On October 4th, BADI held Module 1 live with over 80 participants, including lecturers and moderators from the Bulgarian Drug Agency (BDA), the industry, and academia.

The topics were dedicated to audits and inspections of pharmacovigilance (PV) and quality (QA) systems, signal management, reporting of adverse drug reactions by healthcare professionals, as well as the switch of medicines' prescription status from OTC to prescription and vice versa, directly related to safety.

Summaries of the presentations by the lecturers, along with their references, can be found in this document, which is prepared in English and in Bulgarian language.

Please see the Faculty of Module 1: speakers, moderators and creators of the Program of Module 1 (Figure 1)

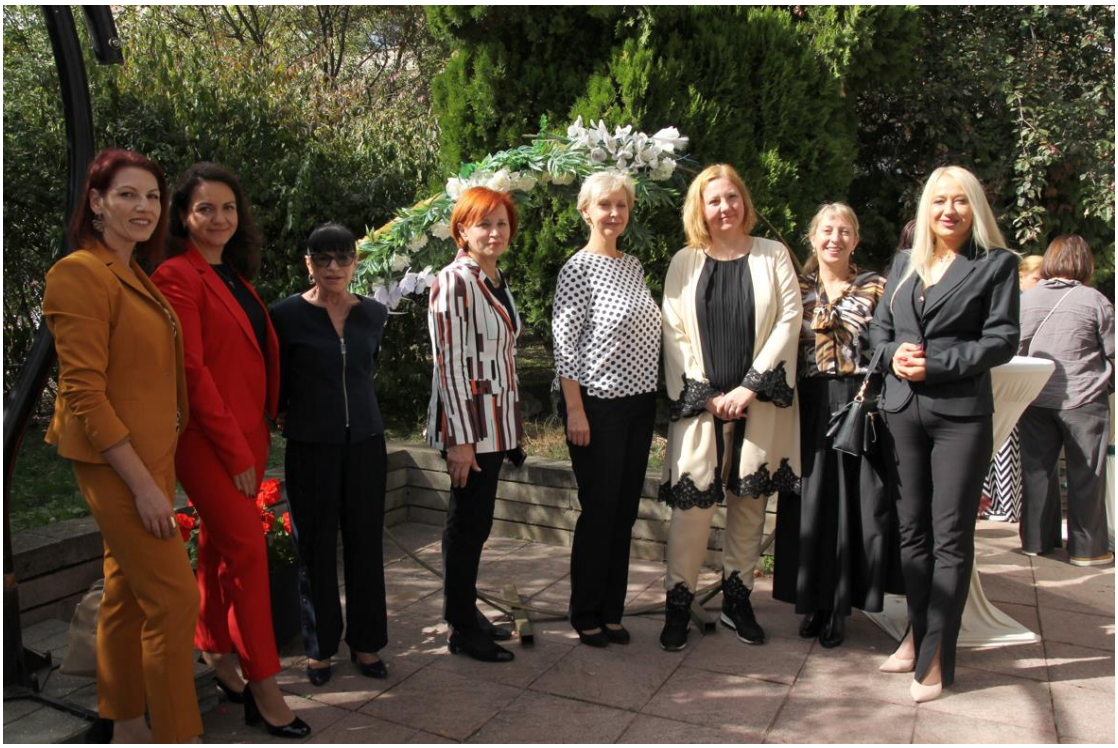
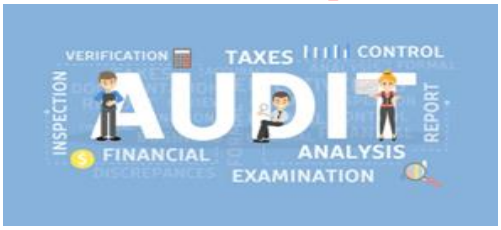


Figure 1 The Faculty at Modul 1 -04.10.2014

Title: Audits and inspections of the PV/QA systems



Theodora Chachevska
Position: Event of BADI 4 of October 2024 – Modul 1 Pharmacovigilance update
Company: Wörwag PharmaBulgaria EOOD
Date: October 4, 2024
Key Areas of Expertise: Quality Management Systems (QMS)

- Pharmacovigilance (PV)
- Regulatory Compliance
- Audit Processes (Internal and External)
- Corrective and Preventive Actions (CAPA)

Professional Summary: The document outlines the essential elements of quality management and pharmacovigilance systems, emphasizing the need for structured audits to ensure compliance with regulatory standards. It discusses the importance of quality documentation, audit preparation, and effective communication during audits. The goal of these audits is to identify and address non-conformities that could impact patient safety and product quality.

Skills:

- Ability to document and improve critical business processes
- Knowledge of regulatory frameworks and compliance requirements
- Proficient in conducting interviews, data collection, and observational assessments
- Experience in preparing audit plans and conducting thorough evaluations
- Expertise in CAPA planning and tracking

Goals of Audits and Inspections:

- Verify compliance with quality management and pharmacovigilance systems
- Assess the effectiveness of processes in place for drug safety
- Identify areas for improvement to enhance public health safety

Conclusion: Audits serve as a crucial mechanism for ensuring the integrity of quality and safety management systems in the pharmaceutical industry. The interaction quality between auditors and auditees significantly influences audit outcomes.

For more information please see the presentation on BADI website Presentations all (badibg.org) the EMA documents

Pharmacovigilance inspection procedures: human

Pharmacovigilance inspection procedures: human | European Medicines Agency (EMA) (europa.eu)

Title: Signal Management in Pharmacovigilance and Update in the Pharmacovigilance

Event of BADI 4 of October 2024 - Modul 1 Pharmacovigilance update

Presenter: Margy Strokova

Overview:

The presentation focuses on updates in pharmacovigilance practices, particularly related to signal management. It highlights recent revisions to Good Pharmacovigilance Practices (GVP) Module IX, and the methodologies for identifying, validating, and prioritizing safety signals arising from medicinal products.

Key Points:

1. **Definition of Signal:**

- New information regarding potential risks, unknown adverse reactions, or changes in known reactions, identified through various data sources like spontaneous reports and clinical trials.

2. **Signal Management Process:**
   - Involves identification, validation, prioritization, and assessment of potential safety signals, followed by possible regulatory ***actions, such as changes to product labeling or withdrawal from the market.***

Topic 2

3. **Revisions in GVP Module IX:**
   - Enhanced guidance on risk minimization measures (RMM) and the effectiveness of these tools.
   - Emphasis on patient-reported outcomes and mixed methods approaches for signal evaluation.
4. **Regulatory Actions:**
   - Depending on the signal's significance, actions ***may include additional studies, product labeling updates, temporary suspension, or withdrawal from the market.***

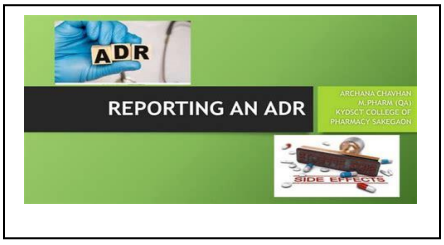
Conclusion:
Signal management plays a critical role in ensuring the safety of medicinal products, with continuous monitoring and updates to regulatory frameworks guiding the evaluation and mitigation of potential risks.

For more information please see the presentation on BADI website Presentations all (badibg.org)

For more information please see the EMA website
Signal management | European Medicines Agency (EMA) (europa.eu)

Topic: Effective Management of Pharmacovigilance Processes,

Attitude of medical doctors to adverse drug reactions reporting in Bulgaria,



Vili Todorova Topalova, MD PhD
Institution: MU - Sofia, Faculty of Public Health, member of BADII
Moderators : Prof. Dobriana Sidzhimova, PhD, MD; Prof. Tatiana Benisheva-Dimitrova, MD

Objective: To analyze attitudes towards reporting suspected adverse drug reactions (ADRs) by healthcare professionals in Bulgaria, especially post-marketing.

Key Achievements:

- Conducted comprehensive literature reviews and analyses on pharmacovigilance legislation and practices in Bulgaria and the EU.
- Developed information materials aimed at enhancing awareness and compliance among healthcare providers regarding ADR reporting.

Methodology:

- Executed two surveys were discussed:

- A voluntary, anonymous study involving 50 doctors and 18 nurses in Sofia.
- A nationwide questionnaire distributed to 650 doctors in collaboration with the Bulgarian Medical Union.

Results:

- **Awareness:** 67.08% of doctors acknowledge the benefits of ADR reporting for patient safety.
- **Compliance:** 45% of surveyed healthcare professionals reported barriers to ADR reporting, including lack of training and awareness.
- **Educational Need:** 83.33% expressed the necessity for educational programs on pharmacovigilance and ADR reporting. Additional education is necessary, which could be organized ay the level of the universities, at the health care professional organizations and at the product company events by the marketing authorization holders

Conclusions:

- ADR reporting by healthcare professionals in Bulgaria is inadequate.
- Enhanced educational initiatives and regulatory support are crucial for improving pharmacovigilance practices.

Contributions:

- First comprehensive assessment of the pharmacovigilance system in Bulgaria, highlighting the roles and responsibilities of healthcare professionals and their NGO, to teach them the rules and the necessity of drug reporting.
- Recommendations for annual training sessions and the creation of concise informational brochures to facilitate ADR reporting in Bulgaria,

For more information please see the presentation on BADI website Presentations all (badibg.org)

For more information view the original publication for that survey in Bulgaria :

Source of information

Attitude of medical doctors to adverse drug reactions reporting in Bulgaria,
Pharmacia,Volume 71,2024,Pages 1-7,ISSN 0428-0296,
Dobriana Sidjimova, Tatyana Benisheva, Vili Topalova, Valentina Petkova,
https://doi.org/10.3897/pharmacia.71.e115559
.(https://www.sciencedirect.com/science/article/pii/S0428029624000507)

Title: Change of the prescription status in the EU

Presenter: Assoc. Prof. . Lubina . Todorova, PhD, Bulgarian Drug Agency, Head of the Marketing Authorisation Department
Event of BADI 4 of October 2024 - Modul 1 Pharmacovigilance update
Presented topic :Change of the prescription status
Overview:
The presentation covers the regulatory framework for prescribing and dispensing pharmaceutical products, particularly focusing on prescription drugs and over the counter (OTC) medications. (Regulation 3 НАРЕДБА № 3 ОТ 4 МАРТ 2008 Г (bda.bg))It explores the criteria for classifying medications, key regulations guiding the Bulgarian and European pharmaceutical legislation, and the impact on patient safety.

Key Points:

1. **Regulatory Framework:**
   - Prescription drug status is determined by national authorities at the final stage of evaluating the marketing authorization documentation.

   - Several directives and resolutions, including Directive 2001/83/EC and ResAP (2007)1, outline standards for prescription and non-prescription drugs.

2. **Classification of Medicines:**

   - Medicines are categorized into those requiring prescriptions, which include narcotic substances and those with significant side effects, and those that can be dispensed without prescription (OTC).
   - Specific drugs, such as opioid analgesics, are controlled through stricter "green" or "yellow" prescription forms, reflecting their potential risks.

3. **Challenges in OTC Classification:**
   - OTC products face risks, including incorrect usage and drug interactions, leading to concerns about patient safety.
   - Expanding the OTC list can provide quicker access to medications but increases the responsibility on consumers to report adverse effects.

4. **Regulatory Amendments:**
   - Changes in drug dispensing status can occur upon renewal or with specific applications (Type II variation), supported by clinical and safety data.
   - National legislation does not allow dual-status drugs, prompting the reclassification or narrowing of indications for certain products.

Conclusion:
The regulatory landscape for generics and OTC medications requires a careful balance between improving accessibility and ensuring safety, especially when expanding the list of non-prescription drugs. The national regulatory framework, guided by European directives, continues to evolve to address these challenges.

BDA is responsible for the change of the prescription status. For centrally authorized medicinal products is EMA responsible.

For more information please see the presentation on BADI website Presentations all (badibg.org)

European Medicines Agency recommended first switch from prescription-only to non-prescription for a centrally authorised medicine in 2008https://www.ema.europa.eu/en/news/european-medicines-agency-recommends-first-switch-prescription-only-non-prescription-centrally-authorised-medicine

Created by Team of BADI on
the presentations of the event
4.10.2024