The World Health Organization (WHO) Department of Immunization, Vaccines and Biologicals (IVB), Quality, Safety and Standards (QSS) team support countries and vaccine manufacturers to strengthen and expand capacities in vaccine regulation. Along with this support, WHO/IVB/QSS manages a Global Training Network on Vaccine Quality (GTN/VQ) through its accredited training centres and delivers various training courses.

Pharmaceutical cold chain management on wheels is a new WHO and Parenteral Drug Association (PDA) training course offered in association with Tip Kurumu (Medical Society - Turkey), Cool Chain Association, DHL, Pfizer, Selçuk Ecza Deposu (Selçuk Warehouse Pharmaceuticals), Hacettepe University Hospitals, Turkish Pharmacists’ Association and the Ministry of Health of Turkey. 2008 course will take place in Turkey between 2-7 June.

INTRODUCTION

Members of the pharmaceutical supply chain have various global requirements to meet during storage, transport and handling of temperature sensitive products. Changing product portfolios, requirements for good storage and distribution practices, regulatory trends, quality management, and risk assessment factors bring many challenges to pharmaceutical cold chain management.

WHO’s purpose in sponsoring the course described in this document is to provide the manufacturing sector with insights into the operation of a complete cold chain from product arrival through to administration of the product to the patient.

The World Health Organization QSS team provides a "prequalification of vaccines" service to UN procurement agencies. This ensures that vaccines used in immunization services are safe and effective and that tender specifications meet the specific needs of individual country programmes. Validation of packaging and the shipping of vaccines are part of this prequalification process.
WHO also publishes guidelines on the international packaging and shipping of vaccines that form part of the contractual agreement between vaccine manufacturers and UN procurement agencies, when vaccine contracts are awarded.

**COURSE OBJECTIVES**

Pharmaceutical cold chain management on wheels (PCCM on wheels) is a training course aimed at developing skills in the critical evaluation of a pharmaceutical cold chain system and improving associated supervisory skills. The course encourages participants to make direct observations at the storage and health facilities which participants will visit whilst physically travelling down the length of the cold chain. This competency based training approach is designed to offer the participants insights into the theoretical background of pharmaceutical cold chain management, combining this with real life, hands-on observation at a variety of storage and health facilities.

By the end of the 6-day training program, the participants will be able to:

- List and explain the importance of regulatory requirements for the pharmaceutical cold chain
- Critically review product arrival procedures
- Observe and evaluate the lay-out of a cold storage facility
- Calculate the required volume of a storage facility
- Evaluate the stock management system
- Observe and assess packaging of temperature sensitive products
- Observe and assess transport of temperature sensitive products
- Observe and evaluate the use of temperature monitoring devices and related processes
- Review and critically evaluate standard operating procedures
- Assess the performance of active cooling units (cold rooms, freezer rooms, refrigerators and freezers)

**TARGET AUDIENCE**

The maximum number of participants for each course is set as 15.

*Primary target audience*

- **Representatives from the pharmaceutical/biopharmaceutical/vaccine industry in the areas of:** Supply, packaging, distribution, logistics and cold chain management. Manufacturers who already supply WHO prequalified products are encouraged to participate.
- **Representatives from the equipment and device manufacturing industry in the areas of:** Active cooling, passive cooling, temperature monitoring, and track and trace. Manufacturers who already supply WHO PQS prequalified products, or who wish to enter this market, are encouraged to participate.
- **Representatives from logistics providers.**

*Secondary target audience*

- **Representatives from the pharmaceutical/biopharmaceutical/vaccine industry in the areas of:** R&D, quality, regulatory, and manufacturing.
• Representatives from the government sector including military services involved in pharmaceutical cold chain in the areas of: regulation, inspection, planning and monitoring.

• Representatives from WHO, UNICEF and other partner organizations: Technical officers responsible for pharmaceutical cold chain management activities at regional level, intercountry logisticians, health officers, EPI officers, and immunization advisers whose involvement in pharmaceutical cold chain is confirmed by their organizations.

• Members of the faculty of institutions of higher education in health professions.

• Independent consultants

APPLICATIONS, SELECTION PROCESS and COURSE FEE

Representatives falling into above mentioned primary and secondary target audiences should apply directly to GTN/VQ secretariat with the attached GTN/VQ application form. Applicants should send their applications along with their CVs to the following addresses:

Dr Ümit Kartoğlu kartogluu@who.int and Ms Sinéad Jones jonessi@who.int by email or +41227914384 by fax.

Deadline for application is **15 April 2008**. Following this date, all applications will be evaluated by the WHO GTN/VQ secretariat and acceptance letters will be sent the following week.

Course fee is established as USD 3,000 (three thousand). Accepted participants will receive detailed information regarding the bank transfer for the course fee.

In addition to the course fee, participants are expected to cover their air travel and accommodation, lunch and dinner expenses throughout the course. There will be no extra charges for the bus, tea/coffee breaks, gala dinner and other extracurricular activities. For details of the hotel costs please refer to Information Bulletin.

MENTORS/FACILITATORS

Three international content experts will be employed for the training. All mentors are WHO certified trainers. Tip Kurumu (Turkey) will be responsible for all logistics of the course. In addition to the mentors, representatives from the PDA, Cool Chain Association, and Turkish Pharmacists’ Association will participate as observers.

<table>
<thead>
<tr>
<th>Dr Ümit Kartoğlu (WHO) - Course Director, Mentor</th>
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</thead>
<tbody>
<tr>
<td><em>Global Training Network coordinator, secretariat for the Performance, Quality and Safety (PQS) project. Twenty years of experience in adult training and cold chain.</em></td>
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<table>
<thead>
<tr>
<th>Dr Rafik Bishara (USA) - Mentor</th>
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<tbody>
<tr>
<td><em>Currently Chair of the Pharmaceutical Cold Chain Interest Group (PCCIG), PDA. Thirty five years of career in pharmaceutical industry.</em></td>
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<table>
<thead>
<tr>
<th>Mr Ticky Raubenheimer (South Africa) - Mentor</th>
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<tbody>
<tr>
<td><em>Chairperson of the Collaborative Centre for Cold Chain Management (South Africa) a WHO accredited training centre for vaccine management and training skills courses. Thirty years of experience in pharmaceutical cold chain.</em></td>
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<table>
<thead>
<tr>
<th>Dr Hakan Gönendik (Turkey) - Training support, tour guide and administration</th>
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<tbody>
<tr>
<td><em>WHO accredited training centre (Tip Kurumu) liaison person.</em></td>
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TRAINING METHODS

Four major training methods that will be used during the training trip: illustrated lectures, guided observations, group discussions and individual and group assignments.

1. Illustrated lectures will be interspersed throughout the course, designed to illustrate the theoretical and practical issues surrounding each day's activities.

2. Guided observation exercises will take place at the facilities which are visited during the course of the tour. Course participants will use checklists to ensure that they observe critical system elements in a real (as opposed to a classroom) environment. There will also be opportunities to interview and interact with local staff.

3. Group discussions will take place in restaurants, cafes and in the open air whilst travelling between facilities along the route.

4. Individual and group assignments will take place throughout the course.

All mentors will be available throughout the programme for coaching, consulting, information sharing and problem solving. Participants are encouraged to network with the course mentors as well as with their fellow trainees.

ROUTE (total 1,410 km)
### COURSE PROGRAMME*

<table>
<thead>
<tr>
<th>MONDAY 2 June</th>
<th>TUESDAY 3 June</th>
<th>WEDNESDAY 4 June</th>
<th>THURSDAY 5 June</th>
<th>FRIDAY 6 June</th>
<th>SATURDAY 7 June</th>
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<tbody>
<tr>
<td>Istanbul</td>
<td>Ankara</td>
<td>Konya</td>
<td>Eskisehir / Bursa</td>
<td>Istanbul</td>
<td></td>
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<tr>
<td>Check-out Opening and warm up</td>
<td>Warm up</td>
<td>Check-out Warm up</td>
<td>Check-out Warm up</td>
<td>Check-out Warm up</td>
<td>Check-out Warm up</td>
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<tr>
<td>Expectations and objectives</td>
<td>Primary vaccine store, Ministry of Health</td>
<td>Hacettepe University Pharma store</td>
<td>Selçuk Pharma Store</td>
<td>Private pharmacy and health centre</td>
<td>Depart for Istanbul (250 km)</td>
</tr>
<tr>
<td>Introduction</td>
<td>Depart for Konya (260 km)</td>
<td>Depart for Bursa (150 km)</td>
<td>Crossing the Marmara Sea with ferry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lunch</td>
<td>Lunch</td>
<td>Warm up</td>
<td>Lunch</td>
<td>Lunch in İnegöl, Warm up and Group work</td>
<td>Lunch</td>
</tr>
<tr>
<td>Warm up</td>
<td>Warm up</td>
<td>Group discussion, evaluation of the day and dinner</td>
<td>Warm up</td>
<td>Warm up</td>
<td></td>
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<tr>
<td>DHL temperature sensitive cargo and Pfizer</td>
<td>Courtesy visit to PHC Department, Ministry of Health</td>
<td>Mevlana mausoleum</td>
<td>Check-in hotel in Bursa</td>
<td>Check-in hotel in Istanbul</td>
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<tr>
<td>Depart for Ankara (410 km)</td>
<td>Anatolian Civilization Museum</td>
<td>Departure from Makas to Konya</td>
<td>Depart for Eskisehir (340 km)</td>
<td>Group discussion, evaluation of the day</td>
<td></td>
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<tr>
<td>Group discussion, evaluation of the day and dinner</td>
<td>Group discussion, evaluation of the day and dinner at Çengel Han, Ankara Castle</td>
<td>Check-in hotel in Konya</td>
<td>Check-in hotel in Eskişehir</td>
<td>Free</td>
<td></td>
</tr>
<tr>
<td>Check-in hotel in Ankara</td>
<td>Return back to hotel</td>
<td>Dinner and evaluation of the day</td>
<td>Dinner and evaluation of the day</td>
<td>Gala dinner</td>
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*All participants must arrive in Istanbul on Sunday before the course and can depart starting on Sunday morning following the gala dinner.

**Legend**

- **Hands-on practices**
- **Group discussions**
- **Extra-curricular**

In each location, participants will be split into smaller groups to study on a particular subject. Initially, participants will be assigned randomly to these groups and then on a rotational basis:

- lay out and volume requirements
- temperature monitoring
- temperature controlled truck distribution
- packaging and dispatch
- stock management / standard operating procedures
During these assignments, two major standard evaluation tools will be used (wherever applies):

- WHO Effective vaccine store management initiative, EVSM assessment form
- CCQI cold chain quality conformance and cold chain quality indicator tools

There is no set typical classroom arrangements. All group discussions take place in rest areas, restaurants and cafes usually in semi-open or open areas.

**LOGISTICS**

Tip Kurumu (an accredited WHO training centre) will be responsible for logistics of the course. Their responsibility includes arrangement of hotels, straight check-in, rental bus, arrangement of social activities and provision of all necessary equipment and stationery materials.