Information on Medicinal Products

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Medicines Authority
February 2011
What is the most important information on medicinal products which industry/health care professionals/patients seek/ask for?
Objectives of the Session

- To better understand what Maltese consumers/patients know about their medicines
- To understand the communication strategy of the Medicines Authority
- To increase awareness on trusted sources on medicines
Session Plan

- Introduction on Information on Medicinal Products
- Medicines Authority Objective
- Core Quality Principles
- Medicines Authority Communication Strategy
- ‘Trusted’ Communication Sources
Introduction on Information on Medicinal Products

- Medicines Authority Objective
- Core Quality Principles
- Medicines Authority Communication Strategy
- ‘Trusted’ Communication Sources
A definition of information

... stimuli

that has meaning

in some context

for its receiver
The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.

Directive 2001/83EC, Preamble (40)
Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.

Directive 2001/83EC, Preamble (52)
- Introduction on Information on Medicinal Products

Medicines Authority Objective

- Core Quality Principles

- Medicines Authority Communication Strategy

- ‘Trusted’ Communication Sources
The Medicines Authority has a national public health remit with respect to pharmaceutical activity, information about medicinal products, and the availability and use of medicinal products on the local market.
- Introduction on Information on Medicinal Products

- Medicines Authority Objective

Core Quality Principles

- Medicines Authority Communication Strategy

- ‘Trusted’ Communication Sources
On 26 June 2007 the Pharmaceutical Forum agreed on a set of core quality principles on information to patients on diseases and treatment options:

- objective and unbiased
- evidence-based
- Reliable
- Accessible
- relevant and appropriate
- patient-oriented
- up to date
- understandable
- transparent
- consistent with statutory information
Objective and Unbiased

Information is objective when it is based on facts and not influenced by prejudices or personal perceptions.

Information is unbiased when it is impartial, non-directive and balanced.

These two definitions do not relate to the source of information which is a separate issue (see the ‘Transparent’ principle).
Patient-Oriented & Understandable

Information provided should be patient-centred taking into account patients’ needs and expectations in order to empower patients.

Patients should be involved in the production and dissemination of information on diseases and treatment options wherever possible.

Information provided should be comprehensible for a patient/citizen.
The evidence base for any information resource needs to be clearly stated, including making clear the level of evidence.

Information should be verifiable, based on comparisons and backed up by scientific peer review where possible.
Information should be kept up-to-date and the date of publication should be included.
Information needs to be factually correct and not misleading.

Information should be scientifically valid and reflect latest knowledge.
Information should be easily accessible via different mechanisms for example, through written documents, websites of certified official bodies etc.

Information should also be accessible to people with disabilities.
Informed choice requires transparency. That entails transparency of what is known as well as what is not known.

Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular treatment, for example, all need to be made clear.
Information should include issues of relevance and importance to patients’ decision-making e.g. including adverse effects.

Impact on quality of life and the consequences of the disease on contribution of the patient to society/the work place are important elements of information on disease.
Information not regulated by statute should, nevertheless, be consistent with the legal requirements of European law (e.g. must not be designed to promote a prescription only medicine, reflecting the prohibition of direct to consumer advertising of prescription only medicines, must not be misleading etc.) and should refer, where appropriate, to statutory information approved through the process of regulation.
- Introduction on Information on Medicinal Products
- Medicines Authority Objective
- Core Quality Principles

Medicines Authority Communication Strategy
- ‘Trusted’ Communication Sources
Sustain health care professionals and consumers' awareness, knowledge and trust in the medicines lifecycle and provide information on the regulation of medicines and pharmaceutical activities.
Inform, educate and empower health care professionals and consumers in choice of medicines.
Provide information on medicines and increase awareness of the available resources and promote use of trusted sources (in terms of information).
Strategy

Research
Malta Medicines List
Micro Site for Consumers
Facebook Page
Information Leaflets/ Posters
Helpline – 23439111
Information Meetings

Participation in Public Events e.g. Science Week
Telephone Interviews

Objectives of the Research

· Identifying participants’ general knowledge on medicines

· Identifying participants’ awareness in the medicines lifecycle

· Identifying participants’ trust in medicines

· And identifying participants’ awareness on choice of medicines.
Telephone Interviews

Participation

- 200 Telephone Interviews
- September 2010 – January 2011, 8am -8pm
- 82 Male, 116 Females
Telephone Interviews

Ages of Participants

- 18-29
- 30-39
- 40-49
- 50-59
- 60-68
- 70+
- NA

Information on Medicinal Products
Medicines Authority
Telephone Interviews

Region

Information on Medicinal Products
Medicines Authority
Telephone Interviews

Education Level

- Bla skola
- Livell primarju
- Livell sekondarju
- Livell post sekon...
- Livell terzjajru
- Halliha/itha vojta

Information on Medicinal Products
Medicines Authority
Do you seek advice or information before taking a new medicine which does not require a prescription?

People may select more than one checkbox, so percentages may add up to more than 100%.
If yes, from the following list, where do you typically seek advice on medicines which do not require a prescription?

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>58%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>29%</td>
</tr>
<tr>
<td>Other HCP</td>
<td>2%</td>
</tr>
<tr>
<td>Family/ Friends</td>
<td>1%</td>
</tr>
<tr>
<td>Television/ Radio</td>
<td>2%</td>
</tr>
<tr>
<td>Internet</td>
<td>6%</td>
</tr>
<tr>
<td>Books/ Magazines</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
</tr>
</tbody>
</table>

People could select more than one checkbox.
### Telephone Interviews

Which source of information on medicines would you trust most?

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>91%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>5%</td>
</tr>
<tr>
<td>Other HCP</td>
<td>1%</td>
</tr>
<tr>
<td>Family/Friends</td>
<td>0%</td>
</tr>
<tr>
<td>Television/Radio</td>
<td>0%</td>
</tr>
<tr>
<td>Internet</td>
<td>0%</td>
</tr>
<tr>
<td>Books/Magazines</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
</tr>
<tr>
<td>Don’t trust any of the above</td>
<td>1%</td>
</tr>
</tbody>
</table>
Do you read medicines' product information leaflet before taking an OTC medicine for the first time?

- Always: 49%
- Frequently: 14%
- Sometimes: 22%
- Never: 14%
### Telephone Interviews

**If not, why?**

<table>
<thead>
<tr>
<th>Source of Information</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>My Doctor gives me necessary information</td>
<td>41%</td>
</tr>
<tr>
<td>Pharmacist gives me necessary information</td>
<td>16%</td>
</tr>
<tr>
<td>Other health care professionals give me necessary information</td>
<td>1%</td>
</tr>
<tr>
<td>Family and friends give me necessary information</td>
<td>5%</td>
</tr>
<tr>
<td>Television / Radio give me necessary information</td>
<td>1%</td>
</tr>
<tr>
<td>Internet gives me necessary information</td>
<td>5%</td>
</tr>
<tr>
<td>Books / Magazines give me necessary information</td>
<td>1%</td>
</tr>
<tr>
<td>Can't be bothered</td>
<td>8%</td>
</tr>
<tr>
<td>No reply (?)</td>
<td>16%</td>
</tr>
<tr>
<td>Other</td>
<td>6%</td>
</tr>
</tbody>
</table>
If a prescribed medicine works for you, do you recommend it to your neighbour / friend / relative with a similar sickness / condition?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>28%</td>
</tr>
<tr>
<td>No</td>
<td>48%</td>
</tr>
<tr>
<td>Depending the condition</td>
<td>21%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>0%</td>
</tr>
<tr>
<td>No reply</td>
<td>3%</td>
</tr>
</tbody>
</table>
Do you know the difference between Originator and Generic Medicine

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>12.5%</td>
</tr>
<tr>
<td>No</td>
<td>85.5%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>3%</td>
</tr>
</tbody>
</table>
71% of those who use the internet find it as a very good or good source of information on medicines.

41% of respondents who use the internet say that the internet effects which treatment/ medicine is bought.

3% of respondents bought medicines over the internet due to wider selection, convenience and price.

8% are not concerned about the authenticity or safety of medicines available for sale on the internet.
75% of respondents store medicines in humid places such as bathroom and kitchen.

60% of respondents keep medicine until expiry date.

93% of respondents dispose of medicines through normal waste or through sewage system.
Medicines Authority
Awtorità dwar il-Medìċini

Know more about Medicines Regulation
- Medicines Regulation
- Herbal Medicines

Know more about Safety of Medicines
- Safety
- Adverse Reactions (ADRs) of Medicines

Know more about the Medicines Supply Chain
- Medicines Supply Chain
- Over the Counter and Prescription only Medicines
- Counterfeit Medicines
- Buying Medicines over the Internet

News and Events
Question and Answer (English) on Medicines
Question and Answer (Maltese) on Medicines
X’TAF FUQ
IL-MEDICINI TIEGHEK?

INFORMA RUHEK

☑ Staqsit lit-tabib u litt-ispiżjar fuq il-medicini tieghek
☑ Aqro l-fjelljett ta’ togħrif li ssib mol-medicino tieghek
☑ Staqsit hawn għal-moterjel bl-informazzjoni fuq il-medicini

www.knowyourmedicines.gov.mt
knowyourmedicines.info@gov.mt
Helpline (09:00 - 12:00) -356 2343 9111

Information on Medicinal Products
Medicines Authority
- Introduction on Information on Medicinal Products
- Medicines Authority Objective
- Core Quality Principles
- Medicines Authority Communication Strategy

‘Trusted’ Communication Sources
The Malta Medicines List helps Health Care Professionals and Consumers to find information about which medicinal products are authorised to be placed on the local market.
Malta Medicines List

<table>
<thead>
<tr>
<th>Record Id: 9633</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Class: ANTINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS</td>
</tr>
<tr>
<td>ATC Code: M01AB05</td>
</tr>
<tr>
<td>Active Ingredients: Diclofenac Potassium 50mg</td>
</tr>
<tr>
<td>Product Name: Areston</td>
</tr>
<tr>
<td>Pharmaceutical Form: FILM-COATED TABLET</td>
</tr>
<tr>
<td>Classification: PoM</td>
</tr>
<tr>
<td>Authorisation Number: MA032/00801</td>
</tr>
<tr>
<td>Licence Number: NOT APPLICABLE</td>
</tr>
<tr>
<td>Licence Holder Name: Medochemie Limited</td>
</tr>
<tr>
<td>Licence Holder Address: 1-10, Constantinoupios Street, 3011 Limassol, Cyprus</td>
</tr>
</tbody>
</table>

ATC Code and Therapeutic Class
It is controlled by the World Health Organisation (WHO) Collaborating Centre for Drug Statistics Methodology (WHOCC), and was first published in 1976. The classification system divides medicines into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics.

In this system, medicines are classified into groups according to the active substance and its indications. Further information may be found on the WHO ATC website: http://www.whocc.no/atc_ddd_index/
<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Product Name</th>
<th>Pharmaceutical Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Potassium 50mg</td>
<td>Areston</td>
<td>FILM-COATED TABLET</td>
</tr>
</tbody>
</table>

Record Id: 0633

Therapeutic Class: ANTINFAMMATORY AND ANTIRHEUMATIC PRODUCTS

ATC Code: MO1AB05

Active Ingredients: Diclofenac Potassium 50mg

Product Name: Areston

Pharmaceutical Form: FILM-COATED TABLET

Classification: PoM

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Patient Information Leaflets: View Documents
Active Ingredient - Some medicinal products may contain more than one active ingredient. An active ingredient is the substance in a medicinal product that is biologically active i.e. produces the desired effect. It is also referred to as active pharmaceutical ingredient (API) or active substance.

Product Name - The authorised name of a medicinal product.
### Malta Medicines List

Information on Medicinal Products

**Medicines Authority**

- **Trusted** Information Sources
- **Access to package leaflet and summary of product characteristics**

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**Export All/ Selection**

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- **POM or OTC**
- **MA, PI, AA**
- **Marketing Authorisation Holder**

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Information on Medicinal Products

Medicines Authority
EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA). EudraPharm has been established to fulfil Articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004.
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