribution of inspected sites and inspections, regardless shared interest or not are presented as follows:
Table 2: A comparison of the total number of sites and number of inspections (total and per authority) between the 2011 – 2016 time period, and 2017 – 2024 time period.

	2011-2016 10 authorities	**2017-2024** 13 authorities
Total sites	**944**	**936**
Total inspections	**1333**	**1684**
Inspections, by authority		
"Europe" *	310	275
ANVISA	-	129
USFDA	762	686

HC-SC	-	63
PMDA	-	292
TGA	130	136
WHO	131	103

* "Europe" includes ANSM, EDQM, DKMA, HPRA, MHRA, AIFA, and EMA

- The number of participating authorities increased from 10 to 13.
- The overall number of sites inspected remained broadly stable over the period.
- The total number of inspections increased by approximately 50%

6.2. Sites of shared interest

There have been 644 sites of shared interest out of 936, distributed as shown below in Figures 1 & 2.

Figure 1: Geographical distribution of sites of common interest. The 644 sites of common interest were in 18 countries: 35% in China and 50% in India, 14% in the remaining 16 countries ("ROW", 14%).

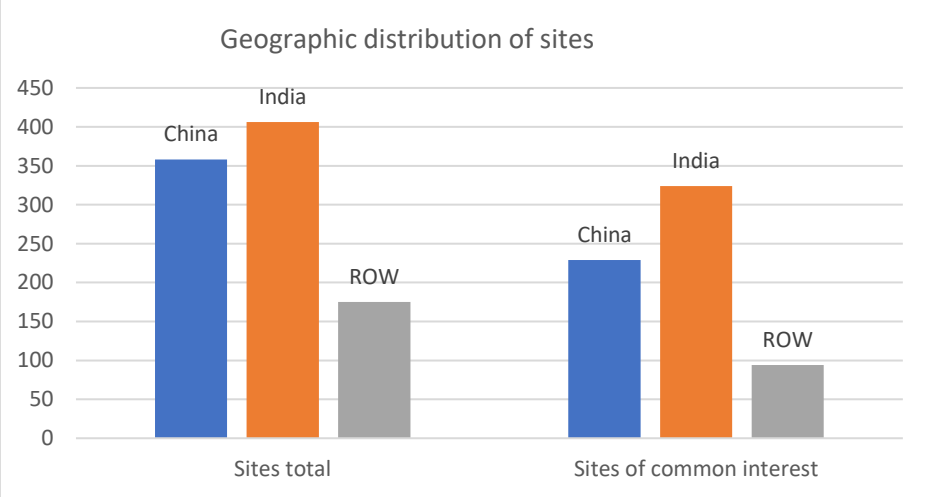
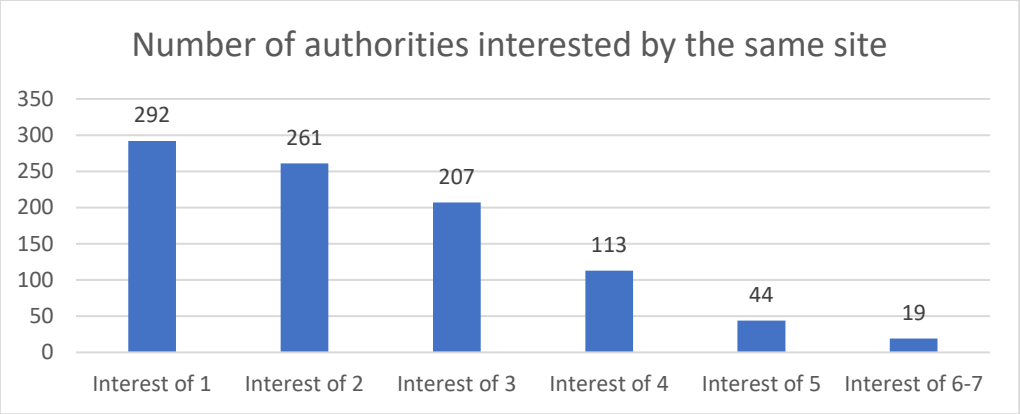


Figure 2: Number of sites that have been of shared interest between two or more authorities between 2017 and 2024. Out of 936 unique sites handled during the period, 644 (69%) were of shared interest to at least 2 authorities. The remaining 292 (31%) sites were of shared interest to 3 to 7 authorities.

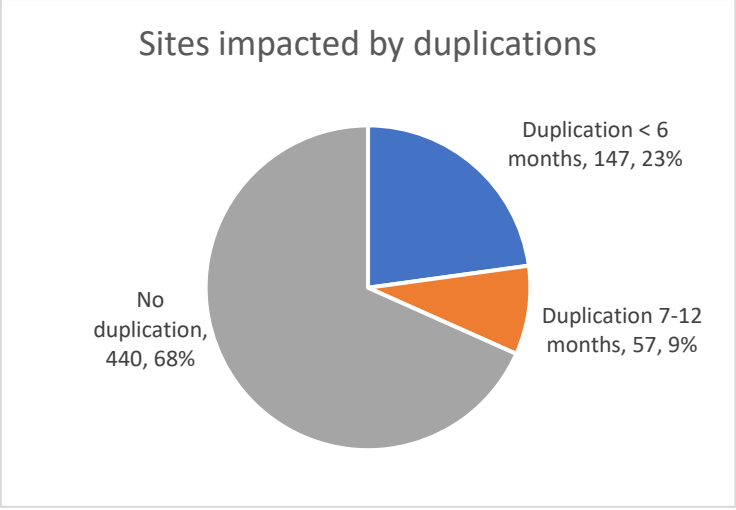


6.3. Multiple (duplicates) inspections

For the purposes of the API Programme, a duplicate inspection is defined as an inspection of the same site conducted by two or more authorities within 12-month timeframe. Overall, 32% of the sites were subject to duplicate inspections during the period.
To enhance the level of detail, this report incorporates two duplication intervals:

- Less than 6 months: 147 (23% of the inspections)
- Between 6 and 12 months: 57 (9% of the inspections)

Figure 3: Number of sites impacted by duplication of inspections.



Comments:

- A single duplication may correspond to two or more inspections.
- Multiple duplications may occur at the same site
- A correction factor of 50% was applied as some sites were affected by both duplication intervals ("less than 6 months" and "6 -12 months")

In addition, as sites with non-compliant outcomes often trigger additional inspections or re-inspections, these data were considered together in the analysis.

Table 3: Average number of duplicate inspections per site by participating authorities from 2011 - 2016.

Duplicate inspections (2011-2016) and correlation with inspection outcome	Nb of sites	Nb of inspections	Average nb of inspections per site by 10 authorities
Sites with more than one non-compliant outcome	46	107	2.3
Compliant sites	205	358	1.7

Table 4: Average number of duplicate inspections per site by participating authorities from 2017 – 2024.

Duplicate inspections (2017-2024) and correlation with inspection outcome	Nb of sites	Nb of inspections	Average nb of inspections per site by 13 authorities
Sites with more than one non-compliant outcome	49	156	3.1
Compliant sites	155	353	2.3

Figure 3 and Tables 3 & 4 show that:

- The majority of duplicate inspections occurred within a period of less than 6 months;
- Sites that received a non-compliant outcome from one authority were more likely to trigger additional inspections by other authorities compared to compliant sites. During the period 2011–2016, such sites

underwent approximately 33% more inspections than compliant sites; this difference increased to 49% in the period 2017–2024. One contributing factor may be the increase in the number of authorities from 10 to 13. As a result, the number of sites of shared interest increased from 458 to 644, significantly raising the likelihood of duplicate inspections. This increase should therefore be interpreted in the context of the growing number of authorities;
- In parallel the number of compliant sites affected by duplicate inspections decreased approximatively by 25% compared to the previous period (2011-2016).

Other factors that may explain the duplicate inspections were already identified in the previous report, and remain valid:

- The scope of inspections may differ significantly. For example, inspection may be limited to a specific API within a preapproval process, or the type of API may vary substantially;
- New information may trigger an inspection, even if a recent inspection has already taken place;
- The Master List may not always contain timely and complete information on inspections, leading to scheduling conflicts that cannot be resolved due to limited time or internal, logistical, administrative, or legal constraints;
- Short notice inspections, particularly those with limited prior notification to companies, may prevent coordination or optimisation of inspection planning.

6.4. Remote inspections

Remote inspections/assessments did not exist during the previous period; they have been implemented by some members as a response to the lockdown situation caused by the COVID-19 pandemic. 91 remote inspections were carried out (5%), mainly during the last years of the 2017-2024 period.

Continuing to use remote inspections/assessments can contribute to smarter use of resources and stronger environmental protection. However, the scope of remote inspections/assessments remains limited: they cannot fully substitute for on-site inspections, and some members have legal requirements to mandate on-site inspections.
In that sense, the ICMRA Collaborative Hybrid Inspection Pilot, which foresees a combination of on-site and remote inspections/assessments of finished products manufacturers, may represent a promising approach.

6.5. Joint inspections

Joint inspections have been one of the tools for work sharing since the beginning of the programme, fostering a high level of trust among participating authorities. The practice was continued occasionally during the 2017-2024 reporting period as a means of continuing to enrich that confidence. While in the first years a reporting form was setup to routinely capture inspectors' feedback for each such inspection, this practice has been discontinued.

Participants acknowledged that joint inspections required significantly more planning and resources than simply sharing inspection information. They require an additional level of communication to coordinate the background information, financial arrangements and logistics within and across the inspection teams, as well as site-level adjustments to accommodate inspectors from more than one region working together. On the other hand, their benefit is to create more opportunities to exchange information among inspectors and their managers potentially allowing for more harmonised approaches and more reliance and trust.

In total 27 joint inspections were conducted at 25 sites, representing 4.2% of the 644 sites of shared interest.
By comparison, in the previous six-year period, 47 joint inspections were performed at 43 sites, accounting for 10% of 458 sites of shared interest.

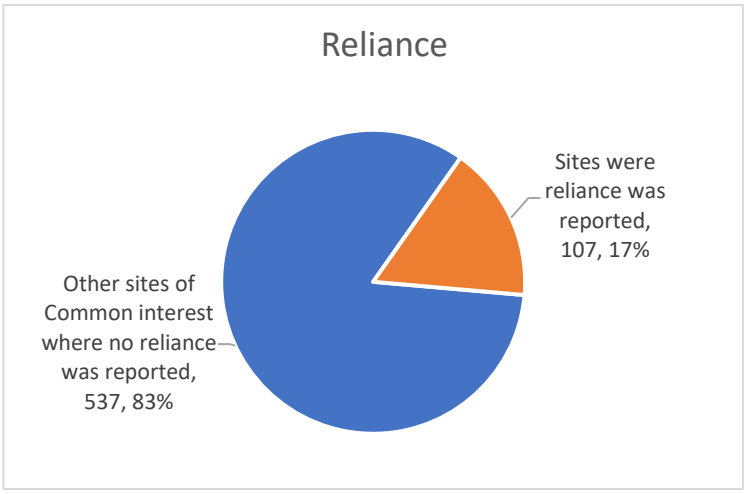
The decline in joint inspections potentially reflects the growing efficiency of information-sharing and reliance practices. This optimizes resources but also strengthens strategic collaboration by reducing redundant efforts.

6.6. Sharing reports and using reliance for the supervision of sites

The group has implemented other mechanisms to recognize or acknowledge inspections conducted by another region for sites of common interest among different authorities. This approach of inspection reliance is defined in WHO's Good Reliance Practices (TRS 1033, Annex 10) and PIC/S Guidance PI 048-1.

Inspection reliance was reported on 107 sites out of 644 (17%), most of them strictly corresponding to the definition of inspection reliance. For example, reviewing GMP certificates or equivalent deliverables, reviewing inspection reports from other authorities, provided either by the companies or by the authorities. For a number of cases, inspections were postponed after getting the knowledge that another authority had planned the inspection.

Figure 4: The number of sites with reported inspection reliance, where the review of GMP certificates, reports and/or supporting documents was done in lieu of an inspection.



The numbers presented in Figure 4 may be underestimated as the group has not discussed beforehand the opportunity to specifically track how often a decision was taken to not inspect, or to postpone inspection for a site that otherwise would have been inspected. Therefore, the practice of each participant may have varied over the review period of this report. For example, inspection reliance may have been reported during the COVID lockdown period and discontinued once the onsite inspections resumed, mainly to manage overall workload.

Sharing reports was noted by participants as a key of the programme, often prompting clarifying conversations during monthly teleconferences.

Challenges encountered in sharing or using reports are:

- The language in which the reports are written and the fact that it is not possible to use online translation tools, due to data confidentiality requirements.
- The necessity to obtain permission from the manufacturer before sharing the report
- The necessity to have specific sections anonymized and/or redacted to comply with local legal requirements. This process is often time-consuming, which delays or even compromise their availability. As an alternative, in some situations, reports can be requested directly from the inspected manufacturing sites.

Overall, inspection reliance was applied to 107 sites, mainly through reviewing GMP certificates or reports and occasionally postponing inspections. Figures are likely underestimated due to inconsistent tracking

and varied practices, especially during COVID. Key challenges include language barriers, confidentiality requirements, and delays in report sharing. Exchanging reports also helps prepare inspections and follow up on major GMP issues.

6.7. Sustained engagement of participating authorities

A questionnaire was developed and circulated amongst the participants between March and May 2024. The objective was to assess the level of commitment of the responders to meet the goals of the International API programme.

Most of the participating authorities showed a generally positive commitment, provided that internal resources and legal provisions allow it.

The strongest ability to commit was observed in sharing planned inspections and outcomes. Practical implementation of other goals such as sharing inspection reports, inspection reliance, and requesting scope expansion, indicated moderate progress with room for improvement. Joint inspections remain the most challenging area, which is confirmed by the 50% decrease compared to the previous period.

Overall, the survey confirmed the sustained engagement of the members and that close information exchange within authorities is the key to success. Therefore, the importance to make improvements centred on increasing the efficiency of information sharing.

7. Achievement of the recommendations from the previous report

Recommendations from the previous reports were not or partially addressed within the period covered by the present report. These recommendations were to develop and implement:

- A shared database with a comprehensive list of API manufacturers registered in the different participants' countries
    - The master list fulfils the needs and has been improved throughout times
    - However, a common share point / host for the Master List with simultaneous access by group members has not been established
- A common policy framework related to the re-inspection of shared sites located in third countries
    - The existing provisions were considered sufficient
- A formal, central repository with write access hosting the Master List, inspection reports, etc.
    - While the principle was agreed by all members, the choice

of a technical solution that meets the security requirements and legal constraints of all authorities could not be identified

- Amplify the usage of the EudraGMDP planning module by all EEA members and API Programme participants
    - Not in place for several members, for technical reasons or resources constraints (need to record in duplicate in EUDRA and in the Master List)
- Guidelines and further remote training sessions amongst participants on how to prepare, conduct and follow-up on joint inspections
    - No specific guideline as one already exists at PIC/S level
- Encourage participants to the API Programme to a more active participation and input during the teleconferences.
    - Improved, still an ongoing process

8. Recommendations for future action and path forward

The review confirms that the International API Inspection Programme remains a cornerstone for global GMP oversight of API manufacturers. While progress has been made in expanding membership, increasing information sharing, inspection reliance and inspections, introducing remote tools, several recommendations from previous reports remain valid.

Moving forward, priorities include:

I. Regular participation and information sharing

1. Attend teleconferences regularly and contribute actively during the discussions by sharing all relevant information in due time

II. Better sharing and planning tools

2. Continue improving the Master List to enable better visibility and quantification of duplicated inspection
3. Discuss the relevance to use of the EudraGMDP planning module by all EU/EEA members and API Programme participants
4. Discuss the relevance to resume uploading the Master List regularly in the protected module of EudraGMDP.

III. Tools and practices for reliance

5. Discuss the relevance to pursue efforts in seeking a technical solution that meets the security requirements and legal constraints of all authorities for a formal, central repository with write access for hosting the Master List, inspection reports etc.
6. Improve inspection reports usability by providing at least a summary in English, together with detailed scope and extent of the inspection to foster reliance
7. Discuss the relevance to share information on inspection reliance within the group and its adequate frequency
8. Discuss the relevance to promote joint inspections, including by hybrid inspections combining on-site and remote inspections
9. From a broader perspective, consider addressing legal and resource hurdles which jeopardize commitments taken within this group.

IV. Decrease duplicated inspections

10. Record and discuss the root causes for duplication
11. Discuss an action plan which includes I, II and III above.

V. Workload for running the API programme

12. Recommend sharing the workload and responsibilities of the secretariat into 2 authorities to ensure continuity and efficiency (implemented mid-2025).
13. Recommend sharing the workload and responsibilities for the preparation of the activity report into several authorities, discuss how to make it easier, more straightforward, and discuss the optimal period.

9. Conclusion

In conclusion, efforts to reduce duplicate inspections have been effective within a number of authorities. However, it highlights the importance to share timely information on planned inspections with the group, to replan the work accordingly, if possible and in line with the objective of the planned inspections. This objective has become both more important and more challenging due to the growing number of authorities within the group.

The benefits of continuing information sharing on planned inspections and reducing duplicate inspections are substantial:

- More strategic allocation of inspection resources,
- Reduced burden for all stakeholders, manufacturing sites and national inspectorates,
- Better preservation of the environment.

With sustained commitment, active participation, deeper collaboration, and enhanced information sharing, including technological and legal advancements, the programme can better cope with increasing complexity, strengthen international cooperation and reliance, optimize inspection resources, and uphold the integrity of the global pharmaceutical supply chain.

10. References

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API Programme Terms of Reference:
https://www.ema.europa.eu/en/documents/other/pilot-programme-international-cooperation-gmp-inspection-manufacturers-sterile-medicinal-products-human-use-terms-reference-participating-authorities_en.pdf

WHO's Good Reliance Practices: TRS 1033, Annex 10
https://www.who.int/publications/m/item/annex-10-trs-1033

PIC/S Guidance PI 048-1:
https://picscheme.org/docview/2475

ICMRA Pilot Programme for Collaborative Hybrid Inspection
https://www.icmra.info/drupal/sites/default/files/2022-06/overall_plan_for_collaborative_hybrid_inspection.pdf