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WHITE PAPER

CEIV VALIDATION PROJECT BY THE SHIPPERS

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EXECUTIVE SUMMARY

Control of the distribution chain and consequently maintain the quality and the integrity of medicinal products is essential for the pharmaceutical industry. Quality issues and temperature excursions have to be avoided to the maximum, but the lack of adapted industry standards often led to incidents in the supply chain. The pharma industry has to be GDP compliant, but this European standard does not take sufficiently into account the specific characteristics of its needs regarding the cold chain from an aviation perspective.

As a response, IATA launched the CEIV-programme specifically designed to meet the needs of aviation pharmaceutical supply chain stakeholders. Implemented in 2015, this programme gains momentum, but the shippers lag behind because they do not feel involved or do insufficiently know the programme.

Since the CEIV certification is a cornerstone of the Pharma.Aero mission, its members were convinced of the need for pharmaceutical manufacturers to evaluate the CEIV pharma checklist and audit methodology. Their collaboration and commitment to the CEIV programme is essential, since a validation of its checklist can result in a simplified and reduced audit frequency of certified stakeholders.

Pharma.Aero organised and coordinated several working sessions with three member pharma shippers. The main conclusion is that all participating pharma shippers have clearly voiced their commitment to validate the CEIV certification, providing IATA integrates their feedback into the CEIV pharma methodology.

This will result in the following items:

- Simplified audit processes: certified suppliers do not have to be audited again by the pharma shipper. Only pharma shipper specific requirements may be audited.
- Aligning of the pharma shipper procedures with the CEIV standards: the pharma shipper activities can be integrated in the CEIV program as a stakeholder, with self audit and a light version training.
- More audit focus on the specific airside transport service providers, where most temperature excursions occur.
- Better audit transparency on station capabilities and performance.

Pharma.Aero and IATA have committed to collaborate and give support to their mutual initiatives, which was confirmed in a Memorandum of Understanding between the two organisations. Therefore, Pharma. Aero has shared the detailed feedback and recommendations with IATA.

IATA is now in the process of integrating the conclusions in the programme, which will presumably lead to a wider recognition of the CEIV pharma certification. This will also lead to simplified and reduced frequency of the audits of CEIV certified stakeholders by the shippers.

1. WHAT IS THE PROBLEM?

Today's distribution network for medicinal products is increasingly complex and involves many players. Control of the distribution chain and consequently maintain the quality and the integrity of medicinal products is essential. It is also crucial to prevent falsified medicines from entering the legal supply chain.

To that goal, the European Commission issued guidelines in order to assist wholesale distributors in conducting their activities, taking these concerns into account. These guidelines are outlined in the Good Distribution Practice of medicinal products for human use, better known as its abbreviation GDP.

GDP includes requirements for purchase, receiving, storage and export of pharmaceutical products and regulates their movement from the premises of the manufacturer to the end user. All wholesale distributors of medicinal products must comply with the principles of and guidelines for GDP.

Why CEIV Pharma?

According to the EU Commission, transport companies do not need to hold a wholesale distribution authorisation to transport medicinal products. However, they should follow the parts of the GDP guideline relevant to their activities. In the transport industry, concerns were voiced that GDPs tend to be more focused on the storage of pharmaceutical products and not necessarily on the transport (especially on aviation). On top of that, the implementation of the guidelines into national law is left to the individual countries, resulting in national divergences in timing, interpretation and enforcement.

The implementation of GDPs in the aviation industry is also particularly challenging because of the structural complexity of this activity. The challenges are not so much inherent to the flying itself, but in the road transport legs, the multiple hand-off points and the handling operations. This complexity and the lack of uniformity in GDP implementation increase the security risks, with all the consequences this entails for product integrity and safety.

In 2013, many stakeholders - not least the industry itself - criticised the lack of sufficient industry standards, which too often led to quality issues and temperature excursions.

Consequently, IATA consulted its airline members and launched a program called 'Center of Excellence for Independent Validators' or CEIV.

CEIV Pharma is specifically designed to meet the needs of aviation pharmaceutical supply chain stakeholders. It combines IATA's own temperature-control guidelines, the GDPs and regional guidelines into more universal standards. They cover the whole supply chain, placing special focus in areas such as ground/tarmac operations, aircraft loading/unloading and storage at the airport.

Acceptance is growing

The standards and certification methodology were issued by IATA in 2015 after a successful pilot community certification at Brussel Airport's cargo community. The CEIV Pharma program is rapidly gaining acceptance as a universal, comprehensive and independent compliance and training scheme. It has become an industry standard which is being implemented by a growing number of air cargo stakeholders, throughout the supply chain: airports, airlines, handling operators, freight forwarders and trucking companies.

In order to be certified, a company has to comply to a checklist, the audit being fulfilled by an independent validator. This checklist helps the company to identify the fields in which it is compliant (or not) and to pinpoint possible corrective actions.

Another component of CEIV is training. The aim is not only to raise the technical knowledge of the quality managers and operational personnel in the field of airfreight supply chain, but also to enhance their awareness of the security risks and the need to respect the standards.

Brussels Airport was the first airport with a certified cargo community. Today, only three years after the launch of the CEIV-program, almost 300 parties worldwide – at over 30 airports – hold the certificate and another 100 are in the process of being certified.

Lack of recognition by the shippers

Despite this growing success, it appeared that some shippers do not feel involved in the CEIV program or do not know it sufficiently. This observation is worrying, since an endorsementof the program – and the validation of the CEIV checklist – by pharma shippers could result in a simplified audit frequency of certified stakeholders. In other words: shippers audit their transport partners using different methodologies and standards. One of the ultimate goals of CEIV is to become a unique certification method, so as to prevent multiple costly and timeconsuming multiple audits. This could lead to a win-win situation for both the shippers and de transport stakeholders.

Evaluation

In order to increase the recognition of CEIV by the shippers and their acceptance of the checklist and audit methodology, IATA entrusted Pharma.Aero with an evaluation of the program by and in collaboration with the shippers. This evaluation had a dual purpose: to increase the confidence of shippers by giving them detailed knowledge of the criteria used; and to allow them to add elements to the checklist so that it would better meet their requirements. Based on this feedback, IATA would complement and adjust the program.

This is why Pharma.Aero started the 'Validation Project' in June 2017. The results where bundled in a technical report published in July 2018.

PHARMA.AERO

The fact that IATA's CEIV-program is gaining momentum is largely due to Pharma.Aero. The Brussels based platform is a powerful cross-industry collaboration for pharma shippers, CEIV certified cargo communities, airport operators and other air cargo industry stakeholders.

It aims to achieve excellence in reliable end-to-end air transportation for pharma shippers and more transparency throughout the supply chain. It also helps members to share market knowledge, expertise and best practices.

This platform, initiated by Brussels Airport and Miami International Airport, is committed to promote the CEIV certification program as the standard for qualitative, reliable and secure transport of pharmaceuticals by air. It uses the CEIV as a basis to become a member.

2. HOW DID PHARMA. AERO PROCEED?

Pharma.Aero invited its pharma shipper members to participate and involve their Quality Agreement and Operations experts to review the CEIV checklist and audit methodology. The aim was to evaluate to which extent pharmaceutical manufacturers can validate them. During six work sessions, the project group assessed the existing checklist and audit methodology, involving shippers' experts in logistics, quality management and compliance in this process. The involvement of experts in different disciplines enabled to identify gaps or inadequacies in their respective domains and to formulate pragmatically oriented proposals.

During these different sessions, the project group successively assessed the audit methodology and priorities and the audit checklist, challenged them, formulated recommended actions and discussed its findings and proposals with IATA.

The project lead was assigned by Pharma.Aero to Brussels Airport and the project management to Mr. Geert Verniers, BD Director, 4Advice, IATA CEIV Independent Validator.

Project Participants

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3. WHAT ARE THE MAIN CONCLUSIONS?

All participating pharma shippers clearly voiced their commitment to validate the CEIV certification, providing that IATA integrates their feedback into the CEIV methodology. In total, they listed 49 proposals (and recommended actions for IATA). They also defined 14 topics that should receive more attention in the CEIV checklist.

This is a breakthrough, since IATA hadn't managed in three years time to get the shippers around the table. As a neutral platform representing the pharma airfreight community, Pharma. Aero acted as a facilitator and managed to break the deadlock in a very short time. The shippers' commitment will result in the following improvements:

3.1 Simplified audit processes

CEIV certified suppliers should not have to be audited again by the pharma shipper or at least less frequently and less strictly. Only shipper specific requirements should be audited.

As an example, the project group recommends that IATA should give reliable transparency about who's already certified and for which specific temperature ranges. CEIV stakeholders who are not certified yet should not have any visibility on the IATA CEIV website. It also recommends to involve the shippers in updating the information if there are any changes. They can help to provide or verify that information, as they are seen as a credible source.

The recommended action for IATA:

> The CEIV Capacity Database should be shared with the shippers. IATA should define a methodology on how to update information, discuss with shippers and publish the process on the website.

3.2 Aligning of the pharma shipper procedures with the CEIV standards

The pharma shippers recognize that CEIV is a sound standard and that they should be part of the program. They confirm there is a need to integrate the pharma shipper (and appointed distribution centers part of the cold airfreight supply chain) in the program as a stakeholder, with a kind of 'light version' for the audits and trainings.

Since GDP and CEIV standards are slightly different, and shippers have to be GDP compliant, the same audit methodology cannot be implemented. The shippers propose to introduce a combination of self-assessment of the own processes and the formal IATA-audit, the result being a sort of light version audit.

They also propose to adapt the training for shippers. This 'light training' would be a good opportunity for raising the awareness and knowledge in the shippers community.

The recommended action for IATA:

> IATA should check the feasibility of pharma training and design it. The expectation for each question should be included into the checklist. IATA should also check the feasibility of a business case to frame a possible trial of the self-assessment and/or a physical IATA audit. IATA should furthermore define the frequency of this 'light audit'.

3.3 More audit focus on the airside transport service providers

The pharma shippers come to the conclusion that some parts of the cold chain are overlooked in the CEIV program. More emphasis should be put on the airside transport service providers, since most temperature excursions occur on the tarmac.

According to the shippers, the CEIV program should guarantee that the tarmac transport service provider is also a stakeholder and that he should be CEIV certified. Since IATA cannot impose the ground handlers to get into the CEIV certification, airlines need to ensure their subcontractors are risk assessed and take the appropriate measures to mitigate the exposure of the products to averse weather conditions.

The recommended action for IATA:

> Keep pushing on the ground handling agents via the airlines, of which they are subcontractors.

3.4 Better audit transparency on the station capabilities and performance

CEIV does not only underexpose some parts of the cold chain, it lacks also transparency on certain parts of the information chain. In case of a temperature excursion, it is very difficult for the shipper to check the ground handler's possible responsibility. He, nor his freight forwarder, has a contractual bond with him. The contract (and contact) is through the airline.

The shippers argue that, as the ground handler has no direct contact with the freight forwarder, the CEIV program should foresee a mandatory communication procedure in which pharma shipments can only be unblocked via a written approval via the freight forwarder and not the airline. Since this cannot be imposed and it remains with the shipper to decide to hold, return or release the product, IATA could address it more on the escalation process.

The recommended action for IATA:

> IATA should update CEIV pharma guidelines focusing more on the escalation process. It should find a way where stakeholders could report to IATA anonymously that certified companies are not performing or there are issues on compliance. In case non-compliancy, IATA should be able to start a monitoring process through spot checks and potentially suspend the company depending on the issue.

More generally, the shippers consider that there is a need to implement transparency in the entire cold supply chain for at least temperature excursions and relevant incidents. It is time consuming for the shipper to now where, why and when these occurred. Thus, in case of failing performance and incidents, a CAPA procedure (Corrective Action Preventive Action) should

be initiated. In order to accelerate the conclusion of a CAPA, there should be an alignment between the freight forwarder and the airlines on the minimal information that has to be shared. To that respect, the Pharma.Aero lane validation (Airport to Airport pharma corridors) and digitization project (Global Pharma Tracker) could be a basis.

The recommended action for IATA:

> IATA should define in the guidelines what minimum information should be included into a CAPA report.

4. WHAT NOW?

As mentioned before, the shippers expressed their commitment to validate the CEIV pharma standard providing IATA integrates their feedback into the CEIV Pharma methodology.

The ball is now in IATA's court. But the message must have got through because, in the meantime, the first recommendations have been implemented by the association.

It is the wish of Pharma.Aero that the CEIV Pharma program gains even more momentum, to the benefit of the stakeholders and the shippers alike. This validation project does not stop here: Pharma.Aero will continue helping IATA to make the program more mature.

This willingness to collaborate is reciprocal: IATA and Pharma.Aero signed earlier this year a Memorandum of Understanding (MoU) formalising this partnership. It will allow to upscale Pharma.Aero's initiatives and enroll its projects within a larger international platform in the life science airfreight industry. The MoU also underlines the vision to foster collaboration with all air cargo stakeholders that support the CEIV pharma industry standard.

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