

QUALITY REVIEW OF DOCUMENTS – PACKAGE LEAFLET – MEDICINES FOR HUMAN USE

Content validity assessment of the package leaflet QRD Template wording

Introduction

As part of the public consultation of the Human QRD Product Information Template wording, we have taken the liberty of conducting a small content validity assessment of the proposed template wording for Package Leaflets. The purpose of this exercise was to provide insights from potential lay reader into the understandability of the proposed wording.

It is hoped that on the basis of the findings (presented verbatim in appendix 1) and our expert opinion, the European Medicines Agency can take these comments into account when deciding on the final wording of the QRD Template for package leaflets.

Study approach

The content validity assessment is essentially eliciting participants' understandability of a given text (in this case the proposed QRD wording) by means of **cognitive interviewing**. This method is commonly used in linguistic validation exercises, such as testing the validity of Patient Reported Outcomes or Quality of Life instruments. We are in no way suggesting a replacement to **formative readability testing methods**, such as those habitually used for readability tests of PILs in the EU, cognitive interviewing offers some distinct advantages for content validity. For example, while readability testing methods aim to assess how items of information can be found and then understood, the cognitive interviewing method focuses solely on the understandability of each item of information and how each item could be improved. Also, cognitive interviewing tends to use far fewer participants than a readability test, as interviews are considerably longer. Accordingly, because of the small participant numbers, we can make no claims regarding the generalisability of the data elicited.

Rather, cognitive interviewing can offer insights into the validity of the proposed wording and this can be used to support expert opinions. In addition, it is within the spirit of consumer evaluation to include lay users in the information design process, as is outlined in the EMA's guidance for target patient group consultations.

Participants

This study recruited 3 participants in Sunderland, United Kingdom. Each participant was recruited by means of convenience sampling. Participant characteristics were as follows:

Participant number	Sex	Age	Educational attainment	Occupation	Use of literature in work?
1	F	30	'A' Levels	Administrator in a small company	Yes
2	M	58	Degree level	Museum supervisor	Yes
3	F	59	GCSE or equivalent	Nursery nurse	Yes

All three participants had previously taken part in a readability test for various English-language package leaflets between 2005 and 2006. Interestingly, all three stated that participating in the test had later caused a behaviour change, namely they always read package leaflets when prescribed new medicines, whereas previously they were barely aware of them. Therefore, each participant was familiar with the 'look and feel', i.e. the structure, content and their expectations, of package leaflets.

Interviews

Participants were asked to read an Information Sheet supporting the spoken information provided by the interviewer, Mark Gibson. They signed a consent form and were paid GBP 20 for their participation at the end of each interview. Prior to the interviewing beginning, each participant was given a 'clean' version of the proposed QRD Template wording for package leaflets, without the track changes. To support the template, a random sample of package leaflets was given to each participant to look at. These were Paracetamol Plus Caplets, Simvastatin 10-40mg Tablets, Atenolol Tablets BP, Beclometasone

10, 100 & 250 microgram inhaler, Tesco Diarrhoea Relief Capsules and Cutivate Ointment. The interviewer showed the participant each leaflet and pointed out where the current QRD Template wording is found in contemporary leaflets. At various points throughout the interview, the proposed QRD wording was compared with the text in these leaflets. This enabled fluid discussion around the proposed wording.

Each interview was conducted on a one-to-one basis and was digitally recorded. All raw data is available to the European Medicines Agency upon request.

Each sentence of the proposed wording was read out to the participant, who also had a copy of the wording to refer to throughout the interview. Participants were then asked:

- What the sentence meant for them
- Whether there were any words in that sentence that would be difficult to understand (for any potential reader)
- Whether they would reword this sentence if they were writing it themselves
- Any other comments.

Interviews lasted 1 hr 8 minutes (participant 1), 1 hr 19 minutes (participant 2) and 1 hr 13 minutes (participant 3), respectively.

A full verbatim framework of the interviews is found in Appendix 1.

1.5 Key findings

Overall, the majority of the proposed wording for the package leaflet QRD template was understandable to the participants. This understandability is proven through the verbatim explanations in their own words from each participant. However, for some sentences and phrases, some issues of understandability did arise. These are explored below.

- **'Keep this Leaflet'**

Participants suggested that more information should be added here, such as 'keep this leaflet safe'.

- **'Note that this leaflet is revised on a regular basis with the latest information on your medicine.'**

'Revised' and 'on a regular basis' might be difficult to understand. It was suggested to reword these as 'updated' and 'regularly', respectively.

- **'Please refer to the date at the end of this leaflet.'**

Participants appeared to confuse this date with the expiry date of the medicine, or that both dates somehow relate to each other. In addition, they wanted to know why it is important to refer to this date and impact it has on people using a given medicine. In addition, it was suggested that 'look at' was a more understandable term than 'refer to'.

- **'This medicine has been prescribed for you.'**

It was suggested that 'only' be added after 'for you'.

- **'You must contact a doctor if your signs of illness worsen or do not improve.'**

It was suggested that 'worsen' might be difficult to understand and '...get worse' would be more understandable.

- **'This medicine is for diagnostic use only.'**

None of the participants understood the word 'diagnostic'. It was suggested that this is reword to a more understandable alternative.

- **'2. What you need to know about X'**

Compared with 'Before you take X', the proposed word of this section heading is possibly too broad. For example, all three participants interpreted this heading as the section where the ingredients of the medicine could be found.

- **'Do not <take> <use> X if'**

It was proposed that a colon is placed at the end of this statement, as it would automatically lead readers to more information about this point.

- **'you are allergic (hypersensitive) to ... or any of the other ingredients of this medicine.'**

The word 'hypersensitive' was not understood by any of the participants and this appeared to distract their attention from what would be otherwise an understandable sentence.

- **'Children'**

'Children' was understood as a person aged between 2 and 12 or under 16. Therefore, the interpretation of 'children' is not clear.

- **'it is not effective'**

'Effective' was identified as being difficult to understand.

- **'The potential benefits do not outweigh the risks'**

All three participants had difficulty interpreting the word 'outweigh', with one participant stating that it was 'poor English'.

- **'Therefore, the European Medicines Agency has waived the obligation to study the effect of this medicine in children.'**

This sentence was largely misunderstood by the participants, who thought that the EMA is not 'bothering' to examine how the medicine in question affects children. In addition, 'waived the obligation' was identified as difficult to understand.

- **'<Taking> <Using> X with food and drink <(amongst others alcohol)>'**

All three participants focused on 'alcohol', rather than 'food and drink'

- **'If you are pregnant or breast-feeding, ask your <doctor> <or> <pharmacist> for advice before taking this medicine if you have any doubts after reading this information.'**

Two participants identified the two 'ifs' in one clause as confusing and difficult to follow.

- **'Effects of other ingredients (excipients)'**

'Excipients' was not understood by any of the participants.

- **'The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.'**

Although participants demonstrated an understanding of the word 'facilitate', it was identified as a word that could be difficult to understand.

- **'The active substance(s) is (are)...**

'Active substance' was not understood by any of the participants.

Part Two: The proposed package leaflet QRD Template wording

- **Section titles**

The fact of using the International Proprietary Name may pose a problem as far as the length of smaller-sized formats is concerned. It could also lead to patients having more difficulty in knowing the difference between a proprietary medicine and a generic medicine.

For products with a commercial name, we recommend that this is used consistently throughout the leaflet and not only in the section titles.

- **Date of revision of the leaflet**

The addition of the date of revision of the leaflet could be reconsidered. This creates more text in a part of the leaflet that this generally not read, does not offer any specific information on the treatment or the condition.

For medicines that have not been updated for several years, this could be a factor for anxiety amongst some patients, who could become worried about knowing if the leaflet has not been updated and whether this is linked with the product's expiry date (see Part One above).

- **Summary text**

The proposal to increase the summary text is a positive step. The rewording of the headings in sections 2 and 6 are also considered positively, bearing in mind the points raised by the content assessment in Part One of this report.

- **Section 1 : Benefit information**

We should not lose sight of the fact that the majority of products do not have a systematic way in their SPCs of informing users about the benefits of their products. When this information is present, pharmaceutical companies may become aware that they must not use such text in their SPCs for legal reasons.

Doing this would lead to significantly more information, creating significant problems for leaflet production. Furthermore, we must not forget that for many patients, information in leaflets needs to be succinct so that they can directly and easily reflect upon the conditions of use of the product (see Part Two above). A leaflet with too much information appended to it concerning, for example, the condition to be treated, could be seen as too technical and may deter the user from reading on.

We propose to add benefit information and condition-specific information depending on the type of medicine. For example:

- For OTC products, it should be obligatory to transmit as much information as possible
- For non-OTC products, only if pertinent to the product.

- **Specific comments on wording for the preliminary section and section 1 of the leaflet**

Proposed wording	Our view
Keep this Leaflet	We suggest 'Keep this leaflet in a safe place', based on participant responses.
Note that this leaflet is revised on a regular basis with the latest information on your medicine.	We support the participants' suggestions of 'updated' and 'regularly' for 'revised' and 'on a regular basis', respectively.
Please refer to the date at the end of this leaflet.	Perhaps a short explanation could be given about why it is necessary to refer to the date at the end of the leaflet, as this is not clear. Also, we support the suggestion to reword 'refer to' as 'look at'.
This medicine has been prescribed for you.	We support the addition of 'only' after 'for you'.
You must contact a doctor if your signs of illness worsen or do not improve.	We support the suggestion of rewording 'worsen' as 'get worse'.
This medicine is for diagnostic use only.	We suggest: 'This medicine is not a treatment. It is only used to find out what condition you have' or '...to diagnose your condition'.

- **Section 2 : Contraindications**

No comment.

- **Section 2 : Conditions of use**

Warnings are frequently redundant with relative contraindications.

We have noticed more than one case of incoherence between the comments put forward for contraindications and for warnings. For example,

Contraindications : All contraindications mentioned in sec. 4.3 of the SmPC should be included.

Warnings : Unless of major safety importance (absolute contraindication) to be highlighted in "do not take if...).

What differentiation is made when the relative contraindications and the warnings are redundant? This point needs to be clarified.

However, we very much welcome the modification proposed to the heading "Talk to your doctor before taking X if..." which generally lists the concurrent conditions to look out for.

- **Section 2 : Children**

We welcome this section for products intended for use in children. However, we are not in favour of adding a lot of information about studies that have been carried out, particularly if a given product is not to be used in children. A medicine that is not to be used in children would only be prescribed to and read by adults.

Placing specific wording to indicate use in children in sections 1 and 3 would be more effective than detailing a body of studies, which would certainly not be read in detail.

This also leads to comments regarding the sub-section '**Driving and using machines**': the fact of inserting specific messages about how the use of some medicines can impact on cognitive functions when the medicine has been developed solely for paediatric populations seems exaggerated.

For serious illnesses, one would expect to have appropriate caregiving assistance.

For less serious illnesses, one would expect a parent or caregiver to make the child rest if he or she is ill.

Are there any figures relating to medicinal harm in children caused by caregiver error?

- **Section 2 : Other treatments**

It seems difficult to include a description in simple terms of the consequences of specific interactions. In fact, the majority of SPCs do not contain this information. In addition, for OTC medicines, this proposal is regarded positively. For non-OTC products, it would make the text longer and less readable, as one paragraph can sometimes contain a long list of products.

We are in favour of the majority of the changes in wording proposed in sections 3 and 4, other than those discussed in the table below.

- **Specific comments on wording for sections 2 to 6 of the leaflet**

Proposed wording	Our view
What you need to know about X	We agree that this proposal could potentially lead to too broad an interpretation, but it is a better proposal than the restrictive 'Before you take' heading.
Do not <take> <use> X if	We support the use of a colon at the end of this sentence. It would naturally draw readers to the usual list of bullet points within this sub-section.
you are allergic (hypersensitive) to ... or any of the other ingredients of this medicine.	We understand the importance of including 'hypersensitive' in this context. We propose to reword it, such as the following: 'you are allergic or your doctor has told you that you are hypersensitive to...'. Of course, this would make this sentence longer, but it could aid understandability.
Children	We have no specific proposals here, but the age range of what constitutes 'children' needs to be made clearer throughout the leaflet, as we appreciate the majority of leaflets already do for paediatric medicines.
It is not effective	We agree that 'effective' may not be very well understood by some lay people. We propose 'It does not work' or 'it will not work'.
The potential benefits do not overweight the risks	We agree that 'overweight' is nonsensical in this context. It is probable that this word was proposed by a non-English native speaker. We propose 'outweigh'.
Therefore, the European Medicines Agency has waived the obligation to study the effect of this medicine in children.	We recognise that this is a misinterpretation by the participants, without seeing the sentence in its real context. However, 'waived the obligation' onwards could be rewritten as 'has decided it is not necessary to study how this medicine affects children.'
'<Taking> <Using> X with food and drink <(amongst others alcohol)>'	It is possible that the brackets draw attention to alcohol and away from food and drink. In addition, 'amongst others alcohol' does not sound native to a UK English reader and could be off-putting. We propose: 'Taking / using X with food, drink or alcohol.'
If you are pregnant or breast-feeding, ask your <doctor> <or> <pharmacist> for advice before taking this medicine if you have any doubts after reading this information.	Stylistically, it is not best practice to have two 'if' clauses in one sentence, let alone without any appropriate punctuation (i.e. commas). We propose to reword this as 'If you pregnant or breast-feeding and you have any doubts after reading this information, ask your <doctor> <or> <pharmacist> for

	advice.'
Effects of other ingredients (excipients)	Is the word 'excipients' necessary here? Does it add anything to the meaning of the sentence? Would lay readers understand it? We propose to remove it.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.	We propose 'The score line is only to help you to break the tablet so you can swallow it easily and not to divide it into equal doses.'
The active substance(s) is (are)...	We understand the importance of the phrase 'active substance'. We propose to qualify it with a lay term: 'The active substance(s) (main ingredient(s)) is...'

Overall, we consider that the proposed changes fall into two categories :

- Some changes have clearly been informed by the results of readability tests (section 4, section 3) and aim to give more clarity to leaflet information in a logical and evidence-based way to enable a more effective use of the product.
- Other proposed changes, particularly in section 2, appear to be contrary to what participants generally comment on in current leaflets.

The fact that a leaflet contains a lot of information can cut both ways : providing information in an academic and encyclopaedic style about a given condition can act as a barrier to patients to use his or her treatment appropriately which can have an impact on compliance to the treatment in question.

For patients in France and the UK, the leaflet is often regarded as a tool which must be practical, simple and in which information already provided by the doctor can be found easily.

Therefore, we propose separate templates for OTC and non-OTC products, for which the quantity of information could be adapted.

Appendix 1

Instrument for the content validity assessment of the package leaflet QRD template wording

Framework for participants' verbatim responses

Sample text	What does this mean to you?	Are there any words that you find difficult to understand?	Would you change any of the words? (What would you put if you were writing this?)	Any other comments
Read all of this leaflet carefully before you start <taking> <using> this medicine.	<p>P1: You need to read it thoroughly before you take the medicine. You need to understand how to take it and when.</p> <hr/> <p>P2: You've got to read the leaflet before you take the medicine.</p> <hr/> <p>P3: It means to me if you've got a prescription from the doctor, I would insist that there is a leaflet so I can see what the side effects can be.</p>	<p>P1: No, it's pretty simple.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: It would be fine they way it was, it's simple to be honest.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: It would prefer 'taking' than 'using'</p>	<p>What is the difference between 'taking' a medicine and 'using' the medicine?</p> <hr/> <p>P1: It's more or less the same to me. I would say using's better though.</p> <hr/> <p>P2: 'Taking' is the word we traditionally, for me 'using' is like an Americanism, it sounds strange to me.</p> <hr/> <p>P3: 'Using' to me sounds like bad drugs, illegal drugs, like injecting yourself.</p>
Keep this leaflet.	<p>P1: You must keep the leaflet for if you need to look at it again, for any more information.</p> <hr/> <p>P2: Don't throw it away.</p> <hr/> <p>P3: Keep it so that you could</p>	<p>P1: It's fine</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: I would suggest 'you must keep this leaflet' because you need to state how important it is to keep it, rather than just 'keep it' meaning 'keep it if you want to.' You need to say 'you must keep it.'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	refer to it.		<p>P2: 'Keep this leaflet' is fine but you could also say 'don't throw it away'.</p> <hr/> <p>P3: I would say 'keep this leaflet safe', you've got to let them know how important it is to keep the leaflet.</p>	
You may need to read it again.	<p>P1: You need to go back to it if you've got any side effects or anything like that or you need to see how you are supposed to take the medicine or why you can't.</p> <hr/> <p>P2: You don't expect to digest it all in the first reading, you might have to read it two or three times. I suppose that applies to all instructions, doesn't it, whatever you do. You need to read this leaflet to make sure you have understood what has been said in the leaflet to make sure you fully understand it.</p> <hr/> <p>P3: Just say that I did start some medication and I didn't feel well, I would read it again, read side effects and I would make sure that this medication that I'm taking doesn't counteract with any other medication that I'm taking.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: That's alright.</p> <hr/> <p>P2: 'You may need to read it again to fully understand the instructions'.</p> <hr/> <p>P3: If you're taking long-term medicines you could put 'it's possible that you might need to read this again, so keep it very safe.'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

<p>Note that this leaflet is revised on a regular basis with the latest information on your medicine.</p>	<p>P1: that it's looked at for any changes or anything like that in the medication or side effects or something like that.</p> <hr/> <p>P2: If new regulation or legislation comes out, it means that whoever is providing this leaflet, it's constantly updated, if there's any feedback to say that someone doesn't understand it properly, the wording might be changed.</p> <hr/> <p>P3: It means the leaflet is looked at at regular times, they may change it.</p>	<p>P1: No, it's fine, simple.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Some people might find 'revised' difficult.</p>	<p>P1: Maybe 'revised', I don't know what to change that to, but something more simple.</p> <hr/> <p>P2: Maybe 'Please note' and 'regularly' instead of a 'regular basis'.</p> <hr/> <p>P3: You could say 'changed at regular times with more up-to-date information'</p>	<p>P1: I suppose 'on a regular basis' could be simpler, but I suppose that's as simple as you're going to get it.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Please refer to the date at the end of this leaflet.</p>	<p>P1: just check out the date that the leaflet was printed or published or whatever, that it's up to date.</p> <hr/> <p>P2: Obviously it would be the date that it was compiled or sort of like published.</p> <hr/> <p>P3: Probably like the sell-by date, like when you shouldn't take them anymore.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: It could be simplified, like 'please look' or 'please check the date'.</p> <hr/> <p>P2: I need to know why this is necessary.</p> <hr/> <p>P3: You could simplify it and say 'please look at the date at the end of this leaflet'.</p>	<p>P1: No.</p> <hr/> <p>P2: Why is referring to the date necessary? Maybe have an explanation why this might be necessary.</p> <hr/> <p>P3: But why do you have to refer to it? To make sure that the tablets aren't out-of-date? Is it like a loaf of bread where it goes out of date?</p>
<p>If you have any further questions, ask your <doctor> <or> <pharmacist> <or nurse>.</p>	<p>P1: If you've got any further questions about the medication, seek medical advice.</p> <hr/> <p>P2: If you don't understand</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: 'medical advice' could be better than 'doctor, pharmacist or nurse' or I suppose 'ask your doctor'.</p> <hr/> <p>P2: No.</p>	<p>P1: Nurse is pointless, really, isn't it? I've never heard that term before. You wouldn't really go to a nurse. In reality, you wouldn't see a nurse about it.</p>

	<p>anything or you're not sure, then just ask a pharmacist.</p> <hr/> <p>P3: This happened to me, with some medicines and when I read the leaflet what was in the medication, I phoned up the doctor's straight away about that.</p>		P3: No.	<p>P2: No.</p> <hr/> <p>P3: No. Maybe there could be some kind of number that you could ring if you were really worried.</p>
This medicine has been prescribed for you.	<p>P1: This medicine has been advised for you from your doctor.</p> <hr/> <p>P2: This medicine has been prescribed for me and it should not be used by anyone else.</p> <hr/> <p>P3: That means that it's for you and nobody else.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: I would put '...for you only'. This emphasises that it is just for you.</p> <hr/> <p>P3: I would say 'this medicine has only been prescribed for you', because you do hear about people who give it to their friends and that, don't they?</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
Do not pass it on to others.	<p>P1: because it's been prescribed to you, don't give it to anyone else who it hasn't been prescribed for.</p> <hr/> <p>P2: Well you can't give the drugs for anybody else to take.</p> <hr/> <p>P3: It means that if you had a friend who has a cold and you say 'Oh, I've got some antibiotics in the house, you can have them if you want', they could have an allergic</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I would say 'please' or 'you must not pass it onto others' and you could say 'it could be very dangerous'.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	reaction or something and become very ill.			
It may harm them, even if their signs of illness are the same as yours.	<p>P1: If you do pass it onto someone else without it been prescribed by a doctor, it can do them harm.</p> <hr/> <p>P2: We're not qualified to diagnose anyone else, we might have the same illness but you cannot pass on the tablets because this person might have an allergy or anything to it, you just don't do that.</p> <hr/> <p>P3: It could make them ill, it could do something to them.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I would try and be more severe, instead of 'harm them' put 'they may become very ill'. I know people sell their medicines, like Valium. You could be brutal, like, 'taking someone else's medicine could kill you.' Because I know people who do do this, take their mam's tablets, especially painkillers or the tablets that they take for depression.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your <doctor> <or> <pharmacist> <or nurse>.>	<p>P1: It's just basically saying if you're feeling something other than the side effects that's listed, seek medical advice.</p> <hr/> <p>P2: If you become ill or you've got some side effects which you are concerned, just go to your doctor.</p> <hr/> <p>P3: Well I was given some tablets a few years ago and they made me, so I was ringing up the doctor's quite a bit.</p>	<p>P1: No, I think it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No, apart from nurses.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: 'If you get any side effects which worry you, you must talk to your doctor or pharmacist or nurse.' Or you could put something like 'it could lead to a more serious condition', especially if you're dealing with hypertension or heart medication.</p>	<p>P1: I would miss out nurse. It's a bit daft.</p> <hr/> <p>P2: I would go back to the doctor because he's prescribed the drugs, he's more qualified than the other two.</p> <hr/> <p>P3: No.</p>
Read all of this leaflet carefully because it contains important	P1: It's telling you to read it because it's important, because it's regarding the medication	P1: No.	P1: No.	P1: Maybe 'has' instead it 'contains', but I suppose contains is the best word to

<p>information for you</p>	<p>being prescribed.</p> <hr/> <p>P2: You've got to read it all in detail because it's important to you.</p> <hr/> <p>P3: Read it. Read it right through and don't miss any out.</p>	<p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P2: No.</p> <hr/> <p>P3: 'It is advisable to read all of this leaflet...'</p>	<p>use, I'd say.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Always <take> <use> X exactly as described in this leaflet or as your pharmacist <or nurse> <has> <have> told you. You should check with your <doctor> <or> <pharmacist><or> <nurse> if you are not sure</p>	<p>P1: It's just basically saying just take as it's listed or as you've been advised by a doctor or a pharmacist and if you're not sure then seek further assistance.</p> <hr/> <p>P2: I would say 'take' exactly as described in this leaflet or as your pharmacist, yes, because they usually give you instructions, don't they?</p> <hr/> <p>P3: Usually if you've been consulted by a doctor or pharmacist or whatever, they will say take this medication three times a day or once a day or something like that, but if you're not sure, or you might have forgotten when you get home, the leaflet is there to remind you to check with the doctor.</p>	<p>P1: Doctor, pharmacist or nurse together is too much.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: I don't understand this really because you take this medicine as described in the leaflet, but then the pharmacist might give you different instructions. It's like 'this is what it says in the leaflet, but the pharmacist might tell you something different', why is that?</p> <hr/> <p>P3: No, but maybe 'your health giver' or something like that instead of reading all of that.</p>
<p>Ask your pharmacist if you need more information or advice.</p>	<p>P1: Ask the pharmacist if you need more assistance regarding the tablets or the medicine.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p>	<p>P1: This is probably over-the-counter medicine because you're asking the pharmacist</p>

	<p>P2: It's to satisfy yourself that there's a pharmacist there to ask if you are not sure.</p> <hr/> <p>P3: You would ring them up if you're a bit concerned about it.</p>	<p>P3: No.</p>	<p>P3: Maybe 'if you are worried or concerned about your medication.'</p>	<p>only.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>You must contact a doctor if your signs of illness worsen or do not improve <after {number of} days.></p>	<p>P1: If you're not feeling any better and you feel worse, seek medical attention or advice.</p> <hr/> <p>P2: Well, if you've got this prescription and the doctor will tell you when you should be feeling better. If that hasn't happened, then you will go back and see him. If the doctor knows that the medicine won't kick in til after 15 days or 14 days, it will tell you in the leaflet, won't it?</p> <hr/> <p>P3: If you're not feeling any better or if you're feeling worse.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: If you are not feeling any better or you feel worse, seek medical advice.</p> <hr/> <p>P2: 'Get any worse' might be better than 'worsen'</p> <hr/> <p>P3: It is advisable to contact..., because 'you must...' might be demanding.</p>	<p>P1: 'feel worse' is better than 'worsen', for people to understand.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your <doctor> <or> <pharmacist> <or nurse>.</p>	<p>P1: Seek medical attention if, it's just like the other one, if you've got any side effects that's not listed.</p> <hr/> <p>P2: If you get any side effects which worry you, talk to your doctor.</p> <hr/> <p>P3: If you start your medication and you start to feel poorly.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Will everyone know what 'effects' meant?</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No, just the nurse, I think that shouldn't be there.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

<p>Where to find information in this leaflet:</p>	<p>P1: I don't know [what it means] [Participant shown 'In this leaflet' in a real PIL]. It's just showing you whereabouts in this leaflet to look for the information.</p> <hr/> <p>P2: Where to find information in this leaflet, if I look down the list here, it will take me to the thing that I am concerned about.</p> <hr/> <p>P3: When you're first looking at the leaflet, you know where to find things, like if you wanted to look at the side effects.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: I think 'In this leaflet' is better. I just think this is a bit long.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>1. What X is and what it is used for</p>	<p>P1: it's just explaining what the medication you're taking is and why you're taking it.</p> <hr/> <p>P2: What the medicine is and what it's for.</p> <hr/> <p>P3: What your medication is compiled from and what you need it for.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>This medicine is for diagnostic use only</p>	<p>P1: I don't know [what it means]</p> <hr/> <p>P2: I don't know what it means, am I supposed to understand that?</p> <hr/> <p>P3: I don't really know. Something that you've been</p>	<p>P1: Diagnostic. I don't know what that word means, to be honest.</p> <hr/> <p>P2: the word 'diagnostic'</p> <hr/> <p>P3: 'diagnostic', what your complaint is.</p>	<p>P1: Don't know what it means.</p> <hr/> <p>P2: Diagnostic seems a bit of an esoteric word.</p> <hr/> <p>P3: Diagnostic is confusing, there are people who aren't very literate, for a lot of people if they don't understand the</p>	<p>P1: rewrite sentence.</p> <hr/> <p>P2: I don't understand 'diagnostic' works.</p> <hr/> <p>P3: No.</p>

	diagnosed with.		words, they just don't go any further.	
How X works	<p>P1: How it's going to make you feel better, how it's going to help you.</p> <hr/> <p>P2: When you take it, what it does, how quickly it will work.</p> <hr/> <p>P3: What it does to your body.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
2. What you need to know about X	<p>P1: Exactly the details of the medicine, the breakdown of it, what it's going to do, the side effects. [Questioned: What do you mean by the 'breakdown of it'? – Response: what's in it, what is in the medicine]</p> <hr/> <p>P2: What you need to know about your medicine, what it contains, how it's made up, where they got it from, what other chemicals are inside it, how long it's been on the go.</p> <hr/> <p>P3: The ingredients, in case they ingredients go against something else your taking, taking more than one medicine.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Could it not be stronger? Like something like 'you need to know this important information about...'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No. 'Before you take' and 'what you need to know about X' are two completely different things to me. It should be 'What you need to know before you take this medicine.'</p>
Do not <take> <use> X if	<p>P1: If there's a problem then don't use it.</p> <hr/> <p>P2: It's just basically telling you don't not take Aspirin if you're taking alcohol or other things,</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No, if and a colon will tell you what's coming.</p> <hr/>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	<p>anything else, if you're going to drive or something like that.</p> <hr/> <p>P3: It would make you want to read on, if what? I would probably list all the things that you shouldn't take this medicine with.</p>		P3: No.	
<p>you are allergic (hypersensitive) to ... or any of the other ingredients of this medicine.</p>	<p>P1: It means if you've got something, a reaction or something to one of the ingredients. If you're allergic to something in the medicine.</p> <hr/> <p>P2: If you are allergic to something, or hypersensitive, I don't know about that, that's a bit of a technical word, obviously I think it means it's going to really affect you.</p> <hr/> <p>P3: It's a warning, to check if you are taking more than one medication.</p>	<p>P1: No.</p> <hr/> <p>P2: Hypersensitive is just a long word put in there and words like that put people off reading instructions.</p> <hr/> <p>P3: 'Hypersensitive', you could be reading it quickly and I thought of 'hypertension'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Could it be 'if you are allergic or sensitive to..'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Children</p>	<p>P1: Children, probably 2 to 12 years or under 16.</p> <hr/> <p>P2: It just means that, maybe you could say 'children and this medicine' instead of just 'children'. It means to me how this medicine would affect children.</p> <hr/> <p>P3: Children, under 12.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: 'Children and this medicine'</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: When you're speaking about children you're thinking about anybody under 16, still at school. But I suppose somebody's who's 14 or 15 will not be pleased about being called a child. Maybe you could say 'Children and young people</p>

				under 16 years'. P3: No.
This medicine should not be used in children between the ages of x and y <years><months> because <of the risk of [...]	<p>P1: It means that between those ages the children can't use the medicine because something would happen, it's not designed for them.</p> <hr/> <p>P2: This medicine should not be used in children between the ages of 'x' and 'y'.</p> <hr/> <p>P3: It's telling you the ages that they are to be given this medicine, because of the risk of, like, some children shouldn't have Aspirin and things like that, dangers.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
it is not effective	<p>P1: It will not work.</p> <hr/> <p>P2: It means that if you take this it wouldn't affect you.</p> <hr/> <p>P3: It doesn't work.</p>	<p>P1: I understand 'effective' but it could be simplified.</p> <hr/> <p>P2: What are they getting at? What is effective? It's a bit vague. Does it not work? It doesn't affect them and so it doesn't matter if they do take it by accident, it doesn't affect them? You could just leave your tablets lying around because it doesn't affect them?</p> <hr/> <p>P3: No.</p>	<p>P1: 'Effective' could be 'it won't work', 'it won't help'</p> <hr/> <p>P2: It needs more explanation.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
the potential benefits do not	P1: I don't know.	P1: The whole sentence, I don't	P1: The whole thing	P1: It's quite confusing.

<p>overweight the risks</p>	<p>P2: That's poor, bad English. The potential benefits to somebody taking this drug, there's too much risk involved, they shouldn't be taking it.</p> <hr/> <p>P3: It's quite hard to understand.</p>	<p>understand it to be honest.</p> <hr/> <p>P2: 'overweight', it's awkward, that.</p> <hr/> <p>P3: 'potential', does that mean what it can do?</p>	<p>P2: It needs to be rewritten, that. I don't know. It needs to be looked at. I was thinking about 'outweigh'.</p> <hr/> <p>P3: I would rearrange the whole thing 'The benefits by changing this medicine do not outweigh the risks.'</p>	<p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>it is unlikely to be safe</p>	<p>P1: It's not going to be safe, dangerous.</p> <hr/> <p>P2: It's unlikely to be safe, but there's still an element of doubt there where it could be. You say, well, this is dodgy this, you're not sure, so don't take it.</p> <hr/> <p>P3: It's not safe.</p>	<p>P1: unlikely.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: I would word it totally different. 'It would be dangerous' or whatever.</p> <hr/> <p>P2: by 'unlikely', is it safe? Are they not sure about this thing?</p> <hr/> <p>P3: It is possible that it is not safe.</p>	<p>P1: 'unlikely' is a bad word, you could misread it if you are reading it fast.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>This medicine must not be used in children between the ages of x and y years/months</p>	<p>P1: Children shouldn't be using it between this age group.</p> <hr/> <p>P2: It's telling you, it must not be used between those ages, so you just don't give it to them.</p> <hr/> <p>P3: It's telling you the ages where it can be used. It's telling you 'must not', so you shouldn't be deviating from it.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

<p>Therefore, the European Medicines Agency has waived the obligation to study the effect of this medicine in children</p>	<p>P1: I don't know.</p> <hr/> <p>P2: It means that they couldn't give a damn, it seems as though they're just saying 'we're not even going to try and test it in children'. They're saying we don't know about this, there's no reason for us to spend money on finding out what effect this is going to have in children because we know they're not going to take it.</p> <hr/> <p>P3: To me it means that they've never looked into it, so you don't know what the dangers are.</p>	<p>P1: The European Medicines Agency. I don't know what it is. 'Waive the obligation' is difficult as well.</p> <hr/> <p>P2: No. Maybe 'waived the obligation' might not be something everyone would understand.</p> <hr/> <p>P3: Some people might not know what 'waivered' means.</p>	<p>P1: The whole thing needs to be rewritten.</p> <hr/> <p>P2: Is it 'waivered' or 'waived'? Maybe it could be '...has decided not to study the effect of this medicine in children'.</p> <hr/> <p>P3: It should be 'waivered'. 'Obligation', there's loads of special needs people who are getting medicines, what happens to people who are illiterate? I would change 'waivered' and 'obligation'. It's really saying 'we don't have to do it, so we won't do it' aren't they?</p>	<p>P1: What is this sentence for?</p> <hr/> <p>P2: Why should they talk their way out of it by saying 'has waived the obligation'. Just tell people, just say 'therefore the European Medicines Agency has decided not to study the medicine in children.'</p> <hr/> <p>P3: I would think twice about giving my child this medicine.</p>
<p>Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or want to start <taking> <using> any other medicines, including medicines obtained without a prescription , vitamins, minerals, herbal medicines or dietary supplements</p>	<p>P1: I would just say if you're taking anything else, whether it would be vitamins or stuff that you've been taking yourself, it doesn't have to be prescribed by a doctor, just let them know.</p> <hr/> <p>P2: It just means that tell your doctor if you've been recently taking something or will take something together with this drug.</p> <hr/> <p>P3: Well, that's me really, I'm not allowed to take anything herbal or anything in case it interferes with my medication.</p>	<p>P1: No.</p> <hr/> <p>P2: No, it's clear.</p> <hr/> <p>P3: No.</p>	<p>P1: No, it's fine because it breaks it down.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I would say 'you must tell your doctor' or 'it is important to tell your doctor'.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

<p><Taking> <Using> X with food and drink <(amongst others alcohol)></p>	<p>P1: It means whether you should take it with food and drink and whether you should be able to drink alcohol.</p> <hr/> <p>P2: Taking food and drink as well as alcohol? Taking medicine with food and drink, and then it would give you a list of things you shouldn't be having with this medicine.</p> <hr/> <p>P3: If I was getting a prescription I would always check to see if you are allowed alcohol.</p>	<p>P1: No.</p> <hr/> <p>P2: It's too vague.</p> <hr/> <p>P3: No.</p>	<p>P1: 'you must not drink alcohol', 'no alcohol is recommended'.</p> <hr/> <p>P2: Does it mean alcohol as well?</p> <hr/> <p>P3: 'Amongst others alcohol', could it not say 'with food and drink and alcohol'.</p>	<p>P1: 'amongst other alcohol', that's pretty confusing, what does it mean?</p> <hr/> <p>P2: Is this to tell your doctor?</p> <hr/> <p>P3: No.</p>
<p>Fertility, pregnancy and breast-feeding</p>	<p>P1: Anything to do with having a child or had a child, pregnant.</p> <hr/> <p>P2: How it will affect your fertility or the person who's pregnant or breast-feeding while you are taking this medicine.</p> <hr/> <p>P3: For someone who's trying to have a baby, who's pregnant or who is breast-feeding.</p>	<p>P1: Fertility.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: I would just break it down to 'pregnancy and breastfeeding'</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>If you are pregnant or breast-feeding, ask your <doctor> <or> <pharmacist> for advice before taking this medicine if you have any doubts after</p>	<p>P1: If you are pregnant or breastfeeding, if you are unsure about anything on there, seek medical advice.</p> <hr/> <p>P2: If you are pregnant or</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: I think it's pretty clear.</p> <hr/> <p>P2: 'After reading this information, if you have any worries or doubts after reading this information and you are</p>	<p>P1: No.</p> <hr/> <p>P2: Two 'ifs' in one sentence, it's like it's repeating itself.</p>

<p>reading this information.</p>	<p>breastfeeding, if you've still got any doubts, go back to your doctor.</p> <hr/> <p>P3: It means if you go to your doctors and you're pregnant or you've just had a baby and you're breastfeeding and he gives you some medication or you're telling him something that you've got a complaint, you say 'look I'm pregnant' or 'I think I'm pregnant' or 'I'm breast-feeding' because it can interfere with the baby.</p>		<p>pregnant or breastfeeding, see your doctor for advice...'</p> <hr/> <p>P3: No.</p>	<p>P3: No.</p>
<p>Driving and using machines</p>	<p>P1: Whether you can use machines or drive when taking the medication.</p> <hr/> <p>P2: It's giving you some advice whether you can take this drug when your driving because of side effects and drowsiness or whatever and the same for using machines.</p> <hr/> <p>P3: if you're a driver or you work in a factory or something, you want to know if the medication is going to make you feel dizzy or something.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Effects of other ingredients (excipients)</p>	<p>P1: Anything that, other ingredients of that medicine, where a side effect could occur.</p>	<p>P1: 'excipients', I don't know what it means.</p> <hr/> <p>P2: 'Excipients' is a bit of a</p>	<p>P1: That's fine but 'excipients' is a bit confusing.</p>	<p>P1: No.</p> <hr/> <p>P2: Excipients – what's that?</p>

	<p>P2: I would not understand what that was, 'excipients'. Other ingredients, what's excipients?</p> <hr/> <p>P3: I don't know what 'excipients' means.</p>	<p>technical word, it's something I wouldn't read.</p> <hr/> <p>P3: All of it.</p>	<p>P2: excipients.</p> <hr/> <p>P3: I can't because I don't know what it means.</p>	<p>P3: No.</p>
3. How to <take> <use> X	<p>P1: How exactly you take the medication.</p> <hr/> <p>P2: It tells you when to take it, morning, noon and night, something like that.</p> <hr/> <p>P3: It's telling you how to take it, when to take it.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Something like 'this is how to take your medication'? It's friendlier, it's like somebody cares about how you take it.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
Always <take> <use> this medicine exactly as your doctor <or pharmacist> has told you. You should check with your <doctor> <or> <pharmacist> if you are not sure	<p>P1: Always take the medication as you've been advised by the doctor or pharmacist, if you're not sure then seek further medical attention or assistance.</p> <hr/> <p>P2: Well you have a look at the instructions and the pharmacist usually tells you take three times a day or something. If you're not sure about it, go to your doctor or pharmacist.</p> <hr/> <p>P3: It's whatever the doctor's told you to do, like take three tablets a day, you take them, and if you've forgotten by the time you get home, ring up the pharmacist and ask.</p>	<p>P1: It's fine, pretty simple.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: 'If you were at all worried, please check with your doctor...' some people might take more notice of instructions if they are friendlier.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

<p>The recommended dose is...</p>	<p>P1: What has been prescribed by the doctor.</p> <hr/> <p>P2: It just tells you how many tablets you can take a day.</p> <hr/> <p>P3: What you take and you shouldn't take any more than that.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Always <take> <use> this medicine exactly as described in this leaflet or as your <pharmacist> <or nurse> <has> <have> told you.</p>	<p>P1: Take the medication as it says in the leaflet or what you've been advised by a pharmacist or a nurse.</p> <hr/> <p>P2: It's telling you, to reinforce that you should take notice of what it says in the leaflet or what the doctor or pharmacist says.</p> <hr/> <p>P3: That it's important to take what you've been told to take.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Do it in a friendlier and personal way, 'this will help you get better sooner'.</p>	<p>P1: When do nurses prescribe you anything? It's always the doctor in my experience anyway.</p> <hr/> <p>P2: Why's the nurse got to come into it?</p> <hr/> <p>P3: No.</p>
<p>You should check with your <doctor> <or> <pharmacist> <or nurse> if you are not sure.</p>	<p>P1: You need to seek further medical assistance if you're unsure about anything in the leaflet or about the medicine.</p> <hr/> <p>P2: If I wasn't sure I would go back to the chemist and ask 'how much did you say of that I should take?'</p> <hr/> <p>P3: If you've forgotten.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: 'If you are not sure, please check with your doctor or pharmacist who will be willing to advise you.'</p>	<p>P1: No, the only thing is again is the nurse.</p> <hr/> <p>P2: I don't see where the nurse comes into it. I've never had to take advice from your nurse, it's either your doctor that tells you, or the pharmacist tells you and that's good enough. They are more qualified, I would think. I suppose when you're in hospital, the nurse would come and give you the drug, but</p>

				surely they've been told by somebody else.
				P3: No.
Use in children	<p>P1: How children would take the medicine</p> <hr/> <p>P2: What effect it would have on a child if they took this drug.</p> <hr/> <p>P3: The medication for children.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No, but it's not really a complete sentence.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: 'If giving this medication to a child'.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.	<p>P1: the score line on the tablet is to help with the breaking for ease of swallowing and to not be broken into equal doses.</p> <hr/> <p>P2: The score line of the tablet, in the centre, like a crease in the tablet, is there to break it and take it.</p> <hr/> <p>P3: Well, some people might think 'I'm just going to take half, I'm not going to take a full one' and when they've got that thing in, they can half it or they can take one and a half. Because that's what they think it's for.</p>	<p>P1: Facilitate</p> <hr/> <p>P2: Facilitate, it means to make it easy for you but somebody might not be able to understand that.</p> <hr/> <p>P3: Facilitate, I know that it means 'help', 'make it easier', but other people might not.</p>	<p>P1: 'Assist' for facilitate</p> <hr/> <p>P2: change facilitate.</p> <hr/> <p>P3: Facilitate.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
The tablet can be divided into equal halves.	<p>P1: It can be split, the tablet.</p> <hr/> <p>P2: It just means that you can break it easily.</p> <hr/> <p>P3: You can break it in half and</p>	<p>P1: No, it's pretty straightforward.</p> <hr/> <p>P2: No.</p>	<p>P1: No.</p> <hr/> <p>P2: 'two equal parts' instead of 'halves'. I suppose 'equal halves' means the same thing.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	you get equal amounts in each.	P3: No.	P3: No.	
The score line is not intended for breaking the tablet.	<p>P1: Even though there's a score line on the tablet, it's not meant to be split.</p> <hr/> <p>P2: If just means that there's a score line there but don't try to break the tablet. It might just all crumble.</p> <hr/> <p>P3: You've got to still take the whole tablet. You shouldn't do it, just leave it whole.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
If you <take> <use> more X than you should	<p>P1: If you overdose, if you take more than it's been advised.</p> <hr/> <p>P2: It would tell you what the side effects would be if you take more than you should.</p> <hr/> <p>P3: Like overdosing.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No, it's pretty straightforward.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: There should be a colon after the sentence.</p> <hr/> <p>P3: No.</p>
If you forget to <take> <use> X	<p>P1: If you forget to take it, if you forgot.</p> <hr/> <p>P2: It just says if you forget to take it, what can you do, do you take two the next day or something.</p> <hr/> <p>P3: Forgetting to take your tablet.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: If you get a colon at the end, it will give more information to tell you what to do.</p> <hr/> <p>P3: No.</p>
<Do not take a double dose to make up for a forgotten	<p>P1: If you miss a tablet and when you finally remember, don't take two at the same</p>	<p>P1: No.</p>	<p>P1: No.</p>	<p>P1: No.</p>

<p><tablet> <dose></p>	<p>time.</p> <hr/> <p>P2: It just means, don't say, the next day, if you forget to take morning, noon and night today, don't take double the dose tomorrow.</p> <hr/> <p>P3: It means that if you did take a double dose you would be making yourself ill, like overdosing.</p>	<p>P2: No.</p> <hr/> <p>P3: No, but I think people have to understand how dangerous it can be.</p>	<p>P2: No.</p> <hr/> <p>P3: I would make them be able to see how dangerous it can be.</p>	<p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>If you stop <taking> <using> X</p>	<p>P1: if you stop taking the medication, if you don't take it.</p> <hr/> <p>P2: If you're prescribed, and you stop taking them, some side effects might happen, if you haven't come off them slowly or whatever.</p> <hr/> <p>P3: If you stop taking them, if you just stop taking the tablets.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I would say 'it is very important that you do not stop taking...'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>If you have any further questions on the use of this medicine, ask your <doctor> <or> <pharmacist>.></p>	<p>P1: if you've still got a question about the medicine, then seek further assistance, medical assistance.</p> <hr/> <p>P2: If you're still not sure and you want to ask, ask them. You know, don't worry about it, just go and ask.</p> <hr/> <p>P3: If you wanted to ask your doctor about a tablet, say he was going to prescribe</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	something to you, and you are a bit worried, you've got to ask the doctor.			
4. Possible side effects	<p>P1: something that may happen because you are using the medicine that you weren't expecting to happen.</p> <hr/> <p>P2: Just means that this might happen when you're taking these tablets and be aware of them.</p> <hr/> <p>P3: the way it can make you feel.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
Like all medicines, X can cause side effects, although not everybody gets them.	<p>P1: It means that basically if, if you cause a side effect, that not everyone can experience them.</p> <hr/> <p>P2: It just means side effects can happen to some people and if it does happen to you, then it's just tough, so go and see your doctor.</p> <hr/> <p>P3: It means that you can have these side effects, like itchy skin, or something like that, but you probably won't get it, but you could.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your <doctor>	<p>P1: if you get any other side effects, if the medicine makes you feel in any way that is not on the leaflet, then seek</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/>	<p>P1: I would say 'seek medical advice'</p> <hr/> <p>P2: No.</p> <hr/>	<p>P1: I would just leave the nurse off.</p> <hr/> <p>P2: No.</p> <hr/>

<p><or> <pharmacist> <or nurse></p>	<p>medical advice.</p> <hr/> <p>P2: well any concerns that you have, it doesn't have to be an exhaustable list, does it? It could be other things, you could have other side effects that's not listed here, and go straight to your doctor to let him know.</p> <hr/> <p>P3: It means that if something does happen, say like a twitch in your face or something and you were worried about it, phone your doctor or your pharmacist or whatever and say 'look, I know this is not one of the side effects, but it's happening to me, could it be the medication?'</p>	<p>P3: No.</p>	<p>P3: it should be 'it is important that to talk to your doctor if you get any side effects....'</p>	<p>P3: No.</p>
<p>5. How to store X</p>	<p>P1: How to store it, how to keep it, do you keep it in the fridge, do you keep it in the cupboard, do you keep it cool?</p> <hr/> <p>P2: It just means the best place to put them, where to keep them, in a cupboard or wherever, you know.</p> <hr/> <p>P3: Where to put them, because you could be putting them in a cupboard above the cooker where they would get too hot.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

<p>Keep this medicine out of the reach and sight of children.</p>	<p>P1: Keep them well out of the way of kids, keep them high, or whatever, so that they can't get them.</p> <hr/> <p>P2: Be aware that you keep this out of the reach of children and so they cannot see it either, because what they can see they'll want to have a go at, wouldn't they?</p> <hr/> <p>P3: Very important that, you've got to put it away out of the sight of children.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I think they should have a sign, like a skull and crossbones, some sign that children learn about from an early age that it is dangerous, not for them.</p>	<p>P1: I've never seen 'sight' before, it's normally just 'keep this medicine out of reach of children'.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Do not use X after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}>.</p>	<p>P1: Don't not use it after the expiry date which is on the bottle because it would be dangerous if you did or it mightn't work.</p> <hr/> <p>P2: Well, that's obvious, it's just saying when it expires and you shouldn't use it after that.</p> <hr/> <p>P3: Like the sell-by date, check them, because sometimes you forget how long you can keep tablets.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No, it's fine.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>The expiry date refers to the last day of that month.</p>	<p>P1: It probably will have April 2010 or something like that and it means that that would be the very last day of April.</p> <hr/> <p>P2: It's because various months</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No, but maybe give a concrete example, such as March 31st.</p> <hr/>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	<p>are different, the number of days, so it's the last day of that month.</p> <hr/> <p>P3: Say it said 4th of 10th, like April 2010, you could keep them until the last day of April.</p>		P3: No.	
Do not use X if you notice	<p>P1: if you notice something, depends if you notice what though? Do not use.</p> <hr/> <p>P2: I can imagine that there's going to be a colon there and it'll give you a list of things that could happen to the medicine and you don't use it, that it's expired, out of date. And also if you get some new drugs, you want to make sure that they haven't been interfered with.</p> <hr/> <p>P3: if you went to take a tablet and it had a bit mould on or something or it was breaking up in its capsule thing, you know what I mean? If you notice something wrong with it, didn't look right.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
Do not dispose of medicines via wastewater or household waste.	<p>P1: Don't put them in the bin.</p> <hr/> <p>P2: It means don't put it down the sink or in the bin.</p> <hr/> <p>P3: It means don't throw them out or put them down the sink</p>	<p>P1: I don't know what 'wastewater' is? What is that? I've never heard that before.</p> <hr/> <p>P2: Does 'wastewater' mean the toilet or the sink or the</p>	<p>P1: No, I wouldn't have 'wastewater'</p> <hr/> <p>P2: 'Wastewater' is a bit vague. I thought it was alright to put medicines down the toilet to</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>

	or something like that.	bath? P3: No.	get shot of them. P3: No.	
Ask your pharmacist how to dispose of medicines no longer required.	P1: Seek medical advice from the pharmacist about how you dispose of the medicine when you don't need it anymore. P2: You can just go to the chemist's and say 'I've got all these tablets, what do I do with them?' P3: Phone up your chemist.	P1: No. P2: No. P3: No.	P1: No. P2: No. P3: No.	P1: No. P2: No. P3: No.
These measures will help to protect the environment.	P1: by doing something it will help to protect the environment. P2: Well, it just means that it's, that you're not putting it into the system, you go through the official channels. It's the green thing, recycling and all that. P3: It means that for example pouring it down with your household waste is a dangerous thing to do, because you've got to protect your environment, it's precious.	P1: No. P2: No. P3: No.	P1: No. P2: No. P3: No.	P1: No, maybe 'these measures' might be difficult to understand for someone people. 'By doing this' or 'it is important that we help to protect the environment by doing this'. P2: No. P3: No.
6. What is in the pack and further information	P1: Exactly the ingredients of the medicine, how many capsules are actually in the pack.	P1: No. P2: No.	P1: I would just say 'Further information', just to simplify it. P2: No.	P1: No. P2: No.

	<p>P2: It's telling you exactly what's there, how many tablets and further information.</p> <hr/> <p>P3: It's telling you what you can be expected to find in the packet or box.</p>	P3: No.	P3: No.	P3: No.
What X contains	<p>P1: What the ingredients are, what is exactly in the tablets or medicine.</p> <hr/> <p>P2: It tells you what the tablet's made up of, what the drug's made up of.</p> <hr/> <p>P3: What's your tablet made up of.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I would say 'What is in your medication'</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
The active substance(s) is (are)...	<p>P1: The ingredients, but this is not very simple for people to understand.</p> <hr/> <p>P2: I'm reading that as though that is what makes up the tablet. It's what binds the tablet together, that's what's going to act in your body when it goes in.</p> <hr/> <p>P3: I don't really know, just something that's in it.</p>	<p>P1: I don't even really understand what it means, I really don't know.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Active substance.</p>	<p>P1: I don't know.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: I would like it rewording so I could understand it.</p>	<p>P1: No.</p> <hr/> <p>P2: Not sure if everyone would understand this.</p> <hr/> <p>P3: No.</p>
What X looks like and contents of the pack	<p>P1: What it looks like and how many's in the pack and what exactly's in the pack.</p> <hr/> <p>P2: it's telling you what it looks</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: What your medication</p>	<p>P1: Why do you want to know what it looks like? I would just say 'The contents of the pack'.</p>

	<p>like.</p> <hr/> <p>P3: What the tablets look like and what's in the pack.</p>	<p>P3: No.</p>	<p>should look like.</p>	<p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>Marketing Authorisation Holder and Manufacturer</p>	<p>P1: People who's actually made the tablets.</p> <hr/> <p>P2: The people who've got the licence to sell it, that's them and the people that made it.</p> <hr/> <p>P3: The people who make them, like the pharmaceutical industry.</p>	<p>P1: 'Market Authorisation Holder'. I understand 'Manufacturer' but what is that?</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Well, Marketing Authorisation, I can work it out, they've been told that they can sell them.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Yes, so people can understand it.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>
<p>For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:</p>	<p>P1: Obviously if you need any more information about the medicine, contact the representative, but who are they? [Participant is shown from sample leaflets where this information can be seen]</p> <hr/> <p>P2: Well if you need to know anything else, you can contact them, who's selling it.</p> <hr/> <p>P3: If you wanted to know any more information about it, you can contact the local Marketing Authorisation.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: Is this to complain about it? I don't know.</p>
<p>This leaflet was last revised on {MM/YYYY}</p>	<p>P1: It was looked at and updated at that time.</p> <hr/> <p>P2: It was when it was last</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p>

	<p>published, it's telling you that revisions have been made and it's telling you the month and the year.</p> <hr/> <p>P3: That was when the leaflet was written.</p>	P3: No.	P3: No.	P3: No.
<p>Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu</p>	<p>P1: If you want any more information about the medicine, it's on that website.</p> <hr/> <p>P2: Well if you're interested, you can just go on the Internet and read about this.</p> <hr/> <p>P3: If you wanted to get in contact with them, you've got to go on the website and you can type that in and you can get all that information easily.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No, well not everyone has access to the Internet, you should have an address to write to as well.</p> <hr/> <p>P3: No.</p>
<p>There are also links to other websites about rare diseases and treatments.</p>	<p>P1: There's other information on there about different diseases and treatments.</p> <hr/> <p>P2: If I've got something wrong with me, then I can find out more information about the disease and the treatments given.</p> <hr/> <p>P3: If you want to look into anything, like if you found out if you've got anything, you can get onto the website.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3:</p>
<p>This leaflet is available in all EU languages on the European Medicines Agency website.</p>	<p>P1: There is also information, you can look at the leaflet as well on this website in different languages.</p> <hr/> <p>P2: it's just that the website</p>	<p>P1: No, maybe 'EU languages', is that just 'European languages'?</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: The website address should be repeated again, because you have to look back over the leaflet to find it.</p>

	<p>what we've just seen there.</p> <hr/> <p>P3: If you need to get information in another EU language, you can get this off the website.</p>			P3: No.
<p>The following information is intended for healthcare professionals only:</p>	<p>P1: It doesn't apply to you.</p> <hr/> <p>P2: That's for doctors, pharmacists, nurses, etc.</p> <hr/> <p>P3: That's like your doctors and your nurses and whoever is treating you.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>	<p>P1: No.</p> <hr/> <p>P2: No.</p> <hr/> <p>P3: No.</p>