



Consumer Medicines Information in Europe; learnings from research, policy and practice

DK Theo Raynor PhD MRPharmS

Professor of Pharmacy Practice,
University of Leeds, UK and LUTO Research Ltd

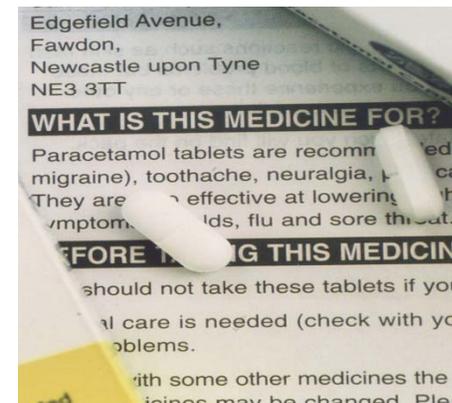
d.k.raynor@leeds.ac.uk

Much consumer medicines information is poor



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- *You throw them away don't you?*
- *They don't inspire you*
- *Things we want to know don't come first*
- *Priorities are those who wrote it, not patients*
- *People who suffer should help write leaflets*



 Raynor DK et al. *We are the experts: people with asthma talk about their medicine information needs* **Patient Education and Counselling** 2004

Parallel Tracks?



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Patient-focused research undertaken in Europe and Australasia in past 20 years

- Significant amount of common learnings

Will outline these learnings today:

- The research evidence
- The legislative environment

1. Current situation in Europe

- Legislation and impact (positive and negative)

2. Systematic Review of research

- What sort of CMI do patients find useful & valuable?

3. User testing

- Legislation and impact on practice



Leeds Research Team



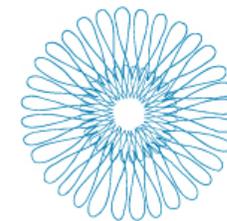
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Key research:

- Impact of EU legislation & User Testing
- Expressing risk and benefit in CMI
- International comparison: UK – US - Australia
- I-CMI Australian project

University Spin Out: LUTO Research Ltd

- Leaflet testing service for pharma companies
- >12,000 participant interviews



luto
Research for
Clear Communication



Current Situation in European Union

DK Theo Raynor PhD MRPharmS

Professor of Pharmacy Practice,
University of Leeds, UK and LUTO Research Ltd

d.k.raynor@leeds.ac.uk

Current Situation



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- Most medicines supplied in ‘original packs’ which pharmacists label (minimal re-packing)
- Mandatory comprehensive patient leaflets inside every pack
- Written by manufacturer according to strict guidance
- Leaflets for new medicines must be successfully ‘User Tested’ for a licence to be granted



European Union Primer



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- The European Union and United States are similar yet different
 - People from UK, France etc will say are 'British', 'French' etc, not 'European'
 - However, many areas of life subject to supra-national legislation
 - includes medicines regulation
- 27 member states
 - Portugal to Poland
 - Malta to Finland
- 23 official languages
- Population 495 million



EU Legislation 1999



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Mandatory patient leaflet with all medicines

- Supplied as package insert
- Full and comprehensible
 - all information in PI / SPC
 - in form understandable to patient
- Mandated headings and ordering of information
- “Readability Guideline” issued (revised 2008)

EU Legislation 2005



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**Wide ranging review of all EU pharma legislation
Included a number of key clauses relating to CMI:**

- Promoting inclusion of more positive information
- Braille wording on every pack
- Mandates user testing

User Testing Mandatory



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The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use

- Results submitted with other mandatory regulatory information necessary for licensing
- Applies to branded, generic and herbals
- Usually interpreted as “User Testing”
- **No tested leaflet**  **no licence**



Raynor DK. *Testing, Testing: The Benefits of User-testing Package Leaflets*
Regulatory Affairs Focus 2008

Leaflet Template



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Produced by EMEA:

- *to ensure clarity, consistency and accuracy of the medicinal product information*

Template is 'guidance' but.....

- Specified headings
- Specified sub-headings - comprehensive
- Wording of fragments
- Never tested

PACKAGE LEAFLET: INFORMATION FOR THE USER
[Heading to be printed]

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

[The (invented) name of the medicinal product (referred to as X throughout this document) followed by the strength and pharmaceutical form (i.e. as it appears in the SPC) should be stated here in bold. This should be followed by the active substance(s) (as stated on the label section 1), which may be written on the line below.]

[For medicinal products available only on prescription:]
<Read all of this leaflet carefully before you start <taking> <using> this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <or> <pharmacist>.
- <This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.>
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.>

[For medicinal products available without a prescription:]
<Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to <take> <use> X carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve <after {number of} days.>
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.>

In this leaflet:

4. POSSIBLE SIDE EFFECTS

[Description of side effects (frequency according to MedDRA).]
[Begin this section with:]
Like all medicines, X can cause side effects, although not everybody gets them.

[Describe, if necessary, the actions to be taken. If the patient needs to seek help urgently, the use of the term <immediately> is recommended; for less urgent conditions, <as soon as possible> can be used.]

[Close this section with:]
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.

[List of information necessary before taking the medicinal product.]

17

- **User Testing developed by CRIA**

- introduced 1998

- **Collaborative approach**

- QUARG
 - Communications Research Institute of Australia
 - **3 column template tested and agreed**
 - A4 sheets printed in pharmacy –up to 5 sheets per drug
 - Despite pharmacy funding, still rarely printed out for patients
- **New study started in 2008: I-CMI**
- Aim to improve format & delivery of CMI in pharmacies



International Comparison



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A comparative evaluation of CMI in 3 continents

- Universities of Leeds, Wisconsin and Sydney



Results showed

- Australian leaflets achieved 90% compliance with criteria for good quality
- UK leaflets: 81% compliance
- US leaflets: 68% compliance
 - 50% compliance for contra-indications and precautions e.g. drug interactions
 - 60% compliance for legibility and comprehensibility

 Raynor DK et al. *Consumer medication information in the United States, Europe, and Australia: a comparative evaluation*. **J Am Pharm Assoc** 2007



Systematic Review of Research

DK Theo Raynor PhD MRPharmS

Professor of Pharmacy Practice,

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d.k.raynor@leeds.ac.uk

Systematic Review



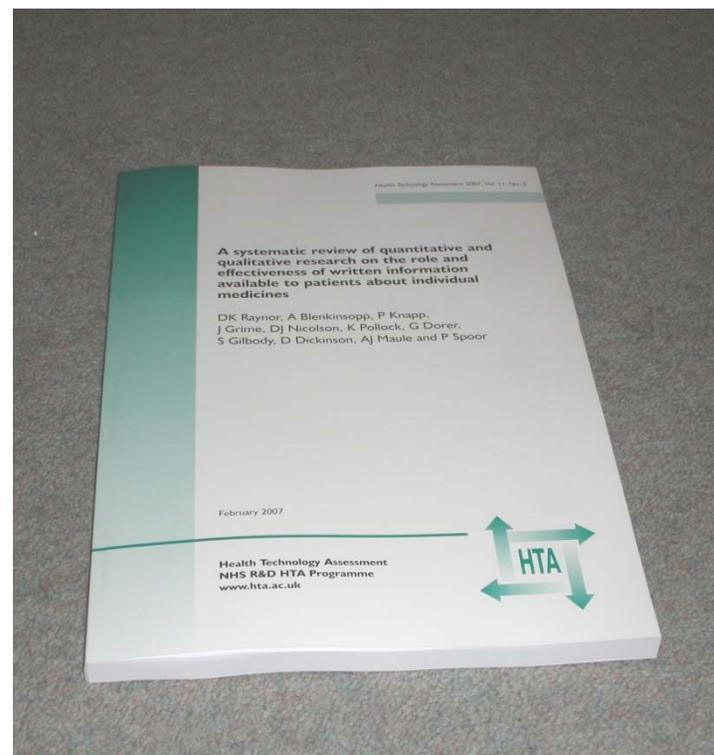
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A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines

- Commissioned by UK Dept of Health

www.hta.nhsweb.nhs.uk

Raynor, DK; Blenkinsopp, A; Knapp et al. *Systematic review of quantitative & qualitative research on role and effectiveness of written medicines information*
Health Technol Assess 2007



1. **Systematic review of Randomised Controlled Trials**

- How well does written medicines information work?



2. **Systematic review of qualitative research**

- What is the use and usefulness of written medicines information?



3. **Information design review**

- What are the key principles for writing good medicines information?



4. **Stakeholder workshops**

- To ensure a patient perspective in preparation of the review and in the interpretation of findings

Key findings



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- Most people do not value the written medicines information they receive
- Patients do not want written information substitute for spoken information from their prescriber
- Great concern about complex language visual presentation of information
- Patients value the idea of information:
 - tailored & set in the context of their particular illness
 - contains a balance of benefit & harm information
- Sufficient detail to meet their needs
 - Most patients wanted to know about any side effects
 - Concise and longer leaflets were valued depending on patient's needs at the time



Two functions of leaflets



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Patients would like written information to help decision-making in 2 ways:

1. Initial decisions about whether to take medicine or not
 - Need information about the range of treatments available (needed before prescribing decision)
 - Also information about the risks and benefits of individual medicines
2. Ongoing decisions about the management of medicines and interpreting symptoms
 - After prescribing decision

Can one document provide both solutions?

Information design: 10 principles



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1. Short familiar words and short sentences
2. Short headings that stand out
3. Type as large as possible
4. Leave 'white space'
5. Use bullets for lists

6. Be conversational
7. Use the 'active voice'
8. Use non-justified text
9. Use bold lower case for emphasis
10. Pictures and graphs do not necessarily help



Raynor DK, Dickinson D. Annals of Pharmacotherapy (in press)



Regulators and producers of written medicines information should:

- Involve patients at all stages of the information development process, enabling their needs to be better reflected.
- Use findings on information design and content to improve the quality and usefulness of their products.

As spoken information remains the priority pharmacists & other health professionals should:

- Ensure written information is not used as a substitute for discussion
- Encourage patients to use written medicines information and welcome the questions this may raise



User Testing

DK Theo Raynor PhD MRPharmS

Professor of Pharmacy Practice,
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d.k.raynor@leeds.ac.uk

Evaluating Written Information for Effectiveness



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Content based testing

- Readability formulae
- Check-lists

Performance based testing

- Based on how leaflet performs, not what it contains
- Assesses if information can be **found** & **understood**



User Testing in Brief



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Select 15 key points

- Relevant to safe and effective use

Design & pilot a questionnaire which tests:

- Finding each piece of information
- Understanding (express in own words)

Recruit 20 people from target patient group

- Interviewed individually
 - For each point, 90% to find the information
 - For each point, 90% of those to express in own words

Interview concludes with qualitative questions

- What did they like and not like about the leaflet?



INFORMATION FOR PATIENTS

Please read this leaflet carefully before you start to take this medicine. It gives a brief outline of the more important things you should know. If you want to know more about this medicine, or you are not sure about anything, ask your doctor or pharmacist.

One of the active ingredients in this medicine is furosemide. This is the new name for frusemide. The ingredient itself has not changed.

THE NAME OF YOUR MEDICINE IS CO-AMILOFRUSE TABLETS BP

The active ingredients in co-amilorfruse tablets are furosemide and amiloride hydrochloride. The tablets are available in three strengths.

2.5/20mg tablets are pale orange in colour marked ARD20 and contain 2.5mg of amiloride (as the hydrochloride) and 20mg of furosemide.

5/40mg tablets are pale orange in colour marked ARD40 and contain 5mg of amiloride (as the hydrochloride) and 40mg of furosemide.

10/80mg tablets are pale orange in colour marked ARD80 and contain 10mg of amiloride (as the hydrochloride) and 80mg of furosemide.

Other ingredients include: lactose, microcrystalline cellulose, povidone K30, sodium starch glycollate, magnesium stearate and sunset yellow E110.

The active ingredient furosemide belongs to a group of medicines called loop diuretics, which get rid of excess water but can cause a loss of potassium from the body. The other active ingredient, amiloride, belongs to a group of medicines known as potassium sparing diuretics which also get rid of excess water and prevent an excessive loss of potassium from the body.

WHAT IS CO-AMILOFRUSE FOR?

Co-amilorfruse tablets are for use (in adults only) in the treatment of heart failure, kidney problems, or fluid retention due to steroids, oestrogens or cirrhosis of the liver.

BEFORE TAKING THIS MEDICINE

You should not take co-amilorfruse tablets if:

- ◆ You are pregnant or breast-feeding (unless your doctor decides it is essential)
- ◆ You are allergic to furosemide or amiloride or to any of the other ingredients in these tablets. Check by reading the list of ingredients above.
- ◆ You have kidney failure or are unable to pass water (urine) at all.
- ◆ You have been told you have high blood potassium levels or any disturbance of other blood electrolytes (salts) which may make you feel dehydrated.
- ◆ You are taking potassium supplements or any other potassium sparing diuretic (e.g. triamterene or spironolactone).
- ◆ You have Addison's disease (underactive adrenal glands).
- ◆ You have cirrhosis of the liver, which is affecting your level of consciousness.
- ◆ You are under 18 years of age.



Patient Information Leaflet

creon[®] 10000 capsules

Pancreatin

Important things you SHOULD know about Creon 10000

- Creon 10000 is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- **Take** the amount of capsules as prescribed by your doctor or dietician.
- **Take** Creon 10000 with a meal or a snack and drink plenty of water.
- **Do not take** Creon 10000 if you are allergic to pork or any pig product.
- If you experience **severe abdominal pain** while taking Creon 10000, contact your doctor immediately.
- Most people do not have problems taking Creon 10000 but side effects can occur. (see section 4)

Please read the rest of this leaflet carefully before you start taking these tablets. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

This leaflet was last approved in ????



How to find the information you need

- 1. About Creon 10000**
What Creon 10000 is and how it works.
- 2. Before you take Creon 10000**
Who can take Creon 10000?
Can you take Creon 10000 if you are pregnant or breast feeding?
Driving or operating machinery.
- 3. How to take Creon 10000**
How much Creon 10000 you should take.
When you should take Creon 10000.
How you should take Creon 10000.
What to do if you take too much Creon 10000.
What to do if you forget a dose.
- 4. Possible side effects**
Abdominal symptoms (such as abdominal pain).
Side effects and what to do if you get them.
- 5. How to store Creon 10000**
How and where to keep your capsules.
- 6. Further Information**
The ingredients in Creon 10000.
More information about cystic fibrosis and pancreatitis.

This medicine has been prescribed for you personally. Don't offer it to other people, even if their symptoms seem to be the same as yours.

1. About Creon 10000

What is Creon 10000

- Creon 10000 is a high strength pancreatic enzyme supplement.
- Pancreatic enzyme supplements are used by people whose bodies do not make enough of their own enzymes to digest their food.
- Creon 10000 granules contain a mixture of the natural enzymes which are used to digest food.
- The enzymes are taken from pig pancreas glands.

How does Creon 10000 work?

The enzymes in Creon 10000 work by digesting food as it passes through the gut. So, you must take Creon 10000 at the same time as eating a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. Before you take Creon 10000

Do not take Creon 10000 if:

- Your doctor has told you that you are in the early stages of inflammation of the pancreas (acute pancreatitis)
- You are allergic to pork or any pig product

If any of the above applies to you do not take Creon 10000. Talk to your doctor or dietician again.

Talk to your doctor if:

- you are pregnant or trying to get pregnant
- you are breast feeding

1055740
1055740



Please tell your doctor, dietician or pharmacist if you think that you should not take Creon 10000 for any other reason.

If you drive or use machines

It is unlikely that Creon 10000 will affect your ability to drive or operate tools or machines.

3. How to take Creon 10000

How much Creon 10000 to take

- **Always follow your doctor or dietician's advice on how many capsules to take.**
- If your doctor advises you to increase the number of capsules you take, you should do so slowly. If you still have fatty stools or abdominal pain, talk to your doctor or dietician.

When to take Creon 10000

- **Always take Creon 10000 at the same time as eating a meal or a snack and drink plenty of water (see section 1).**

How to take Creon 10000

- Swallow the capsules whole or
- Open the capsules and mix the granules with soft food. Swallow the mixture straight away, without chewing.
- Drink plenty of liquid every day.

How long to take Creon 10000 for

You should take your medicine until you doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

Please turn over

- See MHRA "PIL of the Month" for more examples

Patient Information Leaflet

creon[®] 10000 capsules

Pancreatin

Important things you SHOULD know about Creon 10000

- Creon 10000 is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- Take the amount of capsules as prescribed by your doctor or dietician.
- Take Creon 10000 with a meal or a snack and drink plenty of water.
- Do not take Creon 10000 if you are allergic to pork or any pig product.
- If you experience severe abdominal pain while taking Creon 10000, contact your doctor immediately.
- Most people do not have problems taking Creon 10000 but side effects can occur. (see section 4)

Please read the rest of this leaflet carefully before you start taking these tablets. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

This leaflet was last approved in 2007

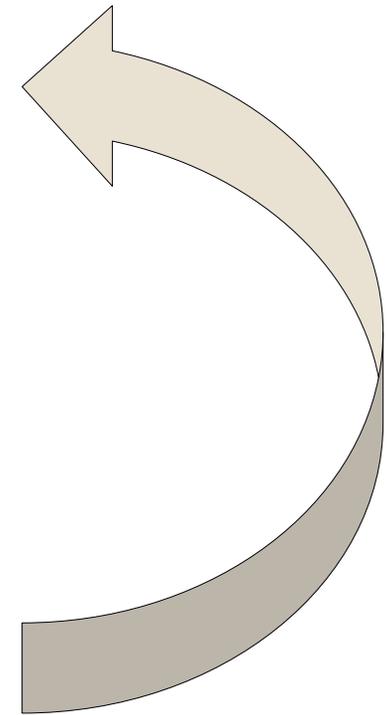


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User Testing is an iterative process

- Test material
- Identify problems
- Remedy problems, applying:
 - research evidence
 - good practice in writing & design
- Test again



Is User Testing working perfectly in the EU?



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User testing can produce excellent leaflets

- when rigorously applied
- in context of good information design & research

However, where focus only on passing test

- poor leaflets can pass
- means some people taking medicines will not get the good quality information they deserve

Faithful translation?



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Page last updated at 19:08 GMT, Friday, 31 October 2008

E-mail this to a friend

Printable version

E-mail error ends up on road sign



The English is clear enough to lorry drivers - but the Welsh reads "I am not in the office at the moment. Send any work to be translated."

When officials asked for the Welsh translation of a road sign, they thought the reply was what they needed.

Unfortunately, the e-mail response to Swansea council said in Welsh:



South West Wales

Find out more about what is going on across the region

SEE ALSO

- ▶ Bladder alert lost in translation
15 Aug 06 | South East Wales
- ▶ Bilingual Welsh sign stumps Scots
06 Sep 06 | Wales
- ▶ School's Welsh sign angers public
13 Sep 06 | Wales
- ▶ Pedestrian sign's forked tongue
16 Jan 06 | North West Wales
- ▶ FA Cup advert lost in translation
17 Nov 05 | South East Wales

RELATED INTERNET LINKS

- ▶ Swansea council
- ▶ Golwg

User Testing is flexible



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User testing can be applied to any information format:

- Large print leaflets
- Audio versions
- Web based medicines information

Can be applied to other forms of patient information:

- Clinical trial information
- Medical devices
- Direct to Consumer adverts?



What are the Learnings?

DK Theo Raynor PhD MRPharmS

Professor of Pharmacy Practice,
University of Leeds, UK and LUTO Research Ltd

d.k.raynor@leeds.ac.uk

Key Issues



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Delivery

- Package insert guarantees supply but unattractive format
- Computer generated leaflets depend on printer capability & motivation of pharmacist
- System must be linked to spoken information
 - *Spoken information remains priority, backed up by written information*

How to evaluate effectiveness?

- Requirement for testing in Europe has been the catalyst
 - *Easy to read and well laid out information*
 - *Patients should input into leaflet development*

What is best format for CMI?

- Template in EU means patients can expect common leaflet format but use of template stifles innovation
- May need different templates for different types of drugs
- What is the most effective order? – EU Template works well in most cases

Key Issues



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What about benefit information?

- *Greater balance between benefit and harm information*
- Need to strike a balance
- Can include positive information about the potential benefits in Section 1 of leaflet

ANTIHYPERTENSIVE DRUG

WITH BENEFIT INFORMATION

PRODUCT belongs to a group of medicines known as angiotensin II receptor antagonists and is used to treat high blood pressure. High blood pressure often causes no symptoms, but if it is not treated it can damage blood vessels in the long-term. In some cases this can lead to heart attacks, kidney failure, stroke or blindness. That is why it is important not to stop taking this medicine without talking to your doctor.

WITHOUT BENEFIT INFORMATION

PRODUCT belongs to a group of medicines known as angiotensin II receptor antagonists. This medicine lowers your blood pressure.

 Always read the leaflet MHRA 2005

Key Issues



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Full or concise information?

- 2008 study: ‘clinically irrelevant information’ & ‘information overload’
- Need for more uniform, ‘user friendly’, concise and clinically relevant CMI
 - *Inclusion of all side effect information*
 - *Concise and longer leaflets were valued depending on patient’s needs at time*
- Who decides what patient should be told and not be told? Information not present in some US CMI included:
 - Pregnancy and breastfeeding
 - Driving and using machines
 - Administration details
 - Action if overdose
 - All side effects, including allergic reactions
- Ease of navigation and the ‘look’ of the information are the keys
 - Achievable through good practice in information design

Headline Section



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- Most important pieces of information they need
- Presented prominently at beginning of PIL
- Summarising a few key messages for safe and effective use
- Such ‘Top 10 points’ may be useful, but not in isolation
- Care needed with design of ‘box’

Ciprofloxacin 250mg tablets

Important things that you need to know:

- Ciprofloxacin is a treatment for some bacterial infections.
- **Take your tablets regularly until the end of the course – read the label.**
- Most people do not have serious side effects, but side effects can occur – see page x for details. Some people may feel dizzy or sleepy, especially when they start ciprofloxacin. Drinking alcohol can make these side effects worse. If you feel dizzy or sleepy, it is dangerous to drive a car or use machinery.
- You must not take ciprofloxacin if you have had problems with your tendons. If you have painful tendons (eg in your ankle) while taking ciprofloxacin, stop taking the medicine and see your doctor.
- If you are pregnant or breast feeding, you should discuss taking ciprofloxacin with your doctor, as ciprofloxacin is not normally recommended.
- Tell your doctor if you have epilepsy or if you are taking pain-killers or anti-inflammatory medicines (for example, for arthritis).

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

This leaflet was last updated on xx/xx/xx

Summary



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- Any mandated process for CMI provision must be firmly linked to provision of spoken information from professional
- Templates can familiarisation but can stifle innovation
- Performance based testing is the only way to ensure people can find and understand the information they need
- People want differing amount of detail at different times
 - Concise information would depend on professionals deciding what patients wanted at any particular time
 - A headline section could help meet patients' needs, along with use of good practice in information design
- Including more 'benefit' information would help meet patients concerns



Thank You

DK Theo Raynor PhD MRPharmS

Professor of Pharmacy Practice,
University of Leeds, UK and LUTO Research Ltd

d.k.raynor@leeds.ac.uk

Key Publications



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Raynor, DK , *Testing, Testing: The Benefits of User-testing Package Leaflets* **Regulatory Affairs Focus** 2008

Raynor, DK , *Commentary: Readability testing of patient leaflets - where to now?* **Scrip** 2008

Carrigan, N; Raynor, DK; Knapp, P, *Adequacy of patient information on adverse effects - An assessment of patient information leaflets in the UK* **Drug Safety** 2008

Raynor, DK; Blenkinsopp, A; Knapp et al. *Systematic review of quantitative & qualitative research on role and effectiveness of written information available to patients about individual medicines.* **Health Technol Assess** 2007

Grime, J; Blenkinsopp, A; Raynor, DK; Pollock, K; Knapp, P, *The role and value of written information for patients about individual medicines: a systematic review* **Health Expect** 2007

Raynor, DK ; Silcock, J; Knapp, PR; Edmondson, H, *How do patients use medicine information leaflets in the UK?* **International Journal of Pharmacy Practice** 2007

Raynor, DK; Svarstad, B; Knapp, P; Aslani, P; Rogers, MB; Koo, M; Krass, I; Silcock, J, *Consumer medication information in the United States, Europe, and Australia: a comparative evaluation.* **J Am Pharm Assoc** 2007

Berry, DC; Knapp, PR; Raynor, DK. *Expressing medicine side effects: Assessing the effectiveness of absolute risk, relative risk, & number needed to harm, and provision of baseline risk information* **Patient Education & Counseling** 2006

Knapp, P; Raynor, DK et al. *Interpretation of medication pictograms by adults in the UK.* **Ann Pharmacother** 2005

Knapp, P; Raynor, DK; Berry, DC, *Comparison of two methods of presenting risk information to patients about the side effects of medicines.* **Qual Saf Health Care** 2004

Raynor, DK; Savage, I; Knapp, P; Henley, J, *We are the experts: people with asthma talk about their medicine information needs* **Patient Educ Couns** 2004

Berry, DC; Raynor, DK Theo; Knapp, PR; Bersellini, E, *Patients' understanding of risk associated with medication use - Impact of European Commission guidelines and other risk scales* **Drug Safety** 2003

Berry, DC; Knapp, PR; Raynor, DK Theo, *Provision of information about drug side-effects to patients* **Lancet** 2002