DIA LEARNING

EU's new HTA Regulation impact on regulatory strategies: How to navigate the future parallel HTA and EMA processes in the EU

17 March 2024 | 13:00-17:00 CET | Basel, CH

Overview

The first ever Joint Clinical Assessment (JCA) submissions under the HTA Regulation are about to start. Regulatory submissions through the centralized procedure after 12 January 2025 to the European Medicines Agency (EMA) will also trigger the JCA process. Both processes will run in parallel and the new legislative framework for exchange of information between regulators and HTA will take effect. The new process will require a close collaboration between the regulatory and HTA/market access teams at company-level.

This course will discuss regulatory preparedness for the JCA process, explain the interface between regulators and EU HTA Coordination Group and which information is shared by the two. The instructors have been very close to the HTA Regulation implementation activities in companies and with the policymakers.

Learning Objectives

- Understand the JCA process and how it links to the marketing authorisation process
- Regulatory documents or information shared to inform scoping process and JCA timelines
- Reducing the risk of the regulatory process to impact the JCA process
- Preparing and aligning internally

Who Will Attend

- Regulatory strategy leads
- Clinical development professionals
- Regulatory authority members
- CROs
- Consultants involved in EMA´s approval processes

Faculty

Isabelle Stoeckert
Independent Regulatory Science Expert

Inka Heikkinen
Regulatory Policy Lead
Lundbeck

Nadege Le Roux
Senior Director, Regulatory Policy & Intelligence
BMS

DIA

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

17 MARCH 2025

12:30 REGISTRATION

13:00 WELCOME AND INTRODUCTION

13:15 SESSION 1 PART 1

JCA LEGISLATIVE FRAMEWORK AND GUIDELINES

Inka Heikkinen, Isabelle Stoeckert and Nadege Le Roux

- Introduction to HTA Regulation and implementing acts
- The HTA JCA process and how it relates to EU Marketing Authorisation Application process
- Rules for exchange of information between the EMA and EU HTA Coordination Group, and its subgroups

14:00 SESSION 1 PART 2

JSC FRAMEWORK AND PROCESS

Inka Heikkinen, Isabelle Stoeckert and Nadege Le Roux

- JSC regulatory framework
- Application process and tips for the application form
- Learnings from previous parallel advice

14:30 COFFEE BREAK

15:00 SESSION 2

IMPLICATIONS FOR REGULATORY STRATEGY AND ENGAGEMENT PLAN

Isabelle Stoeckert, Nadege Le Roux and Inka Heikkinen

- Regulatory relevant aspect of the JCA dossier (PICO concept and dossier content)
- Label considerations and scenario planning
- Narrative alignment and managing the parallel process
- Transparency of the JCA dossier and potential implications

16:00 SESSION 3

INTERNAL ALIGNMENT AND COMMUNICATION AS THE CORNERSTONE FOR SUCCESS

Nadege Le Roux, Inka Heikkinen and Isabelle Stoeckert

- Reducing uncertainties through close communication of timelines, anticipated questions and final indication
- Contribute to a learning system
- Outlook on future development – what can be expected from the policymakers?

17:00 END OF THE COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Venue Information

Congress Center Basel
Messeplatz 21, 4058 Basel, Switzerland
Tel: +41 58 206 28 28
Email: basel@messe.ch
Website: https://www.messe-basel.com/

Hotel Booking
For more information, please visit: https://www.diaglobal.org/en/flagship/dia-europe-2025/hotel-and-travel/hotel

How to get there
If you are travelling by air, you can reach the city via EuroAirport or nearby Zurich Airport. It's very easy to plan your journey via the three railway stations and the major motorways. Cruise ships also travel down the Rhine to Basel every day.
For more infor,ation, please visit: https://www.diaglobal.org/en/flagship/dia-europe-2025/hotel-and-travel/travel

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 3,5 credits.

REGISTRATION FORM

HTA Regulation impact on regulatory strategies # 25151
17 March 2025| 13:00-17:00 CET | Basel, CH

DIA LEARNING

REGISTRATION FEES

Registration fee includes admission to training course, refreshment break and electronic access to training course materials.
Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER EARLY-BIRD valid until 20 Jan 2025	MEMBER valid from 21 Jan 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 450.00 ❑	€ 500.00 ❑	€ 760.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 250.00 ❑	€ 510.00 ❑
A special discount is available for organisations which are listed in the EMA SME register: https://fmapps.ema.europa.eu/SME/. Number of discounted seats are limited.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature