



# NEWS

August 2012

## 15<sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA)

23–26 October 2012, Estonia

Dear Colleagues,

I am pleased to send you this newsletter with the updated information about the 15<sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA) in October 2012.

The preparations are well under way, both of the conference logistics and of the programme. The registration deadline of August 31 is getting closer and to manage the travel and visa documentation the participants are invited to complete their registration forms as soon as possible.

For the detailed updated information about the 15<sup>th</sup> ICDRA venue and other practical details will you kindly visit our website [www.icdra.ee](http://www.icdra.ee) or e-mail us at [icdra@ravimiamet.ee](mailto:icdra@ravimiamet.ee).

In this newsletter, the ICDRA organising team is delighted to have the opportunity to tell you more about the host city. Tallinn is a vibrant city of contrasts, where its historic Old Town takes you back to prosperous Hanseatic days while the modern city with its high-tech solutions for everyday life is only a short stroll away. There are restaurants, cafes and clubs dotted throughout the city for every taste, and shopping possibilities in city-centre malls or boutiques in Old Town.

There is much to see during the Conference social programme – among them KUMU, the main Estonian art museum, an artistic and architectural gem, and the newly-opened maritime exhibition at the Seaplane Harbour capturing the rich Estonian maritime history and excellence of its technical solutions and interesting exhibits.

Being present at ICDRA will give you a unique opportunity to meet old friends and make new acquaintances with the drug regulators attending the meeting from all over the world. To date, over 150 participants have registered for the event and a record attendance is being expected.

Tallinn is a friendly city with plenty of exciting opportunities for visitors. Will you please also have a look at the Tallinn official web-site [www.tourism.tallinn.ee](http://www.tourism.tallinn.ee).

We look forward to welcoming you in Tallinn at this most important regulatory forum.



Yours sincerely,

Kristin Raudsepp  
Director General

The 15<sup>th</sup> International Conference of Drug Regulatory Authorities is held in Tallinn, Estonia on 23–26 October 2012 at the Swissôtel Conference Center. In conjunction with the 15<sup>th</sup> ICDRA, a pre-ICDRA meeting entitled “The quality of medicines in a globalized world: focus on active pharmaceutical ingredients”, is held at the same location on 21–22 October 2012.

The ICDRA is open to government officials and regulators, the pre-ICDRA meeting is open to regulators and all other interested parties such as industry, academia and relevant international organizations.

The conference is hosted by the Estonian State Agency of Medicines and convenes in collaboration with the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM) and the World Health Organization (WHO).

**Deadline for the registrations is August 31, 2012.**

**Please be sure to check the visa requirements and let the organising team know if you need a letter of invitation.**

## 15<sup>th</sup> ICDRA Programme

### Top regulatory experts from all over the World

The ICDRAs are unique events providing medicines regulators from both the developing and developed world with an opportunity to meet and discuss the technical topics that are shaping global medicines regulation. The ICDRAs have also paved the way to collaboration and facilitated harmonization of regulatory standards. Medicines, including vaccines and other biological products but also medical devices included in vitro diagnostics are essential for health systems. It is clear that nowadays health systems cannot deliver meaningful services to the people in need without ensuring access to good quality, safe and effective health products. Thus, regulators should be regarded as an important component of a functional health system. Building appropriate national regulatory capacity is a priority. It is becoming clear that national regulators in isolation cannot effectively safeguard patients in their respective jurisdictions because the development and manufacturing of health products are becoming more and more global. In the future, regulators will increasingly function as parts of various regional and global networks with an increasing need for cooperation and work sharing. This is why the 15<sup>th</sup> ICDRA will be attended by the highest regulatory officials from different countries and regions. Among others, the Executive Director of European Medicines Agency, the Commissioner of the US Food and Drug Administration and the President of the Brazilian regulatory authority ANVISA are expected to attend. In addition, several other prominent regulatory leaders come together in Plenary 4 on Wednesday 24 October to debate how regulators could more effectively collaborate and benefit from both the existing and new networks.

The ICDRA is a unique global regulatory forum, which provides recommendations to WHO and Member States. Historically, many important initiatives have been conceived during ICDRA discussions and many ICDRA recommendations have been followed up, resulting in setting up new initiatives and creating new regulatory guidance documents. The progress since the 14<sup>th</sup> ICDRA, hosted by the Health and Science Authority in Singapore in 2010, is reported during Plenary 2 on 23 October. Other plenaries cover important specific topics such as challenges of ensuring quality of active pharmaceutical ingredients (APIs), future visions of pharmacovigilance and current topics. Plenary 3 which deals with APIs is also creating a link to the 15<sup>th</sup> ICDRA two-day pre-ICDRA meeting, which this time focuses on ensuring the quality of APIs. The final session, Plenary 6, is open to short interventions on current topics of high interest and controversy, for which regulators are welcome to present proposals.

In addition to the plenaries, there are a number of parallel workshops dealing with a variety of topics, which range from general to focused issues on certain product groups. For the first time in ICDRA history, there will be a workshop on how medical devices should be regulated in a globalized world. Another new topic is dedicated to how patient and health care professionals should be involved in medicines regulation (October 25, Workshop J). An important new workshop dealing with current trends in the regulation of blood products focuses on cell therapies (October 23, Workshop A). A rapidly developing scenario of regulatory affairs and regulatory science insists on increasing efforts to maintain and develop regulatory capacity in order to cope with increased demand. A special workshop on assessing and responding to the training needs of regulators is trying to find solutions.



**Lembit Rägo**

Coordinator, Quality Assurance and Safety: Medicines  
World Health Organization

## The main tourist attractions and sightseeing in Tallinn

One of the most pleasant features of Tallinn is its SMALL size. Most of the places to visit are within a walking distance and the ones outside the city centre are easily reachable within a 10–15 minute tram, bus or taxi ride.

Tallinn is an established tourist destination in the region – its old **City Harbour** is one of the biggest and busiest passenger harbours in the Baltic region welcoming over 3 million passengers per year and Tallinn Lennart Meri International airport serving around 2 million customers yearly.



Estonia has made rapid economic progress since regaining its independence and this is reflected in the local prices. Although not extortionate, neither are prices as cheap as in some other East European countries.

The main attractions of Tallinn are in the **two old towns** (Lower Town and Toompea), which are both easily explored on foot. Eastern districts around **Pirita** and **Kadriorg** are also worth visiting and, provided the weather is friendly, the **Estonian Open Air Museum** (*Eesti Vabaõhumuuseum*) in Rocca al Mare, west of the city, preserving aspects of Estonian rural culture and architecture, is an interesting destination.

A mixture of historic and modern can be seen everywhere in Tallinn. Considerable damage to Old Town during the air raids of The Second World War and the recent property boom have both left their lasting marks.



### Toompea – Upper Town

This area was once a separate town (Dom zu Reval), the residence of the Chivalry of Estonia, Roman Catholic bishops of Tallinn (until 1561) and Lutheran superintendents of Estonia, occupying an easily defensible site overlooking the surrounding districts. The major attractions are the walls and various **bastions of Castrum Danorum**, the **Russian Orthodox Alexander Nevsky Cathedral** (built during the period of the Russian Empire on the site that formerly housed a statue of Martin Luther), the **Lutheran Cathedral** (*Toomkirik*) and the **old Palace**, housing the Parliament at present.

### All-linn – Lower Town

This area is one of the best preserved old towns in Europe and the authorities are continuing its rehabilitation. Its major sights include **Raekoja plats** (Town Hall Square), **the town walls and towers** (notably “Fat Margaret” and “Kiek in de Kök”) and **St Olaf Church** tower (124 m).

With a little help from the locals you can find hidden gems for original shopping experience: **Katariina käik** (St. Catherine’s Passage), which is home to St. Catherine’s Guild, a collection of craft workshops, where artists use traditional methods to create and sell glassware, hats, quilts, ceramics, jewellery, hand-painted silk and other wares. The workshops are housed in small, 15<sup>th</sup> to 17<sup>th</sup>-century rooms on the south side of the lane, and are set up in an open-studio fashion, so visitors can watch the artists at work, be it glass-blowing, weaving or pottery making.



Part of Lower Town city wall

St. Catherine's Passage

## Kadriorg

**Kadriorg Park and gardens** are two kilometres east of the centre, served by buses and trams. **Kadriorg Palace**, the former palace of Peter the Great, built just after the Great Northern War, now houses (part of) **the Art Museum of Estonia**, and **the residence of the President of Estonia**. The surrounding grounds include formal gardens and woodland.

The new residence of **the Art Museum of Estonia, KUMU** (*Kunstimuuseum*), was built in 2006. It has an encyclopedic collection of Estonian Art, including paintings by Carl Von Neff, Johann Köler (“Monk’s Impression of Lorelei”), Eduard Ole (“Spring”), Jaan Koort, Konrad Mägi (“Norwegian Landscape”), Eduard Wiiralt, Henn Roode and Adamson-Eric. Not heard of them? Well, one reason more for a visit.



Kadriorg Palace



KUMU

## Pirita

This coastal district is a further two kilometres north-east of Kadriorg. **The marina** was built for the Moscow Olympics of 1980, and boats can be hired on the Pirita River. Two kilometres inland are **the Botanical Gardens** and the 314-meter-high **Tallinn TV Tower**.



Pirita Convent



Tallinn Song Festival Grounds

## Estonian cuisine

*For a lot of foreign visitors, traditional Estonian food can be, frankly, daunting. People from most parts of the world are simply not used to chowing down on marinated eel, or swallowing spoonfuls of jellied meat for that matter. And it goes without saying that a lot of people would flinch before attempting anything called “blood sausage”. Most Estonians, on the other hand, wouldn't think twice before digging into these home-spun delicacies.*

In Your Pocket Magazine



So would you need to bring your own food? No, I dare say, you will not starve in Tallinn. I cannot claim the following tips are from a local, I am also a visitor in Tallinn as the Estonian Agency is located in Tartu (or Dorpat for Germans and for the history of experimental pharmacology), a small university town 185 km south of Tallinn. But I love good food.

For the culinary geographers: Estonian cuisine has been influenced over the centuries by the traditions of more powerful neighbours (Danes, Germans, Swedes, Poles and Russians have taken turns ruling parts of the country). Until the 20<sup>th</sup> century Estonians were earning their living by farming and more often than not food was in short supply. There was never enough meat, milk or vegetables during the constant wars and the short periods between to play around with in any fancy way. So the inventive matrons made use of all kinds of crops and meat to feed the families. Later, with the growing prosperity and urbanisation, the menu shifted towards the more usual European kitchen.

I am not suggesting you spend your week in Tallinn in the culinary research but, should you be interested in local specialities, the **Eesti Maja** (Estonia House) Restaurant not more than a 5-minute-walk from the Conference venue or the more touristy **Kaerajaan** in the Town Hall Square would satisfy your curiosity.

For the less adventurous, there is an abundance of good eateries in Tallinn. Not so far from the conference hotel there is the Italian **Gianni** looking a bit (well, more than a bit) posh but with excellent food (try the fish cooked in salt crust) and more rustic but similarly Italian **La Bottega** and **Controvento** in the Lower Old Town. The up-market **Tshaikovski** in the Telegraaf Hotel and the more relaxed **Klafira** nearby represent the Russian culinary tradition. Modern “Estonian” food cooked by a young Estonian-Russian cook Roman Zastserinski can be found in **Õ**.

My own current favourites among the plenitude of Tallinn eateries are Restaurant **Leib** (Bread), respectfully handling the natural local ingredients, the **Ribe** (simply good food and friendly staff promoting themselves with “fresh, seasonal and definitely domestic” slogan) and the **Café Moon** (Poppy, pronounced [mo:n]), a much simpler venue by the same Roman Zastserinski from **Õ**. Planning to visit these – get the concierge to pre-book a table.



Perhaps time to stop, I am getting hungry and this, after all, is a Newsletter of the ICDRA Conference rather than that of the Tallinn food scene. I hope to see you soon in Tallinn and we will have more useful suggestions for you by the time of ICDRA.

**Alar Irs**  
Chief Medical Officer  
Estonian State Agency of Medicines



## Social programme of 15<sup>th</sup> ICDRA

To provide an opportunity to relax and communicate after the long days of conference we welcome you to two receptions and a gala dinner. Estonians are known for their love of music – from folk tunes and strong choral traditions to excellent jazz and all sorts and species of contemporary music. To give you a glimpse we have invited some of the well-known musicians to perform to the conference audience.

### Siim Aimla

Welcome reception of the ICDRA  
Pre-Meeting, October 21

**Siim Aimla** is a well-known Estonian saxophone player, arranger and a leader of several big and small bands. He is also teaching saxophone both in native Estonia as well as in the Sibelius Academy, Helsinki, Finland. His own groups include FinEst, Siim Aimla Sound System, World´s Smallest Bigband etc. He cooperates with many Estonian musicians and has also played with many foreign artists such as Randy Brecker, Alexi Tuomarila, Tuomas Timonen, Joan Foulkner. Not a hint what he would perform October 21<sup>st</sup>.



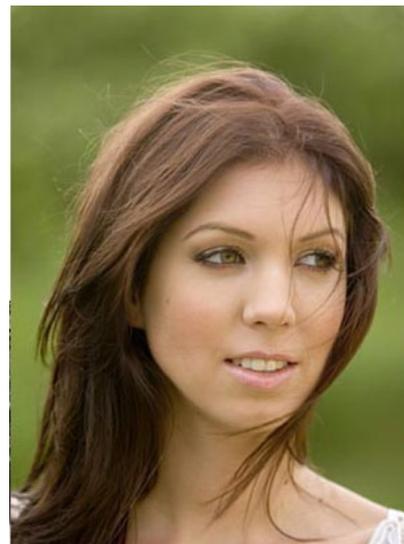
### Raivo Tafenau and Laura Põldvere

Welcome reception of the 15<sup>th</sup> ICDRA, October 23

The professional career of **Raivo Tafenau** as a musician began in 1992 as a member of Urmas Lattikas Ensemble. Only a year later he was named Musician of the Year by Eesti Raadio (The Estonian National Broadcasting Company). His first album "Alone Together" was released in 1998. Ever since he has actively participated in the activities of the Estonian Jazz Union and has offered Estonian and international audiences interesting projects with fascinating guest musicians, among others the Trio Pyramid with Brian Melvin and Peter Barnsley and in co-operation with the Norwegian pianist Anders Arum or, through many years, with Sergio Bastos.



**Laura Põldvere** is a young Estonian singer who started her career in 2005. It seems a must in many careers to be part of a girls group for a time and Laura is no exception – she represented Estonia at the Eurovision Song Contest 2005 as part of the Suntribe group. In 2007, Laura released her debut album "Muusa" and started studies in Berkeley College, Boston U.S., putting her music career on hold. In 2009, Laura was back as a solo jazz singer and in 2011, she released her first compilation album "Sädemeid taevast" (Sparks from the Sky).





# INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES

23-26 October 2012  
Swissôtel, Tallinn, Estonia



Official travel agent:

