"Specifications for Submission by Email"

Subject

AMG-EV <n>

For n, indicate the following:

- if the application is new: the word "new application"
- if the procedure is ongoing: the assigned processing number,
  e.g. "H.00123.01.01"
- in the event of an authorised product: the authorisation number granted for the authorised products,
  e.g. "PEI.H.00123.01.01"

Email Text

Procedure: <Type of procedure>, permitted information includes:
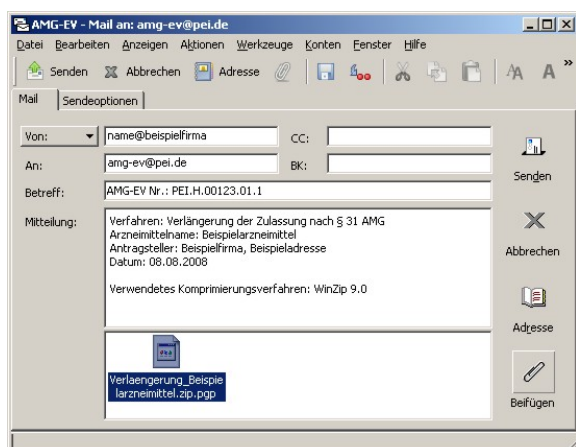
- Marketing authorisation procedure pursuant to Section 21 AMG
- Renewal of the marketing authorisation pursuant to Section 31 AMG
- Variation notifications according to Section 29 AMG.

Name of the medicinal product: <name of the medicinal product>

Applicant: <name and address of the applicant>

Date: <Date of submission of the written version>

Other information: <Information such as the compression program used> We recommend WinZip 9.0 or higher. For reasons of data protection, you should put the entire attachments of the email into an archive file and then encrypt them.

Example e-mail for the electronic filing of documents according to AMG-EV
Source: PEI

Encryption of Documents

For the encryption, please only use programs that support OpenPGP in accordance with RFC 4880 (e.g. PGP (Pretty Good Privacy), GnuPG). These programs and information on their use can be found on the internet.

The public key of the Paul-Ehrlich-Institut (public key) can be found on the following servers:

WITH PGP Public Key Server

pgp.uni.mainz.de

the applicable port is 11371, for which a relatively long loading time can occur.

As search term please use: Paul-Ehrlich-Institut

The correctness of the given key can be verified by comparison with the following fingerprint:

D736 4499 55FE 44A2 F6C6 86C4 95CC 42D2 2A79 8FC7

File Formats

Please save documents you send to the Paul-Ehrlich-Institut by email pursuant to the AMG-EV, as a text file in the format ".rtf". If graphics are included in the text files, please submit them separately in pdf, jpg or png format. The file name must be noted in the text as a hint.