Spring 2008 issue

COOL TIMES

The Quarterly News Letter of the Cool Chain Association

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Event reports

Aircargo Club Deutschland, 12th February 2008, Frankfurt, Germany, by Christian Helms

The Air Cargo Industry is busy and keen for innovative solutions regarding the perishable market with a wide variety of products such as fruits, vegetables, meat, fish and seafood, cut flowers as well as pharmaceutical products. The Aircargo Club Germany invited me to moderate the event, which was attended by a full house of participating members.
Extreme attention is given on the active side of the perishable business, not to forget the money, which is spend, to secure the temperature control during transit. In contrast the passive part is lacking behind.
What is overlooked by the agent airlines and handling people are the respective markings and for the most part have no binding quality assurance sheet on hand that could document any of the set up activities that should be monitored. My remarks were affiliated frankly by the present industry representatives and this led to fruitful discussions.

IATA World Cargo Symposium 2008, 3rd -6th March 2008, Marriot Park Hotel Centre – Rome, Italy**,** by Robert Arendal, Chairman

The IATA World Cargo Symposium was attended by over 900 industry representatives and proved to be a very successful and interesting event. In their Opening Remarks, both IATA Director General – Mr. Giovanni Bisignani - as well as Global Head of Cargo – Mr. Aleks Popovich - highlighted the importance of getting the air cargo industry into further action in order to remain highly competitive.

Key issues were safety; simplify the air cargo business, environment and many other issues. But in his conclusions, the IATA Director General picked one single issue and focused on - E-FREIGHT – as the single most important challenge to move the air cargo industry forward; and I can not more than agree after having pushed this issue for over the 10 years.
The full coverage of the highlights from this event can be seen on www.airtransportnews.aero

Furthermore, over 13 different “track sessions” on specific issues; one of which was the transportation and handling of Perishables and Temperature Sensitive Products. It was a very interesting and productive full day session under the chairmanship of CCA member – Mr. Bruce Clemmons of FEDEX.

The well attended audience was very responsive and involved and during a panel discussion that included Arnaud DeBakker from WFS as well as myself, we got into a very constructive discussion on the importance of stating the "transit and storage temperature on the air waybill" as well as on the package label. Arnaud showed an excellent sample of how several contradiction labels on a PTSP shipment could lead to total confusion and eventually incorrect temperature handling, if not corrected by sensible staff of the handling agent.

Also the CCA's CCQI's were mentioned and referred to many times and the participants supported the CCA efforts to bring global standards to the PTSP industry. The conclusions from this session shall be very useful for our workshop on the CCQI's at our AGM2008 in May, 7th – 9th, 2008.

Attending the IATA symposium also provided an excellent opportunity to review and discuss the efforts undertaken by CCA's Tony Wright and J.P. Emond in reference to the CO_2 footprint and emission, where we have also established an excellent cooperation arrangement with IATA – and again a subject that we shall cover in more details at our workshop in May.
All in all, attending the IATA World Air Cargo event was a very useful and constructive exercise for CCA.

World Air Cargo Exhibition, Bahrain, 12th – 14th February 2008, Exhibition Center, Manama, Bahrain**,** by Kerstin Belgardt, Secretary

The CCA was invited to exhibit at the Word Air Cargo Exhibition in Bahrain by Air Cargo News (the organizers) which gave us the exclusive opportunity to have a booth at a worldwide event. The first booth of the CCA was welcomed warmly by the visitors of the exhibition and a lot of attention was given to the message and scope of the CCA.

The CCA intends to represent their members at several exhibitions in the future. Members of the CCA shall have the opportunity to place their banners, brochures and other marketing material at the shared CCA booth. The costs for the booth will be shared by all participant members on equal basis, which will safe a lot of costs, instead of renting an own booth.

For further info, please contact sec@coolchain.org

Spotlight on: Temperature sensitive pharmaceutical transportation – a changing picture

By Tony Wright, Exelsius

As any manufacturer, producer or logistics expert will tell you, the global supply chain for temperature sensitive commodities is becoming increasingly complex, with a continual flow of guidelines and regulations designed to address consumer and environmental concerns. For the pharmaceutical and biotech sector, the increasing value of individual products in terms of development and replacement cost, as well as their intrinsic value, is also placing a further element of potential 'risk' that all participants within the supply chain must adequately deal with. In addition, the continuing threat posed by counterfeiting is causing manufacturers to constantly review the distribution-to-market process of their products.

Organisations such as the US Food & Drug Administration (FDA) and the EU see the importance of good practices in the area of manufacture, handling, storing and distribution, as being vital to the efficacy of products (as do manufacturers). Furthermore, the World Health Organization (WHO) has also published a working document on Good Distribution Practices (GDP) that sets clear objectives for 'manufacturers, brokers, suppliers, distributors, traders, wholesalers, transport companies, forwarding agents etc'.

Their document also recognises that the supply chain is no longer simply a case of transporting a shipment from manufacturer to end-user, but a complex chain involving several differing methods, process and participants, with resultant increases in a risk of failure. It recommends that in order to maintain the original quality of the product, ''every activity in the distribution of pharmaceutical products should be carried out according to the principles of Good Manufacturing Practice (GMP), Good Storage Practice (GSP) and GDP''.

There are of course many other 'guidelines' and 'recommendations' for the safe transportation of temperature sensitive commodities, but what is becoming increasingly clear is that consumer safety (particularly as seen by the WHO ,FDA, & EU) is placing clear responsibility on producers and manufacturers for effective management of their cold chain.

Growth & the globalisation of manufacturing

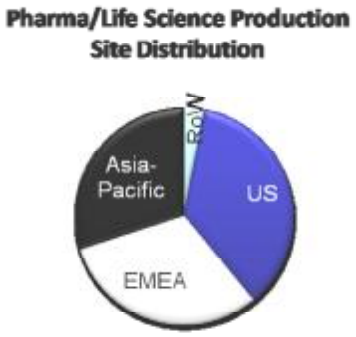
A recent assessment of the global pharmaceutical market by Ernst & Young forecast that it will grow to US$897bn by 2011, equivalent to a CAGR of 6.9%. Furthermore, strong growth in the 10 European markets that joined the European Union in 2004 will help boost European sales over the next five years.

The market also remains polarised between 'big' and 'small' organisations with the top 10 companies accounting for almost 75% of total global sales. Figures for 2006/7 show Pfizer with US$44bn worth of business, followed by Sanofi-Aventis, GlaxoSmithKline, AstraZeneca and Johnson & Johnson, respectively in the top 5.
Furthermore, mergers, acquisitions & partnerships have been a clear strategic growth tactic within this sector and are likely to remain so. The opportunity for larger companies to capitalise on the R & D efforts of smaller, niche and increasingly biotech companies, is likely to be a continuing feature of the growth of 'large pharma'.

Growth of this nature as well as other market factors means the pharmaceutical industry faces continued pressure upon its cost structure – perhaps not surprising given the huge investment in the development of new products and the need to maximise the return on that investment before patent expiry.

Outsourcing production to contract manufacturers is a significant part of many major pharmaceutical organisations strategy and a recent survey showed that in 40% of cases, this was because of a desire to focus on core (and more cost-effective) activities such as R & D and sales.

Figure 1



The most 'popular' regions for outsourcing include India (where there are more FDA approved sites than any country outside the USA), China and increasingly, Eastern Europe. The chart in figure 1 highlights a significant shift in production over the last few years and shows the considerable share of the production market that Asia-Pacific now has.

Compare this to the chart in figure 2 below, which shows the global regions of sale for pharmaceutical products, and the logistical challenges of efficient distribution to distant markets, whilst maintaining product integrity and efficacy become much more apparent.

Figure 2

Transportation and distribution of temperature sensitive products – and across an increasingly wide thermal span – will therefore need to remain at the very top of the agenda, particularly since it is forecast that by 2011, the market for contract manufacturing will have grown to US$45bn.

Air Cargo

For pharmaceutical products distributed by air, there is still too much mystique about how the air cargo world operates, particularly its complex process and procedures & which need to be de-mystified, especially given the pressure upon manufacturers to be using a qualified shipping solution. The evidence for this comes from the recent work by the International Air Transport Association (IATA) when it formed an industry-wide committee to devise a new set of regulations specific to the pharmaceutical sector.

Manufacturers showed considerable misunderstanding about how airlines operate, particularly in areas such as outsourced ground handling and the potential for increased risk. For airlines, there were some clear & wrong assumptions about the temperature sensitivity of specific products that needed to be addressed.

Through its Pharmaceutical Cold Chain Interest Group (PCCIG) the Parenteral Drug Association (PDA), has taken the initiative to create a document known as TR39 which sets out to clarify the responsibilities of supply chain participants and this document is rapidly gaining ground as a leading source of reference. The vision of the PCCIG chairman, Prof. Rafik Bishara PhD, is to harmonize the many global, country and state specific guidelines for distribution, into a single reference.

For the air transportation of pharmaceuticals, what emerges is a common goal – to create a more coordinated approach & simplifying the complexity of the air cargo cold chain whilst also meeting regulatory & product efficacy requirements. Furthermore, the work undertaken for IATA on chapter 17 has undoubtedly opened the opportunity for greater dialogue between airlines, manufacturers and service providers. It must be grasped for the future benefit of all.

Shipment Value & Risk

One of the key drivers for the use of air cargo over other modes is naturally the weight to value ratio of shipped goods.

For the pharmaceutical and biotech sector where product research and clinical trial phases take an average 7-8 years to complete, the development cost of these products is extremely high. In addition, a natural desire for production cost savings, together with the recent spate of merger and acquisitions within the pharmaceutical industry, can lead to larger shipment sizes and it is not unusual for a single LD3 aircraft container's contents to be valued well in excess of $8m

But with these products, risk is not just about the costs of research and production. Many pharmaceutical & biotech products have a correlated sensitivity to temperature and high value which differs with individual commodities. Protein based products, for example have a high temperature sensitivity and significant value.

The risk of failure must therefore be mitigated by a logistic process that takes both elements into account and this can sometimes be exacerbated by the location of manufacturing sites as has been described earlier. Risk assessment as part of a Quality Management System, should therefore not only include all the usual elements of the cold chain (manufacture, production, environmental thermal mapping, packaging, handling and transport etc.), but also incorporate an appraisal of the security processes being used by each and every participant in the logistic chain.

Changes in European surface distribution & mitigating the effects of counterfeiting

The European market for pharmaceutical products is expected to grow by 6%-7% over the next five years, but with the European Commission reporting that 2.7m items of counterfeit drugs were seized in 2007, producers have been keen to reduce any risk within their surface distribution practices.

The most significant step for manufacturers is to establish end-to-end control of their distribution process and whilst technology such as RFID is a valuable tool, so is the reduction in physical handling processes. Clearly the more lengthy and participative the supply chain, the more opportunity there is for counterfeiting of products to take place and potentially inflict business losses. Following a successful trial by Pfizer in the UK in 2007, a system known as 'Direct-to-Pharmacy' (DTP) has gained more participants across Europe and is impacting upon the traditional roles of both European, Regional & National Distribution Centres (EDC, RDC & NDC).

Figure 3

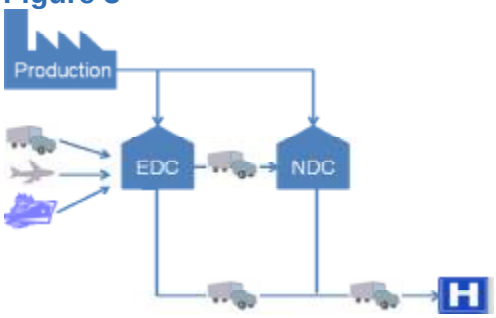


Figure 3 depicts what may be the first stages in a continuing process of change, where large EDC's in popular locations such as the Netherlands, coordinate products both from local and distant production sources and have the potential to deliver direct to hospitals and pharmacies across Europe.

Using 'last-mile' specialist distributors who may also operate the distribution centres under contract, it is claimed possible to remove the role of the wholesaler and using DTP, deliver direct to pharmacies and hospitals within the same logistical provider. The advantages of reduced exposure and increased security are obvious.

Not surprisingly however, the 650 or so wholesaler companies across Europe have challenged the efficiency claims of such a move, particularly on the grounds that these streamlined systems will not able to provide the level of patient access to local stockholding of drugs. However, given the background of increased counterfeit risk, it is difficult to see anything but a continuing growth towards streamlined distribution of this nature and specialist companies already operating in this sector are well placed to maximise this opportunity

Conclusion

For some logistics providers, meeting the needs of the pharmaceutical business may seem a daunting challenge- but this need not be so. Through incorporating high quality & independent expertise into their marketing, sales and operational procedures ***and at an early stage***, those with a strong focus on quality and performance have an opportunity to serve a growing industry sector and create profitable long-term partnerships.

By Tony Wright

Tony Wright is Managing Director of Exelsius, a Cold Chain Management Consultancy and a former executive of British Airways World Cargo & Senior VP of Envirotainer.

COOLCHAINASSOCIATION

Cool Chain Association AGM2008:

"Keep Cool and Healthy", 7th – 9th May 2008, Bonn

The event is hosted by the CCA member RUNGIS express, subsidiary of CCG Holding AG. Rungis Express AG is the biggest trading company for luxury and exclusive food articles in Germany, a well known brand for over 25 years in the upper class gastronomic market. Rungis offers a wide range of products with 5.000 daily available fresh- and dry-food articles, by advance order of clients this number is raised up to approx. 20.000 articles. During our stay we will visit the facilities and storage rooms and are invited to an exclusive on-site dinner.

Highlight of our meeting will be the presentation and workshop to the subject "CO2 – Emission and the Environmental Debate". Almost everyday new facts regarding carbon footprint is reported in the media. It is very hard to separate speculations from real facts since most of the sources are not identified. Thus the CCA worked with JP Emond, University of Florida and Tony Wright, Exelsius through the publications and researches and will present the results at the AGM2008. The event will take place in the city of Bonn, Germany in the Hotel Königshof Bonn.

More details to come soon! Mark your calendar for the challenging and stimulating debate with industry experts and the excellent opportunity for networking! www.coolchain.org

Members Update

The CCA is pleased to present the companies who have decided to become our newest members. Let's give them a Cool Chain Association welcome!

mohebi logistics
The Benchmark

COOLCARGO

ambient

DB SCHENKER

Coming Events/Conferences with CCA Participation

22nd – 24th April 2008
Multimodal 2008
Birmingham, UK
Robert Arendal will represent the CCA

12th – 14th May 2008
TIACA Executive Conference and AGM 2008
Copenhagen Airport/SAS Cargo, Copenhagen, Denmark
Robert Arendal and Christian Helms will attend the meeting on behalf of the CCA

24th – 25th June 2008
3rd Reefer Logistics Conference
Lloyd's List event, Antwerp, Belgium
Christian Helms will present the pilot project PPECB
Robert Arendal will moderate one day as well as present the CCA to the audience

9th July 2008
3rd Cold Chain China Summit 2008
Shanghai
Steven Boyd will represent the CCA and will present the CCQI Standard

COOLCHAINASSOCIATION

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