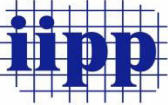


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GOOD DISTRIBUTION PRACTICE REQUIREMENTS FOR VEHICLES INTENDED FOR TRANSPORT OF TIME AND TEMPERATURE SENSITIVE PHARMACEUTICAL PRODUCTS

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INTRODUCTION

World Health Organization (WHO):

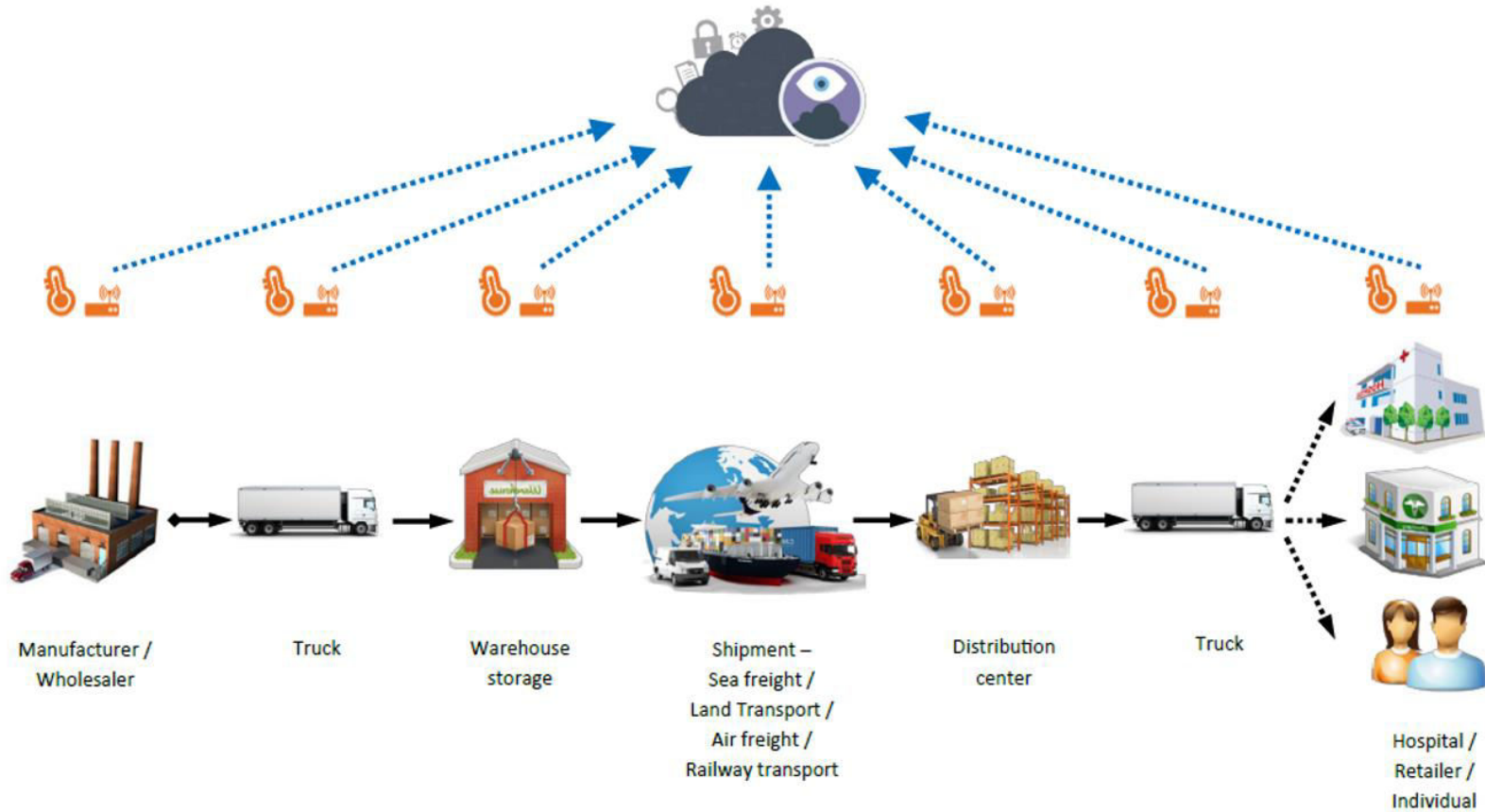
- A United Nations specialized agency, coordinates available resources related to international public health
- Provides objective and reliable information in the field of human health
- Large number of publications (practical handbooks, instructions and various materials are being published for the training)
- Progress towards a better health system requires the dissemination and exchange of information on a global level

COLD CHAIN



- System of activities that include storage and transport from production to application of the product
- The usual transport mode is from +2 °C, to +8 °C, depending of the type of the product
- Transported products are time and temperature sensitive (TTSP)
- Storage exclusively on a specific temperature prescribed by the manufacturer
- Different temperatures and atmospheric conditions may be required from production to application

COLD CHAIN

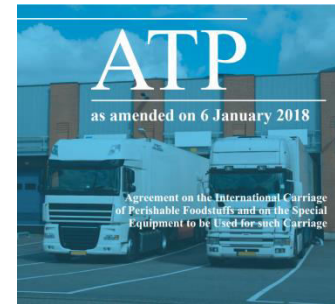


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ATP AGREEMENT



- Agreement on the international carriage of perishable foodstuffs and on the special equipment to be used for such carriage
- Abbreviation originates: "*Accord Relatif Aux Transports Internationaux de Denrées Périssables Et Aux Engins Spéciaux à Utiliser Pour Ces Transports*"
- Made in Geneva on September 1st 1970 by the United Nations Economic Commission for Inland Transport for Europe

WP.11:

- Working party (WP.11) on the transport of perishable foodstuffs was established
- Regularly changes and updates the agreement and its annexes
- The latest version is dated on January 1st 2018

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ATP AGREEMENT

Example of refrigerated and insulated equipment:



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ATP AGREEMENT

K coefficient :

- Represents total heating or cooling power by degree of temperature difference - between interior and exterior walls and the surface of the chamber
- S_i – inner surface of the box
- S_e – outer surface of the box
- ΔT – the difference between the average internal temperature T_i and the average external temperature T_e
- W - heating power or the cooling capacity

$$K = \frac{W}{S \cdot \Delta T} \left[\text{W/m}^2\text{K} \right]$$

$$S = \sqrt{S_i \cdot S_e}$$

VEHICLE DESIGN

- Designed specifically for this purpose in order to ensure the quality of the pharmaceutical product and to prevent contamination
- Desirable to install systems for remote tracking of movement of goods and for monitoring atmospheric and temperature conditions that contribute to the safety of the products
- Recommendation is that all new vehicles which are designed for transport of pharmaceutical products have a value of $K \leq 0,4$ W/m²K

CONTROL AND TEMPERATURE MONITORING EQUIPMENT

Basic requirements of vehicles that transport TTSP:

- Capable of maintaining the set temperature throughout the whole transport section, regardless if the vehicle is in motion, if it is stationary or the engine is off
- Equipped with a system that protects medical cargo from too low temperatures
- Cargo bay area equipped with calibrated sensors for temperature and humidity, set at the most unfavorable location
- Device for alarming the driver if there is a temperature deviation from the foreseen range
- The door of the load compartment is provided with safety markers indicating whether an unauthorized access has occurred

CONTROL AND TEMPERATURE MONITORING EQUIPMENT

Basic requirement of equipment that monitors temperature

- Sensors for monitoring the temperature with precision of ± 5 °C
- Temperature record of the state of each sensor (minimum every 10 min).

Basic requirements for humidity monitoring equipment:

- Air humidity monitoring sensors with precision $\pm 5\%$ RH
- Record of the humidity of each sensor (minimum every 10 min)

QUALIFICATION OF TEMPERATURE-CONTROLLED ROAD VEHICLES

Qualification of temperature-controlled road vehicles:

- Show that the temperature and humidity of the air in the cargo bay is reflected within the prescribed limits during the planned transport route
- Display areas within the cargo bay which should be exempt from direct exposure temperature sources (cold air flow)
- In case of failure of the temperature control, the time display of the temperature reach out anticipated working range

CONCLUSION

- The goal of the pharmaceutical product suppliers is to provide safe transport from the starting point to the destination point and to deliver products
- Transport of these products is time sensitive, especially in emergency situations
- If a slightest deviation of the product is noticed, the responsible person should report how the pharmaceutical product was disturbed
- Clearly identify the cause of the problem
- Resolve and improve all weak spots in cold chain distribution

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THANK YOU FOR YOUR ATTENTION!

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