



Communication in drug safety

Approach of State Institute for Drug Control

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State Institute for Drug Control

- Drug regulatory agency working in the framework of national and European legislation
- Quality, efficacy and safety Assessment for Registration (national, mutual and centralised)
- Market surveillance, consumer protection
- Post-authorization issues
 - Routine Pharmacovigilance, PSUR assessment
 - Renewals, variations

Transparency

Not trying to keep anything secret

The full, accurate, and timely disclosure of information

- Annual report, budgetary reporting
- Legislation - European and national
- Legal requirements, Guidelines for applicants
- Description of Procedures, SOP
- Advisory bodies
 - Statute, SOP
 - List of Members
 - Time frame of meetings
 - Minutes of meetings
- Links to external resources

Basic data on registered Medicines

Actual version available on internet
In Slovak language

- SmPC
- PL
- Conditions and restrictions
- EPAR, PAR
- Other information (ATC code, reimbursement, prescription status, type of registration, etc.)
- Availability of medicines

Other information on medicines

- *(sales data)*
- Other information available on MoH website
 - List of reimbursed medicines
 - Prescription conditions for reimbursement
 - Possibilities for Generic substitution
 - Therapeutic guidelines

Medicines with conditions

- Materials for
 - Physicians, Pharmacists, Health care providers
 - Patients or caregivers
 - Restrictive distribution of products
 - Pregnancy Prevention Plan
- Role of Competent authority
 - Approve, comment, check
 - Confirm implementation of requirements
 - Surveillance, sanctions

Medicines with conditions

- Conditions are published on internet
- Separate category in databank
- List of products is available

We plan

- New Guideline for industry
- Mechanisms for monitoring of compliance

Target groups for dialogue

with different expectations

- Industry including distributors
 - Meetings, lectures
- HP
 - Use as Experts
 - Congresses, lectures
- Patients organisations
 - Meetings
 - Special programs

Risk and Crisis communications

Examples

- Restrictions in supply
- Results of referrals
- Changes in registration
- Quality defects and withdrawals from market

Type of communication

- Rapid alert system with mailing list
- Press release
- Questions and answers
- Bulletin
- Additional explanations for media

DHPC (DDL)

- Triggered by signal, referral, quality defects etc.
- Our role
 - Initiate (sometimes)
 - Check, comment
- Experience
 - Quality of translation sometime poor (MaH without local contacts)
 - National conditions and national comments sometimes not taken into account.
- Available on web site

Individual communication

- Requests, queries, claims, complaints, proposals
- Patients reports of ADR, medication errors, quality defects
- Media interests
- Always letter or email to individual
- Requires special extra work
- Source of new ideas for communication

Communication in NCA

- Transparency - all
- Dialogue – organisations
- Education, promotion – industry, HCP, patient
- Communication of risk – media, HCP, patient
- Individual communication – patient, media

Communication in NCA

- Role of NDA is not always recognized
- Different types of communication are part of legal requirements
- Are belong to everyday activities of employees in national competent authorities
- Special training of employees is needed
- Additional recourses (of different kind) are required