

Langen, 10 May 2021

INFORMATION FOR PHARMACEUTICAL COMPANIES

PEI-C Rebuild – Electronic Transmission of the Batch Release Documents

Applying pharmaceutical companies can submit their applications for a batch release electronically, both for human and for veterinary products using the PEI-C rebuild portal on this link: www.PharmNet-Bund.de.

As per 11 May 2021, the Paul-Ehrlich-Institut has also started to provide batch release documents electronically for certain product groups for human use in the PEI-C Rebuild portal.

These product groups include:

- Microbiological and viral vaccines,
- Immunological medicinal products
- Mono and polyclonal antibodies,
- Test and therapy allergens,
- Medicinal products made from human blood and plasma.

By late 2021, the Paul-Ehrlich-Institut will also have included all other product groups for human and veterinary use into the electronic procedure.

For a transitional period of four weeks after the introduction of the electronic procedure, applicants for a batch release will also receive the release documents by ordinary paper post. Thus, the Paul-Ehrlich-Institut ensures that, in the unlikely event of a technical error in the electronic transmission, release notifications are received smoothly.

The pharmaceutical company can print out the batch release documents from the portal if required. Thus, a separate application for additional uncertified copies will no longer be necessary.

Certified copies can still be applied for via PEI-C Rebuild at an extra cost.

Further information

PEI-C Rebuild – Electronic submission of batch release applications