Information Transparency Policy managed by the National Agency for Medicines and Medical Devices of Romania NAMMDR

INTRODUCTION

The National Agency for Medicines and Medical Devices of Romania (NAMMDR) is committed to ensuring transparency in its activities and facilitating public access to relevant information regarding the safety, efficacy, and quality of human-use medicines and medical devices. This transparency policy establishes the principles, categories, and procedures for disseminating the information held by NAMMDR.

GENERAL PRINCIPLES

Information is public, except in cases expressly provided by the applicable legislation as confidential.

Information is accessible through the NAMMDR website, www.anm.ro, and all other official channels.

NAMMDR complies with the legal provisions regarding the protection of personal data, with information available on the website in the section Personal Data Protection - GDPR.

PURPOSE AND OBJECTIVES

The main purpose of NAMMDR's transparency policy is to ensure maximum openness and easy access to relevant information regarding the agency's activities, decisions, and public interest data, contributing to:

- High accessibility to information by eliminating barriers to obtaining public interest information.
- Dissemination of accurate and current information to ensure that patients, healthcare professionals, industry, and the public have easy access to relevant data on human-use medicines and medical devices.
- Publication of public interest information – access to activity reports, leadership agendas, budgetary information, and other relevant documents.

- Regular updates of the website www.anm.ro – ensuring up-to-date information on medicine leaflets, product characteristics summaries, public assessment reports.
- Facilitating access to information through electronic means – using online platforms for submitting documents and accessing data.
- Enhancing transparency in the decision-making process – publishing agendas, minutes, and reports while respecting applicable confidentiality laws.
- Publication of sponsorships and expenses – pharmaceutical and medical device companies must declare and publish sponsorships and other expenditures granted to healthcare professionals and relevant organizations.

Transparency Policy Objectives includes

- *Increasing public trust* – by providing clear and accessible information, NAMMDR aims to build trust among citizens, healthcare professionals, the pharmaceutical industry, and international partners.
- *Agency accountability* – transparency allows stakeholders to monitor and evaluate NAMMDR's activity, promoting greater accountability.
- *Improving decision-making* – by public consultation and sharing relevant information, NAMMDR gains valuable feedback for more informed and better-grounded decisions.
- *Clarifying regulations* – publishing detailed procedures, guides, and rules helps stakeholders better understand the legal framework and requirements.
- *Fighting corruption* – greater transparency reduces the risk of illegal practices and contributes to institutional integrity.
- *Providing accurate information to patients and professionals* – access to updated, precise information on medicines and devices is essential for informed health decisions.
- *Efficient communication* – a well-defined transparency policy improves communication with all stakeholders, reducing ambiguity and misunderstandings.

COOPERATION

NAMMDR collaborates with various regulatory institutions, both nationally and internationally, to enhance openness, information exchange, and alignment with global standards.

The purpose of collaboration in the context of institutional transparency:

- **Improving information access** – sharing data with other European agencies and the European Medicines Agency (EMA) allows NAMMDR to provide comprehensive and current public information.
- **Building trust** – collaboration with nationally and internationally recognized institutions strengthens NAMMDR's credibility as a regulatory authority.
- **Standard harmonization** – participation in international networks ensures NAMMDR's regulations and practices align with top European and global standards.
- **Knowledge sharing** – collaboration facilitates the exchange of expertise, improving problem understanding and solution identification.
- **Supporting cooperation** – strong relations with other institutions aid in market surveillance and crisis management.

SCOPE OF APLICATION

This policy applies to all NAMMDR employees and all information held by the agency, regardless of format (electronic, written, audio-video, etc.).

PUBLICLY AVAILABLE INFORMATION

Lista cu documentele de interes public și lista cu documentele produse/gestionate de instituție – ANMDMR

INFORMATION AVAILABLE ON REQUEST

According to Law no. 544/2001 on free access to public interest information and Government Ordinance no. 27/2002 on petition handling, NAMMDR ensures free and unrestricted access to any public interest information, in line with Romania's Constitution and international treaties ratified by the Romanian Parliament, as well as EU regulations. Special website sections:

- Formular de solicitare în baza Legii nr. 544/2001 privind liberul acces la informațiile de interes public, cu modificările și completările ulterioare – ANMDMR
- Petiții online – ANMDMR

Requests by media for public information can be sent to: comunicare@anm.ro
Public interest information can also be requested via email at: secretariat@anm.ro

EXEMPTED INFORMATION

Public interest information exempted from disclosure, as per Article 12(c) of Law no. 544/2001 (as amended), to uphold NAMMDR's confidentiality principle, can be consulted via the document published on the website: Decizia nr. 175_21.08.2019 - Lista informațiilor exceptate.pdf

ARCHIVED INFORMATION

Access to the agency's archives is granted according to the National Archives Law, respecting applicable retention periods.