



23 November 2011  
EMA/551789/2011  
Information and Communications Technology

## The EMA eSubmission Gateway, Version 1.0

### 1. Introduction

The EMA is in the process to implement an electronic regulatory submission environment, the EMA eSubmission Gateway, which follows the ICH M2 Gateway Recommendation for the Electronic Transfer of Regulatory Information (ESTRI-Gateway).

The purpose of the EMA eSubmission Gateway is to operate a single, common, European Economic Area (EEA)-wide Gateway for receiving regulatory electronic submissions in eCTD format in a fully automated and secure way including all aspects of privacy, authentication, integrity and non-repudiation of all transactions.

The EMA eSubmission Gateway will allow applicants for marketing authorisations for medicinal products to submit applications within the context of the centralised procedure in eCTD format to the EMA.

### 2. How do I connect to the EMA eSubmission Gateway?

The eSubmission Gateway is intended to become the most efficient way to securely submit marketing authorisation applications for the centralised procedure to the EMA.

The process of establishing the connection requires several steps:

#### Step1: Document Transport Choice

The eSubmission Gateway supports EDIINT – AS2 (with http) and AS3 (FTP). The EMA's eSubmission Gateway does not accept incoming AS2 https messages but can deliver AS2 https to a partner.

#### Step 2: Exchange of Profile Information

In order to use the eSubmission Gateway for secure document exchange you must provide the EMA with the necessary information in order to create a profile. The EMA in turn will provide the same information to you so that you can create a profile on your system. This information consists of name and address, contact person, and transport details. This information exchange can take place using email. Please refer to the Annex for the required information to create a profile.



### **Step 3: Exchange of Public Keys for Encryption**

The eSubmission Gateway uses a combination of public/private key encryption, which is also known as asymmetric encryption and symmetric key encryption. This hybrid system uses the best characteristics of each method and minimises the shortcomings of each. It follows the widely adopted S/MIME standard for securing messages.

The eSubmission Gateway uses Triple DES encryption and requests that you select a 1024 bit or higher key length to provide enhanced security.

The public key is sent with the profile information document on a zip file to new partners.

### **Step 4: Testing the connection**

When a successful connection has been established electronic submissions in eCTD format can be sent to the EMA eSubmissions Gateway. This is accomplished by sending an encrypted eCTD file to the eSubmissions Gateway, where it is unencrypted, checked for basic accuracy, then forwarded for further technical validation before being loaded into the EMA's Central Repository of marketing authorization applications.

From an eSubmission Gateway perspective, the test is successful when the eCTD message has been received successfully and the sender receives a positive MDN, confirming receipt of message.

A list of registered applicants from pharmaceutical industry who have applied for a connection to the eSubmissions Gateway and have subsequently set it up correctly is maintained by the EMA.

The successful completion of the testing between the EMA and the EDI Partner will be certified by the EMA so that the EDI Partner can move into production pilot. However the move into production pilot and later full production will need to be scheduled in collaboration with the EMA's IT Support, the relevant EMA business sectors and the EDI Partner.

Annex

*Connecting to the European Medicines Agency Gateway  
eSubmissions communities using an AS2 or AS3 compatible  
product.*

You will need to provide the following information to the EMA, and we will create a profile on our system for you. The information about our system is shown on the next page and should be sufficient for you to create a profile for us on your system. If there is any other information you need, please ask.

Please use this form to enter your organisation details and return via email to [esubregistration@ema.europa.eu](mailto:esubregistration@ema.europa.eu).

Please remember to include your encryption certificate as well. Also note that only standard ASCII characters can be used in profile information.

The Routing ID's must be composed of capital A to Z and/or the numbers 0 to 9.

We do not allow the use of special characters.

<b>Community Type</b>	<b>TESTING</b>
<b>Organisation Name</b>	E-Submissions Pre-production
<b>Routing ID</b>	ESUBVAL
<b>Address</b>	7 Westferry Circus Canary Wharf London E14 4HB
<b>Gateway Support Name</b>	European Medicines Agency Gateway Support
<b>Gateway Support Phone</b>	+44 207 418 8400
<b>Gateway Support Email</b>	<TBC>
<b>Gateway Transports</b>	
	<b>TESTING</b>
<b>AS3 SFTP</b>	sftp://ESUBVAL@vgateway.ema.europa.eu:4022/cyclone/Esubmissions/ftp/ftpin
<b>OR</b>	
<b>AS2 IP Address</b>	195.144.18.238
<b>AS2 Hostname</b>	vgateway.ema.europa.eu
<b>Receive Port</b>	8080
<b>Transmit Port</b>	4080
<b>Exchange Point</b>	/exchange/ESUBVAL
<b>AS2 ID</b>	ESUBVAL
	<p><b>Please note the following Items for AS2:</b></p> <p>We transmit and receive only on the above ports. MDN's must be ASYNCHRONOUS</p>