



Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

# eSignature @ Fimea

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## Fimea's process and IT renewal Program

Fimea is in the middle of a transformation program to:

- Renew all processes (digitalized processes)
- Develop eChannel capabilities for customers
- Develop Case and document management support
- Renew all registries (towards international standards)
- Develop eArchiving capabilities

Implementation in small steps and starting from internal capabilities.

eChannel  
For  
Customers

Case &  
Document  
management

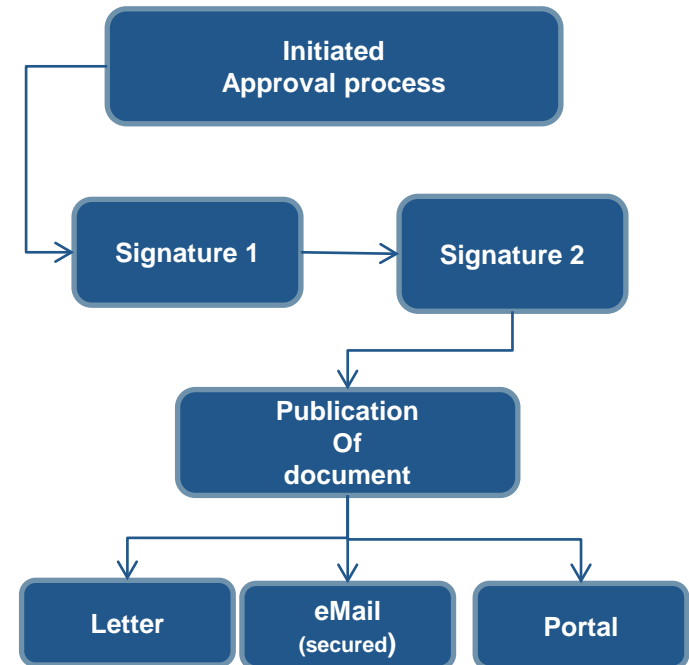
Registries

eArchive

## eSignature@Fimea

Goal is to use only eSignature for document and other approvals.

- All approvals within the new system are done by using eSignature and personal smartcards
- eSignature can be done by one or more persons
- Details of each signature is stored together with details of the document (or set of information)
- After the approval process the document can be delivered to the customer using different channels (eChannels preferred)
- Signature file is not delivered together with the document (at the moment)
- Signature verification capabilities to be developed



## Certificates and smartcards provided by Population Register Center

- The Population Register Centre is currently the only so called Certificate Authority of qualified certificates in Finland that is able to issue Pan-European certificates.
- The certificate can be used for identifying, encrypting e-mails and documents and providing electronic signature.
  - Electronically signed document is legally as binding and undisputed as a document with a traditional signature
- Certificate system is based on Public Key Infrastructure (PKI) and is STORK compliant
- Certificates issued and their revocation lists are published and downloadable
- An issued Smartcard (= eID) is required