# Visual information about medicines for patients:

# Designing for Don Quixote?

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- 1 Some examples: Medicines information
- 2 Motivations for current practice
- 3 What's wrong?
- 4 An alternative approach?
- 5 Windmills?
- 6 Closing remarks

## Example 1:

A persona: a lady with asthma.

She has just returned from the pharmacy.



What does she see?

## Example 1: front box a



# Example 1: front box b



## Example 1: inhaler



### Example 1: leaflets

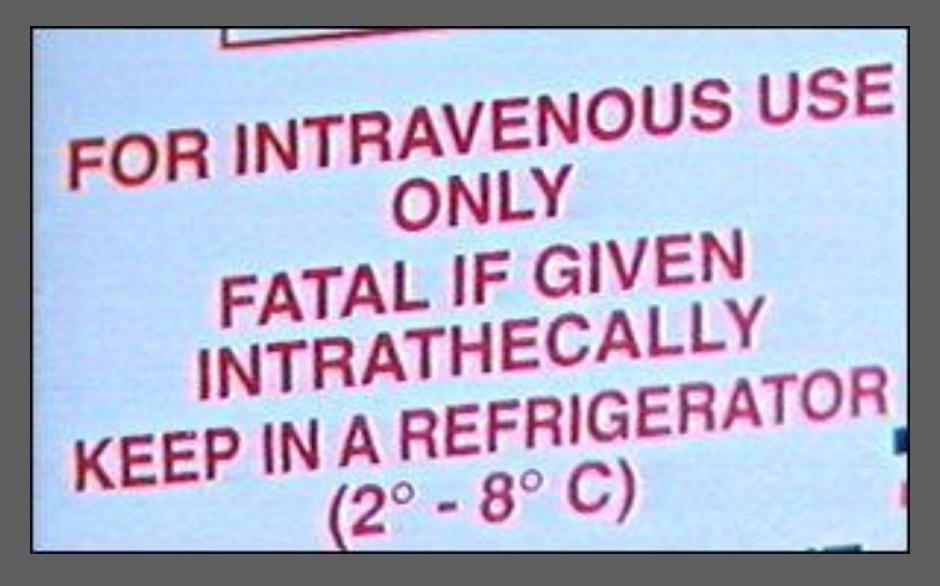
### Adults and Elderly:

For the relief of symptoms of acute asthma attack and intermittent asthma the starting dose is one puff (100mcg) that may be increased to two puffs (200mcg). To prevent symptoms before exercise or contact with whatever triggers your asthma attack the starting dose is two puffs (200mcg) that may be increased to four puffs (400mcg).

# Example 2: syringe



# Example 2: label

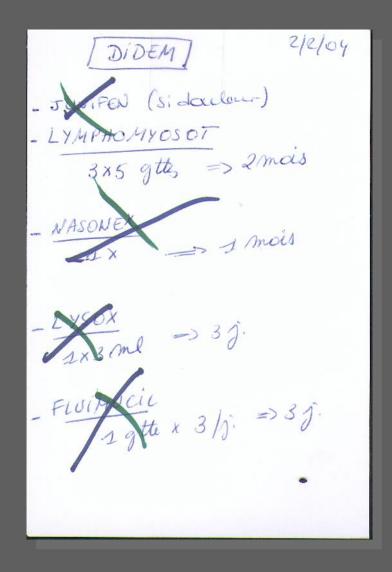


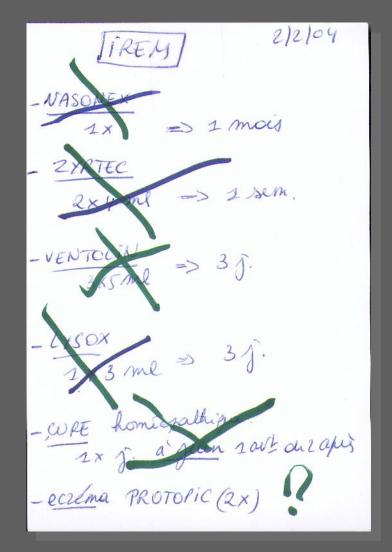
# Example 3 Pharmacy



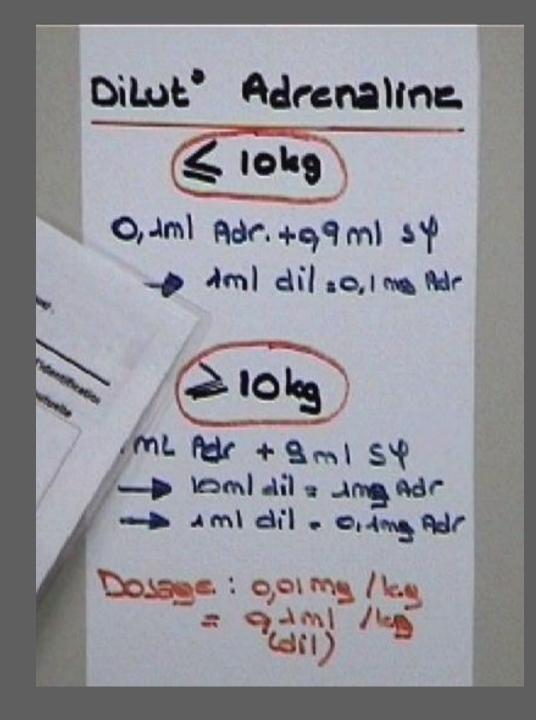


# Example 4: medicines for children

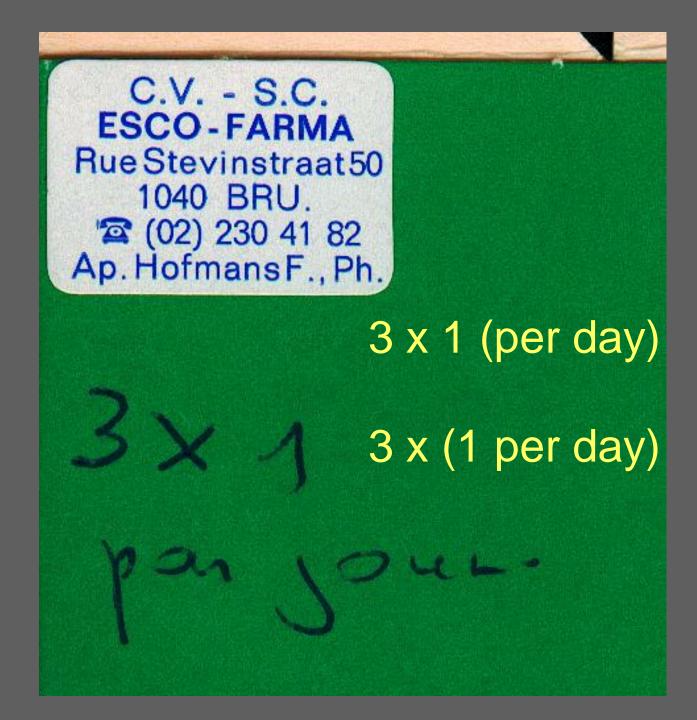




# Example 5: hospital



C.V. - S.C.
ESCO-FARMA
Rue Stevinstraat 50
1040 BRU.
(02) 230 41 82
Ap. Hofmans F., Ph.



# example 7: Pictograms



# example 7: Pictograms



### What does single-use mean?

Do not reuse. A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

## Not entirely satisfactory?

Patients, pharmacists, doctors, and nurses have problems using information because it is:

- inappropriate,
- -confusing,
- -poorly designed,
- -incomprehensible.

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## DG3: Enterprise and industry

### DG3 priority:

'To regulate the pharmaceutical sector in the dual interest of protecting public health while completing the single market for pharmaceuticals.'



## Current priority: single market

### Aims:

- •Free movement of medicines across Europe
- •All Europeans must have complete access to 'full and comprehensible' information about medicines.

### Regulations and guidelines

- Directives: 92/27/EC 2004/27/EC
- Readability guideline 1998 2009
- Range of advice, templates, guidance, glossaries

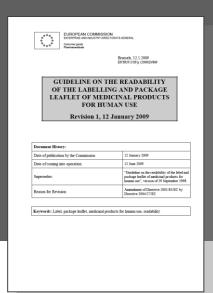
also about visual design ...

# EU-Directive 2004/27/EC 2004



'2. The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market.

# EU-Readability Guideline January 2009



#### GENERAL CONSIDERATIONS

The package leaflet is intended for the patient/user. If the package leaflet is well designed and clearly worded, this maximises the number of people who can use the information, including older children and adolescents, those with poor literacy skills and those with some degree of sight loss. Companies are encouraged to seek advice from specialists in information design when devising their house style for the package leaflet to ensure that the design facilitates navigation and access to information.

# **QRD-template** (Quality Review of Documents)

#### In this leaflet:

- What X is and what it is used for
- Before you <take> <use> X
- How to <take> <use> X
- Possible side effects
- 5. How to store X
- Further information

#### WHAT X IS AND WHAT IT IS USED FOR

### [Pharmacotherapeutic group.]

[The pharmacotherapeutic group or type of activity should be stated here using patient understandable language.]

### [Therapeutic indications.]

[The therapeutic indications should be stated here, using patient understandable language. If appropriate, specify that:]

<This medicine is for diagnostic use only.>

#### PACKAGE LEAFLET: INFORMATION FOR THE USER {(Invented) name strength pharmaceutical form} {Active substance(s)}

Lotte is a vinimite vinimin par best results from may need to read it again. A your plannassist if you need more information or advice. Our mast contact a doctor if your symptoms women or do not improve <aller {number of}

- 1. WHAT X IS AND WHAT IT IS USED FOR

2. BEFORE YOU <TAKE> <USE> X

<Taking><Lising> other medicines

"Please tell your "doctor" "op" - pharmacist" if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

<Taking> <Using> X with food and drink

Pregnancy and breast-feeding



#### Lisinopril 2.5mg, 5mg, 10mg and 20mg tablets

### In this leaflet:

- 1 What Lisinopril tablets are and what they are used for
- Before you take How to take
- Possible side effects
- How to store
- **Further information**

#### In this leaflet:

- What X is and what it is used for
- Before you <take> <use> X
- How to <take> <use> X
- Possible side effects How to store X
- Further information

### 1 What Lisinopril tablets are and what they are used for

Lisinopril belongs to a group of medicines called ACE inhibitors. These cause the blood vessels to relax, making it easier for the blood to pass through them.

#### WHAT X IS AND WHAT IT IS USED FOR

#### [Pharmacotherapeutic group.]

[The pharmacotherapeutic group or type of activity should be stated here using patient understandable language.]

#### [Therapeutic indications.]

[The therapeutic indications should be stated here, using patient understandable language. If appropriate, specify that:]

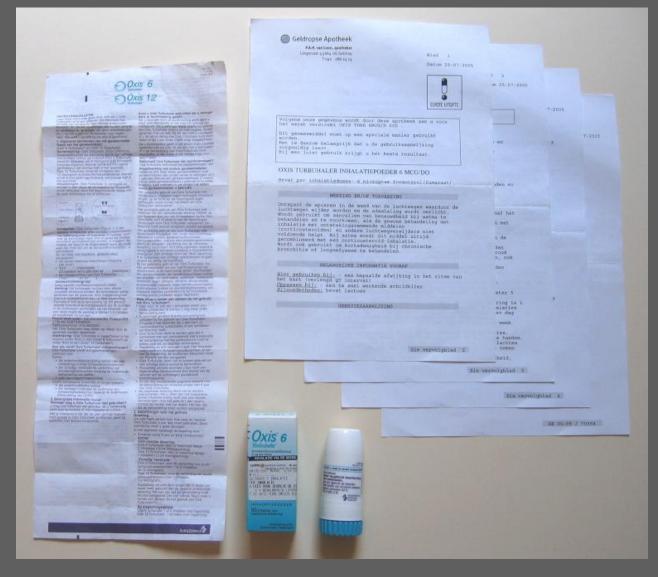
<This medicine is for diagnostic use only.>

## Results after 18 years

- Free movement of medicines across Europe
- All Europeans have more access to 'full and comprehensible' information about medicines

but from a visual point ...

# Information for patients?



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### Motivations for involvement:

- High error rates (1 fatality per million per day)
- Increasing costs (+ 10% per year)
- Poor effectiveness (around 50%)
- Increasing use: more medicines, more elderly

### More cracks in the system

- patients, pharmacists, nurses: problems using information
- industry: problems with following guidance
- regulatory authorities: problems with controlling

# Industry: Guideline and template?

### 6. STYLE

When writing, an active style should be used, instead of passive. For example:

- 'take 2 tablets' instead of '2 tablet should be taken','
- 'you must....' is better than 'it is necessary ...'

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

## Industry problem: Pictogram-use?



Vinercyd is given to you through a drip in a vein (an infusion).

### 2. DESIGN AND LAYOUT OF THE INFORMATION

The use of "justified" text (that is text aligned to both left hand and right hand margins) should in principle not be used.

Line spaces should be kept clear. The space between lines is an important factor influencing the clarity of the text. As a general rule the space between one line and the next should be at least 1.5 times the space between words on a line, where practical.

Contrast between the text and the background is important. Factors like paper weight, colour of the paper, size and weight of the type, colour of the type and the paper itself should be considered. Too little contrast between the text and the background adversely affects the accessibility of the information. Therefore, background images should in principle not be placed behind the text since they may interfere with the clarity of the information making it harder to read.

A column format for the text can help the reader navigate the information. The margin between the columns should be large enough to adequately separate the text. If space is limited a vertical line to separate the text may be used. Related information should be kept together so the text flows easily from one column to the next. Consideration should be given to using a landscape layout which can be helpful to patients. Where a multi-lingual leaflet is proposed there should be a clear demarcation between the different languages used; all the information provided in each language should be assembled.

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## Conflict between template and reality



'Keep out of the reach and sight of children.'

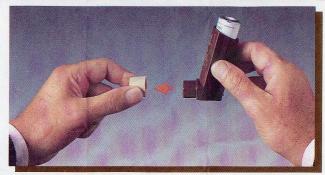
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## Inhaler leaflet 1985: United Kingdom

### IF YOU TAKE TOO MUCH

\* Tell your doctor as soon as possible if you accidentally take a larger dose than you were recommended.

#### **HOW TO USE YOUR INHALER**



Remove the mouthpiece cover and check the mouthpiece inside and outside to see that it is clean.



Tel: 071-226 2260 and The British Lung Foundation

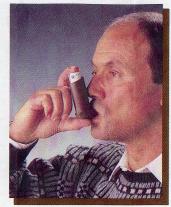
#### **TESTING YOUR INHALER**

If you have not used your inhaler for a week or more release one puff into the air to make sure that it works

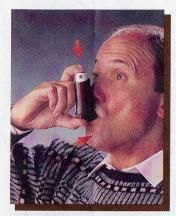
These instructions have been devised in agreement with the National Asthma Campaign 300 Upper Street, London N1 2XX 250 Kings Road, London SW3 5UE Tel: 071-376 5735



Hold the inhaler upright as shown above with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable and then....



Place the mouthpiece in your mouth between your teeth and close your lips firmly around it but do not bite it.



Just after starting to breathe in through your mouth press down on the top of the inhaler to release Becotide while still breathing in steadily and deeply.



2 Shake the inhaler well.

# Alternatives: Target Pharmacy 2003





### Alternatives

012

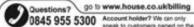


Mrs X Smith 27 Smith Street. Smithampton, Smithshire SM7 2MS

### **Գի**ֆիլիլեգիլեկոեց**Ա**ֆիլի

### You could save energy and money

Let us do the workout to help you shed pounds off your energy bills. Just complete our free Energy Savers Report on www.house.co.uk/reportenergy and we'll work out your personalised plan, to help you save energy and money with no effort at all.



Your salitymay be inscribered and? If you require summore to said or recorded for quality assurance. on your behalf, please make

Account holder? We can only speak to customers named on the Mon-Fri lam-dom. Sat Barn-6pm. account/bill in most circumstances. Please red page 2 before calling. Sure that you have given us your permission.

Custome reference number 8500 XXXX XXXX This is yournew customer reference number Please gott this when you rell us.

Bill date 21 Mar 2007

### Your gas bill

Price Protection 2010

Please pay £159.98 by 3 Apr 2007

### Billing summary

Bill period 15 Dec 2006 - 20 Mar 2007

£95.48
£95.48 credit
€00.00
£152.36
£7.62
£159.98

See below for ways to pay. We must receive your payment by 3 Apr 2007. Please slow enough time for payment to reach us.

Thank you for choosing British Gas

### Ways to pay your bill

Your payment slip is on the back of this bill. +

#### Internet or phone banking At a bank 24 hour service

You can set up payment with your own bank's phone or internet home banking service. Our sort code 40-65-30 our account number 71584685 You will also need your oustomer reference number.

You can pay by cash or cheque at any bank using this payment slip (see over). Please make your cheaue payable to British. Gas Trating Ltd and write your customer reference number on the this paymen slip to: British Gas. back. Some banks may charge for Payment Ana 55, Camberley this servor.

#### By post

Please male your cheque payable to fritish Gas Trading Ltd and with your name and customer reference number on the back. Sind your chaque with GU95 1AB Please do not send cash through the post.

#### By phone

Call us on 0845 955 5300 and have your debit card and oustomer reference number handy.

#### By PayPoint

You can also pay at any PayPoint. sutlet by taking the whole of this MR and your cash payment with you. PayPoint agents cannot accept cheques made payable to British Gas.

### EU-Directive 2004/27/EC

'2. The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State in which the medicinal product is placed on the market.

## 'enabling the users to act appropriately'

- Who are the users?
- Which actions need to be enabled?
- What do we consider 'appropriate'?

### 1. Who are the users?

- pharmacists, elderly, children, nurses?
- in which specific situation do they use medicines? (night shifts? several medicines at the same time, anxiety?)



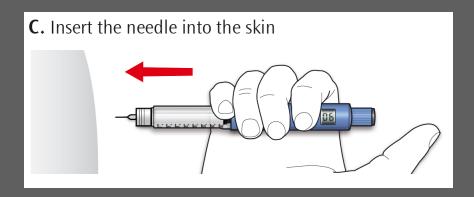


### 2. Which actions?

- considering whether to take or not
- storing correctly
- taking at the right time

This depends on the medicine, context, user,

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## 3. What is appropriate?

- Establish current performance beforehand
- Consider if improvement is required
- Modify the information (situation)
- Measure again.

## Example

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

- 1. How do patients throw away their unused medicines?
- 2. Is this acceptable?
- 3. Modify information and situation
- 4. Test to see if modification has an effect

# Context: hospital use.



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not necessary to involve all stakeholders

pharmacists? doctors? nurses?

- not necessary to involve all stakeholders
- not necessary to look at alternatives

web-based, patient-generated?

- not necessary to involve all stakeholders
- not necessary to look at alternatives
- not necessary to differentiate

context, language, medicine, patient, ...

- not necessary to involve all stakeholders
- not necessary to look at alternatives
- not necessary to differentiate
- not necessary to look at design processes

writing, designing, testing?

- not necessary to involve all stakeholders
- not necessary to look at alternatives
- not necessary to differentiate
- not necessary to look at design processes
- not necessary to look at practical use

hospital, home, emergency?

- not necessary to involve all stakeholders
- not necessary to look at alternatives
- not necessary to differentiate
- not necessary to look at design process
- not necessary to look at practical use
- not necessary to discuss criteria

- focus on regulation of pharmaceutical industry
- focus on package leaflet
- focus on single template
- reduce design process to simple rules
- ignore practical use
- use only criteria 'finding' and 'understanding'

## **Opportunities**

- involve all stakeholders
- look at alternatives
- differentiate (context, language, medicine, patient, ...)
- look at design process
- look at practical use
- discuss criteria

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### Conclusion 1:

If we want to optimise information, than we need to consider who we are optimising for.

At the moment, we optimise to register medicines and make information similar and accessible across Europe.

That does not really help people ...

### Conclusion 2:

If we want information 'to enable the users to act appropriately' than we must reconsider our approach.

'users', 'actions' and 'appropriateness' must form the basis for the design of information about medicines.

## Giants or windmills?



# Thank you.

### Dr. Karel van der Waarde

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