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NAMMDR POLICY FOR WEBPAGE UPDATES

At National Agency for Medicines and Medical Devices of Romania, we are dedicated to upholding transparency in our operations, particularly in updating our webpages in order to disseminate accurate and current information to the public. This transparency policy delineates our approach to webpage updates, encompassing frequency, responsibility, level of information dissemination and specific guidelines for updating critical documents such as Patient Information Leaflets (PILs), Summary of Product Characteristics (SmPCs) and Public Assessment Reports (PARs).

1. Frequency of Updates:
    - We will ensure regular updates of our webpages, in order to maintain currency and accuracy of the information provided.
    - Routine updates will occur at least monthly, with additional updates made promptly to reflect significant changes or developments.
    - Specific sections such as regulatory news, guidelines or safety information will be updated promptly, following relevant events or announcements.
2. Responsibility:
    - Responsibility for updating the webpages ensuring alignment with regulatory standards and internal policies is compliant with the internal procedures of the Information and Communications Technology Service of the National Agency for Medicines and Medical Devices of Romania.
    - The appointed representatives of the various departments will supervise and guarantee the compliance and accuracy of the web content, as well as permanent updates.
    - Experts in the field will be consulted to verify the accuracy and relevance of information prior to publication.
3. Level of information presented to the public:
    - We are committed to providing comprehensive and understandable information to diverse stakeholders, including healthcare professionals, patients and regulatory authorities.
    - The information presented will be clear, concise and tailored to meet the needs of various audiences.

- Multilingual presentation of information will be implemented where necessary, in order to enhance accessibility.

4. Specific Guidelines for PILs, SmPCs, and PARs Updates:

    - PILs, SmPCs, and PARs will be updated promptly following the granting of a new Marketing Authorisation (MA) for a medicinal product, or any other relevant related regulatory action.

    - Updates will accurately reflect any changes in the authorised product information, including indications, dosages, contraindications, warnings, precautions, adverse reactions and other relevant details.

    - Revised versions of PILs, SmPCs, and PARs will be made available on our website alongside previous versions to ensure transparency and traceability.

    - Stakeholders will be notified of updated PILs, SmPCs and PARs through appropriate communication channels.

This transparency policy aims to foster trust, accountability and informed decision-making among stakeholders by ensuring timely access to accurate and up-to-date information on our website. We welcome feedback and suggestions for improvement to continuously enhance our transparency efforts.