This policy was adopted by the 31st EMSA Autumn Assembly held online on the 10th of October of 2021.
Must be reconsidered until: 10th of October of 2025.

Electronic Information on Pharmaceutical Products

Authors, Version 2018: Cornelia Reitmeir, Josua Sellmaier, Finn von Maltzahn, Karoline Keller.

Authors, Version 2021: Stella Goeschl, Faith Musa.

The European Medical Students´ Association (EMSA) represents medical students across Europe. We envision a healthy and solidary Europe in which medical students actively promote health. EMSA empowers medical students to advocate health in all policies, excellence in medical research, interprofessional healthcare education and the protection of human rights across Europe.

Problem statement.

Before the European Union (EU) came into existence, all pharmaceutical products had to be authorised by National Competent Authorities (NCA), who are now primarily responsible for the authorisation of medicines available in the EU that do not pass through the centralised procedure (NCA human, n.d.). This data for scientific evaluation and public use was registered on a national level. Ever since 1995, the European Medicines Agency (EMA) has been responsible for the scientific evaluation, supervision and safety monitoring of medicines that are centrally authorised in the EU. In 2006, EMA and its partners developed EudraPharm (EMA, 2016.), an online interface providing access to information on medicines authorised in the EU, which failed its intended purpose and has since been revoked. Ten years later, EMA published a paper that detailed plans for a common European medicines web portal, though these were never fully achieved. In response to the EC's recommendations on product information, the following year, EMA drafted a more detailed action plan. This resulted in the collaboration of EMA, the Heads of Medicines Agencies (HMA) and the EC across 2018 and 2019 for the development of an electronic product information system (ePI).

The digitalisation of the healthcare system is currently transforming the medical practice and patient information. Our societies are becoming increasingly more digitally literate, and patients often seek our healthcare information online. Through digital tools, digital healthcare technologies, and electronic health records, several EU frameworks are currently aiming to promote digitalisation in the healthcare sector (ED, n.d.). While several national and regional product registers currently exist, there is a lack of a common database or common European website. We see a need for the digitalisation of information on pharmaceutical products within this database.

The ePI framework developed by EMA, HMA and the EC has been a great step toward a comprehensive medicines database at a common EU standard. This system aims to harmonise existing electronic information on pharmaceuticals by the use of a joint strategy across all medication in Europe. Through joint technologies and regulations, the ePI shows promising developments of streamlining the regulatory process of medicines in the EU while also becoming a valuable resource to healthcare as a whole. We recognise the efforts made toward accessibility, efficiency, and public health within a common legislative framework (EMA, HMA, EC, 2020).

In the face of the ongoing COVID-19 pandemic, it has become even more apparent that there is an increasing need for readily available information on pharmaceutical products. While different vaccines for COVID-19 were undergoing approval processes across Europe, it became clear through the public confusion, controversies and misinformation surrounding the vaccines that there is a need for a central source of information. The importance of and need for a central database for the authorised medicines within Europe is now highlighted in the pandemic, where expedited drug approvals consequently increased the need for a trusted, up-to-date database.

EMSA Secretariat Rue Guimard 15 1040 Brussels, Belgium Tel : +32 2732 72 02 emsa-europe.eu info@emsa-europe.eu

Our view. Aim.

At present, gaining access to adequate online information on pharmaceutical products from European authorities presents a challenge to patients and clinicians alike. These problems originate from the lack of a central database accessible to all European citizens. A large portion of the information is currently only available in national languages or on national databases (Pharma infolinks, n.d. And WHO, n.d.), with few exceptions, such as Drugbank and the European Medicines Agency (EMA) medicine portal (EMA, n.d.).

We, the European Medical Students' Association, envision a central website that is accessible to all European citizens, based on a centrally organised database implemented and supervised by the EMA. This database should be created by an interdisciplinary and international team (including European Commission (EC), NCAs, pharmaceutical experts, consumer and patient representatives, health care professional representatives). This database should be digitised, and the team responsible for its construction process should be representing the EC, NCAs, pharmaceutical experts, consumer and patient representatives, health care professional representatives. We strongly recommend the implementation of such a database in the spirit of transnational mobility and international collaboration.

EMSA expresses its appreciation for the efforts already taken by the EC and EMA in the pursuit of a comprehensive medicines database. Due to the nature of the database, we see an increased need for further digitalisation and standardisation. We recognise the necessity of including liability concerning international teamwork that is based on mandatory rather than voluntary involvement of NCAs (especially the feed of data into the database). Further, we see a need for improvement of data accessibility and transparency to provide for a clear and comprehensive database. Additional efforts for creating an accessible database would be beneficial for all Europeans seeking electronic information on pharmaceutical products.

Recommendations.

EMSA calls upon the European Medicines Agency (EMA) to:

- Work towards a complete and comprehensive medicines database, minimising the number of missing nationally authorised medicines in the central database;
- Consider the needs of the patients at whom pharmaceutical products are targeted while constructing a database for these products;
- Develop the content of the database beyond a website in order to be accessible in multiple formats and various locations;

EMSA Secretariat Rue Guimard 15 1040 Brussels, Belgium Tel : +32 2732 72 02 emsa-europe.eu info@emsa-europe.eu

- Implement usage of Europe-wide QR codes and centralised ID numbers for all authorised pharmaceutical products irrespective of the date and member state of authorisation;
- Encourage and ensure international and interdisciplinary contribution to the database;
- Ensure that the information within the database on authorised medicines is accessible in English and provide for multilingual translations by trained and certified translators.
- Demonstrate transparency on current timelines, involved parties, resources of data, and plans;
- Continuously increase the capacity of the database by updating it on a regular basis.

EMSA calls upon the European Institutions to:

- Encourage EU citizens to access and make use of the central medicines portal;
- Support and contribute to the efforts of the EMA on digitalising an electronic database of medicinal products;
- Lead and promote global collaboration and the transfer of knowledge for the advancement and integration of pharmaceutical products and new health technologies into the new system at a national level;
- Promote fair and equitable patient representation during the construction of the database;
- Advance the aim of the database by supporting it with data on pharmaceutical products.

EMSA calls upon Clinicians and Healthcare providers to:

- Aid in the creation of the database by contributing relevant data and collaborating on its development;
- Make use of the medicines database in clinical practice;
- Promote evidence-based patient information on pharmaceutical products through the central medicines database;
- Support further developments in regards to digitalisation of the medical field.

EMSA calls upon EMSA members and medical students to:

- Contribute to the expansion and use of the central database among medical students, patients, and healthcare professionals;
- Raise awareness on the importance of a central database for information dissemination about pharmaceutical products;
- Follow up with the progress and developments during the process of building a sustainable pharmaceutical product database with easy access.

List of Abbreviations.

EMSA Secretariat Rue Guimard 15 1040 Brussels, Belgium Tel : +32 2732 72 02 emsa-europe.eu info@emsa-europe.eu

EMA: European Medicines Agency
EMSA: European Medical Students' Association
ePI: Electronic Product Information
EU: European Union
EC: European Commission
NCAs: National Competent Authorities

References.

- EMA. (2016): "Development of the European Medicines Webportal". Retrieved June 28, 2021 from http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/10/WC500213925.pdf.

- EMA. (2017): "EMA action plan related to the European Commission's recommendations on product information". Retrieved June 28, 2021 from http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/11/WC500238305.pdf.

- EMA. (2017):"About us". Retrieved June 28, 2021 from http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/08/WC500211862.pdf.

- EMA, HMA, EC. (2020): Electronic product information for human medicines in the EU: key principles. Retrieved June 28, 2021 from https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf.

- EC. (n.d.).: *eHealth*. Shaping Europe's digital future. (n.d.). Retrieved June 28, 2021 from https://digital-strategy.ec.europa.eu/en/policies/ehealth.

- EC. (2017):"Report from the Commission to the European Parliament and the Council". Retrieved June 28, 2021 from https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf.

- EMA. (2016, October 6). :"DevelopmentoftheEuropeanmedicineswebportal" Retrieved June 28, 2021 from https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-development-european-medicines-web-portal_en.pdf.

- EMA. (n.d). : Medicines. Retrieved June 28, 2021 from https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253A.

- NCA Human. (n.d). : National competent authorities (human). Retrieved June 28, 2021 from https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human.

- Pharma infolinks. (n.d). : National drug databases - EU :: INFOlinks Retrieved June 28, 2021 from https://pharm-infolinks.webnode.cz/drug-databases/national-drug-databases-eu.

- World Health Organization. (n.d.). *List of MRA Websites*. Retrieved June 28, 2021 from https://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf .

EMSA Secretariat Rue Guimard 15 1040 Brussels, Belgium Tel : +32 2732 72 02 emsa-europe.eu info@emsa-europe.eu