

Pharma via air freight – Hype or valuable business?

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In recent years, the issue of pharmaceutical products and how they are handled has become a major topic on the air freight industry's agenda, we even might want to call it "hype".



The Covid-19 pandemic and the resulting worldwide lockdowns have shown the fragility of global supply chains in an alarming way. Even with the drastic cut in cargo capacity on passenger aircrafts the air cargo industry proved its vital role in society by providing crucial personal protection equipment (PPE) to affected countries. Via Frankfurt Airport alone, 3.5 billion protective masks were imported in 22,000 shipments without a glitch. Pharmaceutical exports nearly doubled due to the disruption of sea freight. This was made possible by the agile and trusting cooperation in the Air Cargo Community.

The next challenge lies ahead with the expected supply of treatments and vaccination fighting the pandemic. Frankfurt is ready for it. As Europe's leading pharma hub Frankfurt provides unrivalled capacity in exclusive, temperature controlled pharma handling space and long-standing expertise in all matters of temperature controlled transport. Since the introduction of the EU GDP regulation in 2013 the Community has consistently enhanced the common pharma product. Since then, numbers increased by 20 %. Hence Frankfurt is the airport probably best prepared to supply Europe and the world with Covid-19 related pharmaceutical shipments.

Since the introduction of the EU GDP, pharmaceutical handling has increased from 100k to 120k tons.

This paper explains the background to the trend, draws conclusions for the situation today, and examines the outlook for the sector in the future.

On 5 November 2013, the EU Commission's Good Distribution Practice of medicinal products for human use (or GDP for short) came into force, replacing the 1994 (94/C 63/63) guidelines and

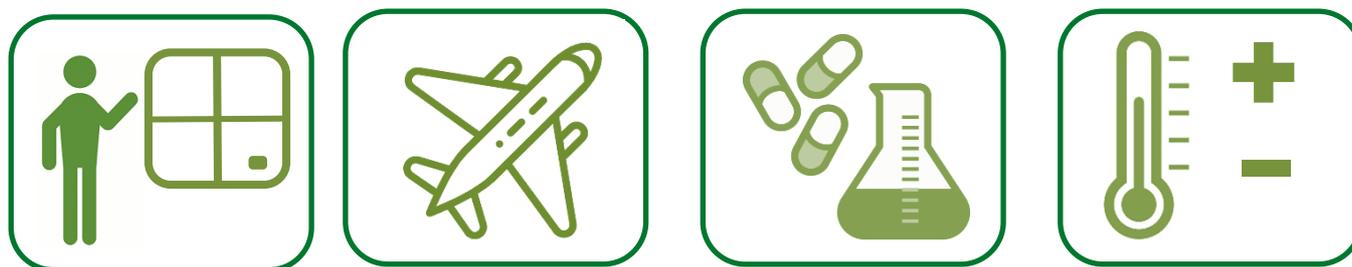
significantly tightening up the regulatory requirements that apply to the sector. The regulations apply not only to wholesale distributors, but to all companies involved in the supply chain, creating a whole new set of challenges for companies and even entire industries, including the air freight sector. Germany has implemented the EU GDP guidelines in §1a (quality assurance systems) of its ordinance on the trade in medical products (Arzneimittelhandelsverordnung – AM-HandelsV) and, as such, is legally bound by the regulations.

The following list details some of the requirements arising from the legislation:

- Implementation and expansion of (internal) quality management system
- Designation of a responsible person for pharmaceutical product handling
- Development and implementation of training programmes
- Ensuring robust and permanent documentation and archiving processes
- Expansion and modernisation of the relevant infrastructure
- Performance of temperature mappings (in transit warehouses, road vehicles and aircraft)
- Implementation of preventive maintenance and calibration processes
- Development of complaints and quarantine procedures
- Development and implementation of supplier management processes
- Performance of regular self-inspections
- Optimisation and monitoring of (sub-) processes
- Development of an emergency procedure to ensure product integrity

Around the same time as these changes were coming into force, the air freight industry was also contending with the fact that the proportion of pharmaceutical products transported by air worldwide fell to 11 % between 2000 to 2013, representing a drop of six percentage points. One of the primary reasons for this decline was a shift towards sea freight.

In this challenging environment, the air freight industry was faced with the question: Should the sector make the investments needed to meet the new, more stringent standards, to enable pharmaceutical products to be transported by air in the future?



Pharmaceutical product handling as an opportunity?

Alongside the challenges it faced, the air freight industry also identified a number of significant opportunities – so its answer to the aforementioned question was a resounding “YES”. In 2015, the IATA (International Air Transport Association) founded the “Center of Excellence for Independent Validators” (CEIV). With the creation of this centre came a new industry standard derived from the EU-GDP guidelines, WHO Annex 5, and a number of national regulations. The IATA’s “Temperature Controlled Regulations“ (TCR) are the basis for this new standard. In turn, the CEIV programme used these regulations to create a checklist comprised of over 250 questions, which are validated and verified by independent auditors.

Over 200 sites belonging to more than 160 service companies around the world are now certified, or even re-certified, to the IATA CEIV Pharma standard. A further 70+ companies are currently progressing through the certification process. The high take-up of the standard within the industry has created a large global network, and the commitment of the individual companies and airports to the standard is a clear sign of the industry’s will to increase the proportion of pharmaceutical goods transported by air in the future.



The temperature-controlled apron transport in Frankfurt has been in use since 1996 and is the world's first with IATA CEIV Pharma certificate.

Frankfurt: A Pharma Hub

Frankfurt Airport is currently the base for 11 IATA CEIV Pharma-certified service companies. The airport is also home to a number of other freight and air freight companies certified in line with the EU-GDP standard. Based on the volumes of goods in tonnes transported by freight processors, ground handling service providers and airlines, over 75 % of the transport taking place via the airport is certified. To meet the required high standards of quality, Frankfurt Airport has spent the last five years rapidly developing its freight infrastructure. The airport now has a

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total of ≈12,000 m² of GDP-compliant, temperature-controlled storage capacity with direct access to the ramp. The number of temperature-controlled transporters/dollies for transporting freight around the apron area has been increased to over 20 vehicles. The central location of the airport not only in Europe, but also in Germany, gives it a significant competitive advantage.

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Ten of the top 20 pharmaceutical manufacturers are located within a 250-kilometre radius of the airport. Frankfurt Airport also offers more direct connections than any other airport in the world (the 2019 summer schedule listed over 300 destinations). This extensive schedule reduces the need for stopovers and minimises the product integrity risks associated with breaks in the air freight journey.

Back in 2014, Air Cargo Community Frankfurt e.V. founded its own pharmaceutical competence centre to optimise processes at the airport across providers. This centre also provides a platform for engagement with the pharmaceutical industry.

After six years of exchange and communication, strategic positioning, significant investment and a number of diverse marketing campaigns, the question now is this: Have all of the airport's efforts paid off, and how will the air freight sector develop in the future?

Six years later – where is the air freight industry today?

On a global level, the air freight industry has made a return to its position as a significant player in the world of pharmaceutical transport – as evidenced by the consistent upward trend in the volume of goods transported, as well as the high levels of utilisation of the sector's current capacity.

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For service companies, focusing on the transport and storage of pharmaceutical products can be a very profitable move. Even if pharmaceutical goods only account for less than 10 % of the total freight volume, it is becoming increasingly clear that a provider's ability to handle this product group can be the make-or-break criterion for an entire contract – making it an area of major strategic relevance.

What does the future hold?

When it comes to the future of air freight, there is one major question that remains open: Does the sector still harbour growth potential? EvaluatePharma is predicting average global growth of +6.9 % per year in the prescription medicines market between 2019 and 2024 – a figure that is significantly higher than the +1.9 % growth that the sector achieved between 2013 and 2018.

It is also important to consider how demand for specific treatments and medications is changing, and how this will impact on transport. EvaluatePharma is expecting to see oncology-related treatments increase their market share from 14.3 % (2018) to 19.4 % (2024).

Global revenue generated by leading bio-tech companies increased rapidly between 2007 and 2018, with companies reporting a rise of 17.1 % per year. Due to their very nature, the ongoing development of oncology therapies and biotechnology suggests that demand for air freight will rise, which in turn suggests that this means of transportation will play an increasingly important role in global distribution.

In terms of regional distribution, the USA and Europe will continue to be the leading producers. Within the continent of Europe in particular, certain air freight hubs will be able to solidify or even build on their market share.

With the aforementioned growth forecasts in mind – as well as the strategic importance of pharmaceutical handling in a wider context – we can also expect to see the number of certified service providers increase, and companies that are already certified will likely seek to obtain recertification.

It remains to be seen how transport in active temperature-controlled air freight containers (RKN and RAP) will develop. This form of transport currently accounts for around 5 % of temperature-controlled pharmaceutical shipments. The aforementioned changes in the types of medication being transported – and the associated stricter safety and temperature control requirements – might boost this figure. However, there is also the issue of the ongoing development of passive packaging solutions to take into account. This affects primary, secondary and tertiary packaging solutions.



How the air freight industry develops across this product area as a whole will also be a crucial factor. Industrial and developed nations already satisfy the regulatory requirements and the associated industry standards. These countries are often pharmaceutical producers and exporters. Germany, for example, exports over 85 % of its pharmaceutical products. Developing countries, which often import medication, cannot satisfy the relevant standards.

On a local level, climatic conditions can also make the requirements even harder to meet. There is no doubt that leading service providers are doing the right thing in their attempts to develop the standard and improve quality and product integrity in developed regions. However, it is important to bear in mind that doing so will require further investment and will increase complexity. A chain can only be as strong as its weakest link – and this is also true of the temperature-controlled transport chain. The continued development of end-to-end transport must play a central role.

Conclusion

In conclusion, it is clear that the air freight industry has bravely overcome the challenges it was facing at the end of 2013 and that, for some air freight hubs, taking a business risk has paid off. This fact has been widely reported in marketing material – and rightly so. Advertisements, publications and conferences can all create a subjective impression of a temporary state of “hype” surrounding the sector. However, it is important not to underestimate the societal role

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that air freight plays in the global medicine supply chain and the relevance that this niche area has for the overall development of a service provider or air freight hub. As we can assume that growth will continue at least in the medium term, it must be ensured – for economic reasons, if nothing else – that investments made will at the very least pay for themselves.

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This White Paper was developed by a project team of the Pharma competence team of the Air Cargo Community Frankfurt e.V.