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UPDATE: Cover letter template for renewals

UPDATE: Cover letter for Variation Applications in the Mutual Recognition Procedure

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UPDATE - Overview AR Template (incl. instructions)

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EUROPEAN MEDICINES AGENCY (EMA)

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28/07/2025	Document: Procedural advice on paediatric applications	Updated
28/07/2025	Medicine: Voriconazole Accord	Updated
28/07/2025	Page: COVID-19 vaccines: key facts	Updated
28/07/2025	Event: EMA workshop on primary efficacy endpoints for antivirals and monoclonal antibodies intended for the treatment of COVID-19 and influenza	Updated

NOTICE TO APPLICANTS

No updates since July 07th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
01.08.2025	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
30.07.2025	**Erreichbarkeit der zuständigen Behörden der Länder sowie der zuständigen Bundesoberbehörden und der zuständigen Dienststelle der Bundeswehr zur Meldung von Risiken aus Medizinprodukten "außerhalb der Dienstzeit"**

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.