HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Common European Submission Portal

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CESP: A simple and secure mechanism for exchange of information between stakeholders and recipients.

Features:

- Delivery system for all types of electronic submissions

- Accepts all submission types and includes mechanisms to handle resubmitting of updated information.

- Not dependent on submission standards, i.e. will accept eAF, eCTD , NeeS , vNeeS.

- One-way, from Industry to Regulator, with simple notification system.

- Can manage submissions of varying sizes.

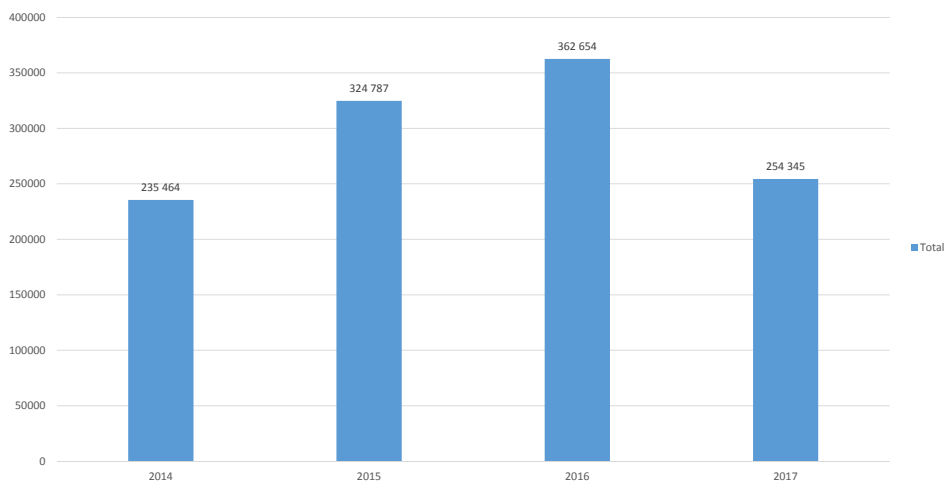- Eliminates the effort for handling CD/DVD submissions

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- ✓ Reduces manual processing of submissions for applicants and recipients.
- ✓ Multi purpose delivery system, can be used for any type of digital information transfer.
- ✓ Simple , fast , efficient delivery system with integrated statics, reporting & notifications.
- ✓ Single submission platform to with multiple submissions processed in parallel.
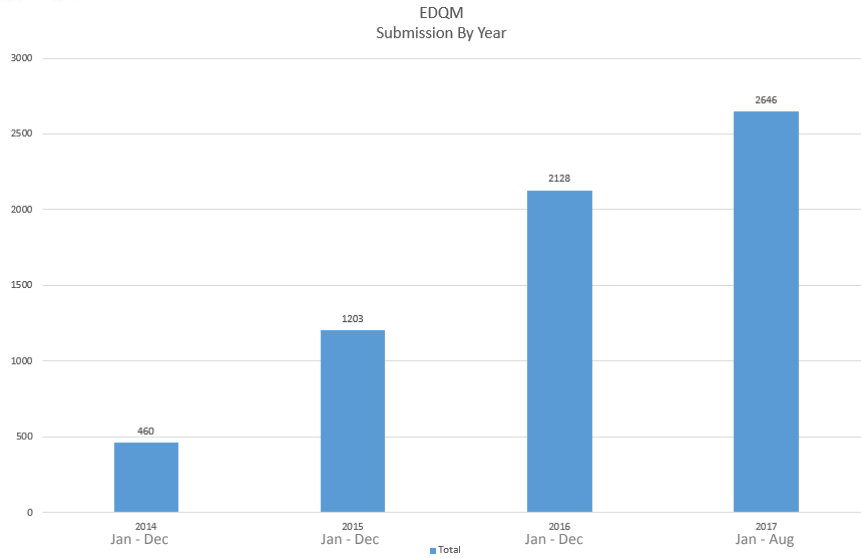- ✓ Available 24 x 7

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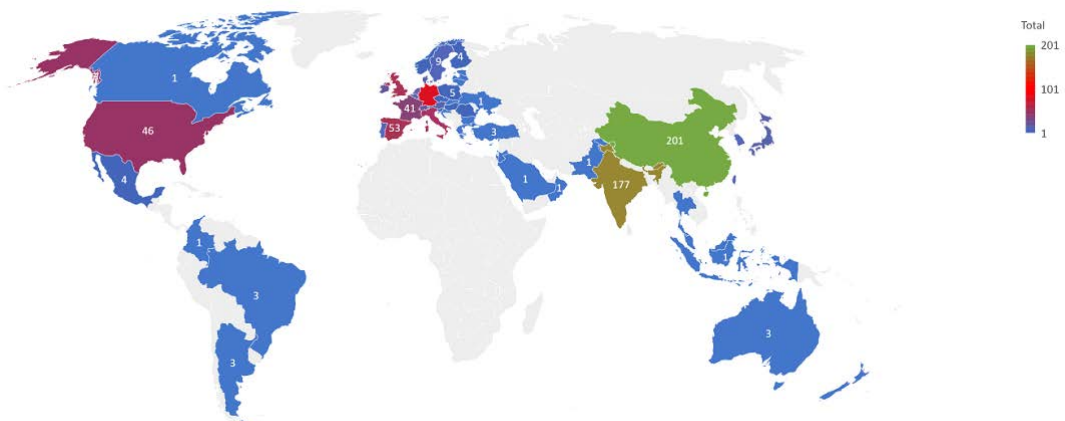
Overall Submissions By Year 2014 – 2017

Year	Total
2014	235 464
2015	324 787
2016	362 654
2017	254 345

EDQM Submissions By Year 2014 to 2017

EDQM Submission By Year

	2014 Jan - Dec	2015 Jan - Dec	2016 Jan - Dec	2017 Jan - Aug
Total	460	1203	2128	2646

Organisations By Country

908 Organisations Subscribed to EDQM on CESP

201 China	50 Italy	16 Netherlands	11 Portugal	6 Malta	4 Norway	3 Bulgaria	3 Hong Kong	2 Greece	1 Croatia	1 Malaysia
177 India	46 USA	15 Japan	10 Korea, South	5 Czech Republic	4 Romania	3 Slovak Republic	3 Turkey	2 New Zealand	1 Canada	1 Oman
81 Germany	41 France	14 Belgium	9 Sweden	5 Poland	4 Slovenia	3 Argentina	2 Estonia	2 Thailand	1 Colombia	1 Pakistan
58 UK	23 Ireland	14 Denmark	9 Taiwan	4 Finland	4 Canada	3 Australia	2 Lithuania	1 Cyprus	1 Indonesia	1 Saudi Arabia
53 Spain	21 Switzerland	13 Austria	7 Israel	4 Hungary	4 Mexico	3 Brazil	2 Latvia	1 Luxembourg	1 Jordan	1 Ukraine

Slide 1

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- Log on to https://cespportal.hma.eu/

Registering with the Common European Submission Portal

- Registering a New Organisation on CESP
- Registering a New User
- Uploading on behalf of another Organisation
- Registering on behalf of a Research Facility

- Complete the information required
  Submit registration request

✓ Request will be processed with 2 working days

✓ You will receive an email with your login details
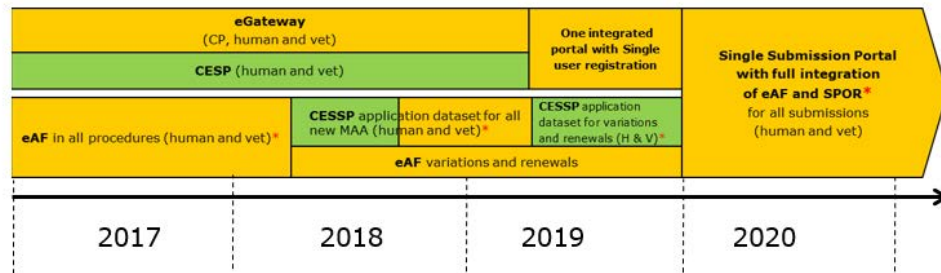
✓ Training sessions held monthly via webx , register at
https://register.gotowebinar.com/rt/2317834655267596033

HMA Common European Submission Portal

Home   Announcements   FAQs   General Information   Contacts   Terms & Conditions   Register

Welcome to the Common European Submission Portal

This system provides a simple and secure mechanism for exchange of information between applicants and regulatory agencies.
The purpose of the system is to:
- Provide a secure method of communicating with the Regulatory Agencies via one platform
- Allow submission of an application once to reach all required Agencies
- Reduce the burden for both industry and Regulators of submitting/handling applications on CD-ROM and DVD

Login
Username
Password
Forgot password?
Log in   Register

- Select Register, chose an option

Company Registration

Complete the form to register a new company on the CESP system. The details entered in this registration form will be used to create your Company account and setup the registered user as the Company Administrator.
Once you submit your registration, you will be contacted via the email address provided to verify the account setup. Once your setup is approved by CESP the registered company administrator will receive access to the system.

User Information   Company Information

First Name *
Last Name *
Email *
Confirm Email *
Job Title
Contact Number *
--- Intl. Code ---
Please select the international dialling code with your phone number.
To assist us in any troubleshooting of your access to the system please indicate the following:
FTP Client
Bandwidth

Slide 2

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Q: "I can't select EDQM when creating a delivery file."

A: To access EDQM via the CESP delivery file dropdown each organization must subscribe to the EDQM Area. This area can be added by a local Company Administrator via their Company Management area. Simply select the company name, select EDQM in the area list and save the change. The next time users for the given company access CESP the EDQM option will be available when creating a delivery file.

Area *

EDQM x

- Cosmetics
- Currently In Testing
- Food and Nutrition
- GxP
- Human Medicines
- Laboratory
- Medical Devices
- Notified Bodies

➢ EU eSubmission Service Desk
- Level 0 - Self Help FAQ & Training Videos
- Level 1 - Basic support, troubleshooting & Call Routing
- Level 2
  - Technical Support (CESP)
  - Regulatory Guidance (EMA)
- Level 3 & Level 4 – Software, Hardware & Hosting

➢ Single Submission Portal eSubmission Gateway Integration

➢ EMA – Identity Access Management Integration
- Single Sign On
- Centralised Account Management
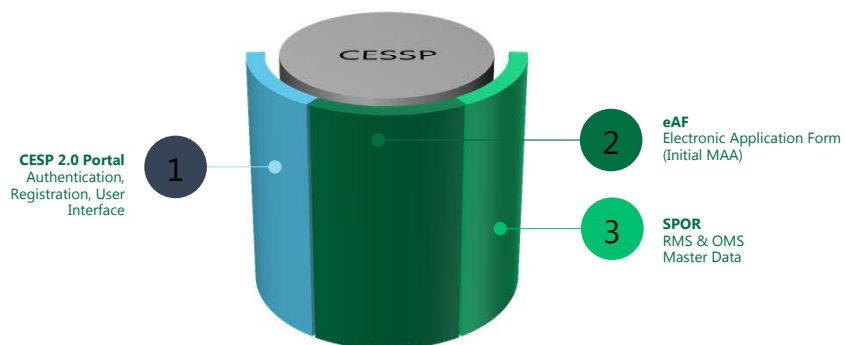
➢ EMRN – Change Management Board

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➤ SPOR Integration

- Phase 1: Map and Sync Reference and Organizational Management Service
- Phase 2: Local API service to update internal applications
- Phase 3: Compare local Data to SPOR data (Product Verification)

➤ CESP Submission Automation & Tracking

- Administration of CESP Delivery Area (Push or Pull Folder)
- Unpacking, Importing and Distribution & Backup of CESP Submission
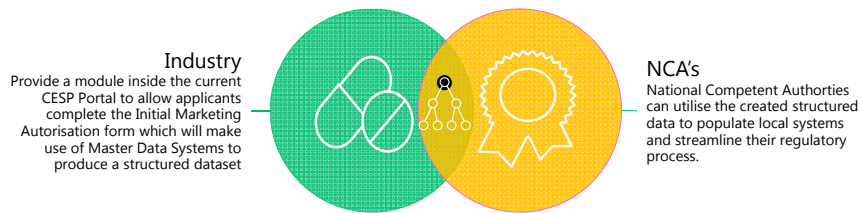- Provide real-time Submission Tracking from the internal agency systems

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CESSP – Phase 1

Brings together 3 elements

CESP 2.0 Portal
Authentication,
Registration, User
Interface

1

2 **eAF**
Electronic Application Form
(Initial MAA)

3 **SPOR**
RMS & OMS
Master Data

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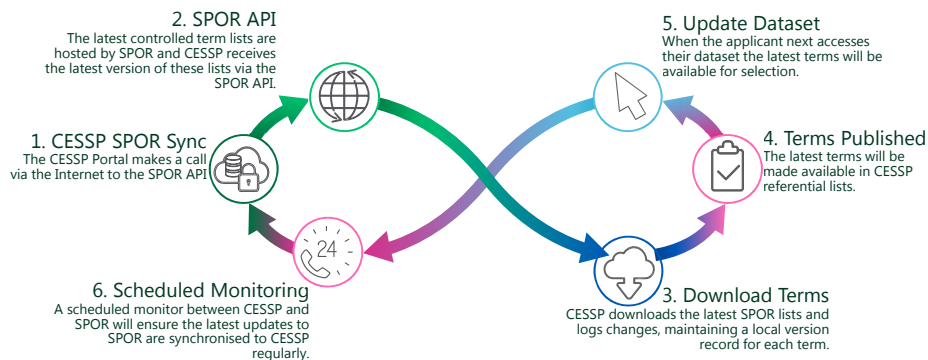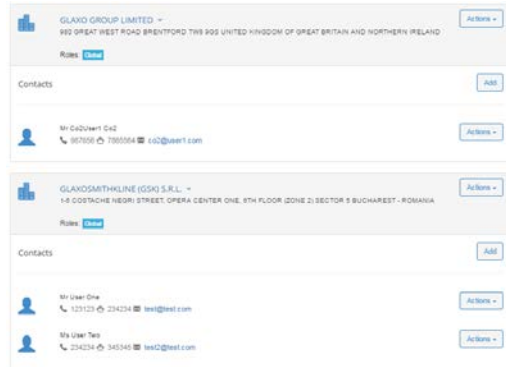Health Products Regulatory Authority

CESSP – Phase 1 Scope

- Replace the eAF pdf for Initial MAA
- Create a streamlined online tool to provide XML structured data as the common language between Industry & NCA's
- Utilise RMS and OMS from SPOR

Industry
Provide a module inside the current CESP Portal to allow applicants complete the Initial Marketing Autorisation form which will make use of Master Data Systems to produce a structured dataset

NCA's
National Competent Authorities can utilise the created structured data to populate local systems and streamline their regulatory process.

SPOR Integration

2. SPOR API
The latest controlled term lists are hosted by SPOR and CESSP receives the latest version of these lists via the SPOR API.

1. CESSP SPOR Sync
The CESSP Portal makes a call via the Internet to the SPOR API

6. Scheduled Monitoring
A scheduled monitor between CESSP and SPOR will ensure the latest updates to SPOR are synchronised to CESSP regularly.

5. Update Dataset
When the applicant next accesses their dataset the latest terms will be available for selection.

4. Terms Published
The latest terms will be made available in CESSP referential lists.

3. Download Terms
CESSP downloads the latest SPOR lists and logs changes, maintaining a local version record for each term.

SPOR use via CESSP Address Book

RMS and OMS

Are integrated into CESSP Phase 1. RMS will feed all standard dropdown lists inside the application while OMS will feed the new CESSP Address book where organisations can be added once and reused throughout the application. As the from requires contact information individual contacts for each organisation can be added in the address book and picked up in the application form as required. Allowing applicants to write once and use many times. The reuse of date should lead to better data quality and more efficient input and regulatory process.
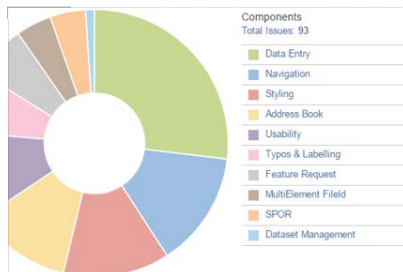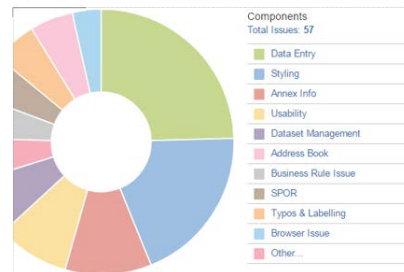

UAT#1 Summary

Users Registered: 96

Organisations Represented: 53

Human Datasets: 180

Veterinary Datasets: 50

Components
Total Issues: 93

- Data Entry
- Navigation
- Styling
- Address Book
- Usability
- Typos & Labelling
- Feature Request
- MultiElement FileId
- SPOR
- Dataset Management

Suggested Improvements

Components
Total Issues: 57

- Data Entry
- Styling
- Annex Info
- Usability
- Dataset Management
- Address Book
- Business Rule Issue
- SPOR
- Typos & Labelling
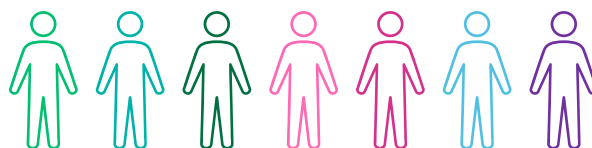- Browser Issue
- Other...

Bug Reports

UAT#1 Communication & Feedback

> I liked the system and I am looking forward for the next UATs ;)
> — Verena Gloeckner (Heumann)

> Just wanted to give good feedback. Users found it logical and the form easy to navigate, it was fairly quick to search for items and intuitive.
> — Leigh Sandwell (Pfizer)

> Intuitive at the most, so I can only say positive things. Few bugs and improvements to make from my side, but I had already pointed it out. And this is quite normal too.
> — Fernanda Manhaes (EXTEDO)

> I found the multi-element fields easy to use, and thought it was a nice neat way to display the information. Generally found the system intuitive and user friendly. Looking forward to the next round of UAT
> — Vishal Patel (AbbVie)

Next Steps

❖ The CESSP project team are currently working to deliver the system for UAT #2 which will take place in Q4 2017.

❖ A call of interest for participation in UAT #2 will be published by the CESSP Communications team in the coming weeks.

❖ All updates and information regarding the CESSP project can be found on the EMA e-submissions website at
http://esubmission.ema.europa.eu/cessp.htm

Thank You