

## Enabling users or readability?

Although the implementation of Directive 2004/27/EC and related EMEA-templates are likely to improve the quality of package leaflets, it might be worth looking at the wider scope of information about medicines. This paper outlines some arguments.

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### Summary

EU-Directive 2004/27/EC significantly changes the motivation for supplying information about medicines to patients. Since 1992 (92/27/EC), the focus was on 'making information readable and understandable'. Directive 2004/27/EC adds that information must be provided in order to: 'enable the users to act appropriately' (article 63(b)2). Not only should information be provided in such a way that people can understand it, but people must now be able to apply this knowledge and handle medicines in an appropriate manner.

*Information design* has a long tradition in developing information that enables people to achieve their aims. The primary concept is that the only person who can judge if information really enables actions, is the actual user of information within a specific context. Therefore, it is essential to involve people in information development processes. This can be done by observing people in context when they try to achieve things, and by conducting diagnostic tests to determine if information achieves its aims. Both observations and tests will reveal in which situations information is successful and where information fails. Observations and tests form the basis of 'performance centred information'.

The current approach of the regulatory authorities is to provide templates for package leaflets. This approach, although understandable in its historical context, has several drawbacks. The main problem is that the templates do not differentiate between medicines, users, actions, languages, and contexts. A single template is unlikely to: 'to enable users to act appropriately', because templates cannot incorporate the practical context and do not relate to actions and criteria that are relevant for users. The template approach seems therefore in conflict with article 63(b)2 of Directive 2004/27/EC.

The template-approach is also unlikely to be effective when a longer term view is considered. Their use does not address larger issues related to the application of information about medicines in practice, such as a reduction in errors, costs-consciousness, or improvements in medicine taking behaviour (compliance or concordance).

I would therefore advice to reduce the use of templates and consider alternative approaches.

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## Directives 1: Users, patients or consumers?

The EU-Directives about the provision of information about medicines do not clearly identify the recipient of this information. Directive 92/27/EC, 2001/83/EC and the most recent 2004/27/EC all use three different descriptors: ‘users’, ‘patients’, and ‘consumers’.

The definition of a package leaflet (2001/83/EC, point 26) states: ‘A leaflet containing information for the *user* which accompanies the medicinal product.’ In this article, the word ‘user’ can refer to patients, but equally well to nurses, pharmacists, hospital pharmacists or medical doctors.

Directive 2001/83/EC, point 40 states: ‘The provisions governing the information supplied to *users* should provide a high degree of *consumer* protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.’ In this phrase, a ‘user’ is seen as a ‘consumer’. This is an appropriate term for Over-the-counter medicines, where people can make a commercial decision themselves, but it is not suitable for Prescription-only-medicines. Furthermore, if health-care providers are ‘users’ (point 26), than this article labels these professionals as ‘consumers’ too.

Directive 2001/83/EC, article 59(c) mentions: ‘... take into account the particular condition of certain categories of *users* (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions), ...’. In this paragraph, ‘users’ seems to be equal to patients, and seems to exclude healthcare providers.

Article 63(2) states: ‘The package leaflet must be written in clear and understandable terms for the *users* and be clearly legible ...’. This is replaced in 2004/27 by: ‘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 this article, there is a clear difference between ‘users’ and ‘health professionals’. This seems to be in conflict with the terminology in point 26.

However, article 67 clearly makes a difference between users and patients; ‘The competent authority shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors. The text of this leaflet shall be established in accordance with the provisions of Article 59. In addition, the leaflet shall include any precautions to be taken by the *user* and the *patient* during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.’ In this article, ‘users’ are health care professionals, and ‘patients’ belong to a different group.

### Concluding

The EU-Directives do not make it clear for whom information is intended. This confusion causes serious problems, because it makes it very difficult to develop appropriate guidelines and to determine valid criteria to evaluate the effectiveness of the provision of information about medicines.

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## Directives 2: Criteria

### What needs to be achieved?

The Directives and Guidelines mention several criteria related to the quality of information. A brief inventory provides the following:

- The Readability guideline (1998): 'Ensuring that the label and package leaflet are *readable* is the primary objective of this guideline.'
- Directive 2004/27/EC, article 59(a)2: '... the pharmaco-therapeutic group or type of activity *in terms easily comprehensible* for the patient.'
- Directive 2004/27/EC, article 63(b)2 states: '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'.
- EMEA annotated QRD template (version 7, 03/2005, page 22) 'The leaflet must be *readable* for patients: please refer to the Guideline on the Readability ...'

These statements seem to suggest that it is possible to measure 'readability' accurately. Unfortunately, 'readability' has proven to be a slippery concept in practice. The main problem is that information can be very easy to understand and very easy to read, but at the same time, it can be inappropriate for a user in a particular situation. For example, the title of a section in a package leaflet is 'Before you take x'. This is clear and understandable, but this heading might also cause anxiety and is confusing for a hospitalized patient who gets an intravenous infusion.

A second practical problem with 'readability' is that it cannot be quantified easily. The Readability guideline refers to a number of correctly answered questions, and suggests that 16 out of 20 people must be able to answer a question correctly. Unfortunately, neither the validity of the method ('do questions about a text really measure its readability?'), nor the score ('is 16 out of 20 really acceptable?') have been investigated.

Directive 2004/27/EC raises the bar substantially through the phrase '*enabling users to act appropriately*'. This creates an opportunity to apply appropriate and valid methods and use quantifiable criteria which assess if users can act appropriately.

### Concluding

Directives 92/27/EC and 2001/83/EC did not make it very clear what the aims of the supply of the information were. Criteria as 'clear and understandable', 'clearly legible' or 'patient friendly' are difficult to quantify. Directive 2004/27/EC makes it obligatory to 'enable users to act appropriately'. This necessitates a reconsideration of the criteria to evaluate package leaflets. It now becomes necessary to determine which 'users' need to be taken into account, which 'actions' should be evaluated, and which levels of success can be seen as acceptable for 'appropriate use'.

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## Information design 1: Performance based

It is essential to describe and analyse the activities of people when they handle and use medicines. Different users in different situations undertaking different actions need to be investigated. 'User experience mapping' is one of several techniques to accurately determine the different actions. Observing and recording the current state of affairs needs to be done to find out what is going well, and which activities need additional or a different type of support. Both 'best practice' as well as 'worst cases' need to be recorded with supporting evidence of potential causes. An added benefit of this description is that information can build upon the expectations and experience of people.

One specific situation can be used as an example:

A patient has just arrived home from a visit to a dispensing pharmacist where she has acquired some Prescription only medicines. At her kitchen table, she unpacks a small plastic bag. A first step is that this patient needs to *identify* the products (what is it and what is it for?), to *locate* a starting point (which box and leaflet do I read first?, which information is most relevant for me?), and keep leaflets, boxes and medicines together (*avoid confusion*). As a second step, she needs to *make a decision* (Can I take this medicine?), *consider* if she wants to take it ('Do the benefits outweigh the risks?'), *remember* the effects ('I've got to drive later on today, but this makes me drowsy. I better take it later.') and *learn to understand* how her medicines work. The third step consists of taking the medicines. This consists of *following the instructions* ('Before dinner'), *noticing* any effects ('I feel drowsy'), *check* the leaflets again ('Where did it state that I could get drowsy?'), *react* appropriately ('Do I need to call a doctor?') and *store* the medicines in a safe place ('Roomtemperature?'). After taking the medicines, a patient has to *make a decision* whether to stop or continue, and *decide* whether to consult a doctor again. A final action is to *dispose* of any remaining medicines.

Each of these activities must be supported by relevant information in order to make it possible to take medicines correctly, or as the Directive states: 'the package leaflet ... must enable users to act appropriately.'

Each of these activities can be tested when suitable criteria are chosen, and minimally acceptable standards can be discussed. For example, storage might be of major importance for a particular medicine, and special attention could be given to establish if the storage instructions can be understood and applied by patients in practice. Other situations in which medicines are used need to be described in a similar way.

It should be noted that these activities are not equally important for all medicines and that acceptable standards might vary in different situations. For example, the identification of an outer package by a pharmacist in a pharmacy differs from the identification of the same outer package by a patient in a medicine drawer in a kitchen.

### Concluding

Directive 2004/27/EC makes it necessary to accurately describe the actions of users in detail, apply relevant tests, and develop and agree on standards for each action.

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## Information design 2: users, context, information

The approach used by information designers, usability specialist and human factor experts can help to determine which actions of users in context need to be investigated and described. In order to be effective, this description needs to be integrated into a larger process. The main aim is to develop information that supports specific activities of people within a specific context effectively. Establishing the actions, criteria and thresholds is only a part of successful information design developments.

A thorough approach consists of five steps (Sless, 1995 a&b). These steps are:

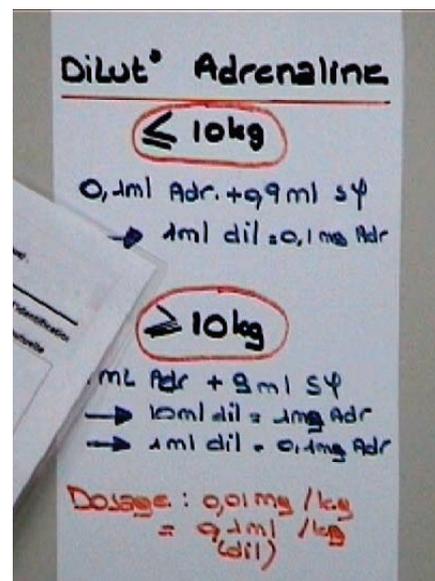
1. Describing the current state of affairs through observation and benchmarking. Collecting data, evaluating the validity of appropriate criteria, and analysing influences, with the aid of user experience maps or task analysis.
2. Involving all stakeholders. Projects require the input from all relevant perspectives, and it is vital for the success of a project to involve all factions from the start.
3. Development of prototypes, consisting of several cycles of writing, designing and testing.
4. Implementing solutions in practice.
5. Monitoring practice, to see which changes occur and deciding if these changes warrant a new development.

This approach has proven to be successful in the development of effective labeling and effective labelling legislation in Australia (Therapeutic Goods Order) and its related *Labelling Code of Practice: Designing usable non-prescription medicine labels for consumers*.

The information design approach is effective because it starts from the activities and expectations of people who are dealing with pharmaceutical information: patients, pharmacists, nurses, doctors and hospital pharmacists.

**Figure 1. Observing information use.**

The photograph shows a handwritten note on a wall in a treatment room of a hospital for children in Brussels (Belgium, 2004). It describes how adrenaline (epinephrine) needs to be diluted before injection. This note might be an indication that the original instructions provided with this product were not suitable. Someone took the effort to make them more appropriate for a particular situation. Interviewing and observing healthcare providers provides solid benchmark data that can be used to develop and evaluate appropriate and relevant information.



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## Considering alternatives 1: Templates?

At the moment, the EMEA provides digital templates to aid pharmaceutical industries during the application procedures in Europe. These *QRD product information templates* are based on an example of a model leaflet which was published in the Readability guideline in 1998 (annex 1a). The QRD templates 'Provide useful guidance as to the content of the information to be supplied' (EMEA website, May 2005). The text of the template has regularly been developed and modified, and version 7.0, dated March 2005, is currently being discussed. The template is now available in 22 languages and it is the de facto basis for many package leaflets across the European Union.

The following arguments might need to be considered.

### a. The template does not differentiate

The template does not vary according to type of medicine (POM or OTC, parenteral or self-administration), users (patients, nurses, pharmacists, doctors), actions (take, identify, decide, remember, react, ...), contexts (home, hospital, emergency, sport, ...) or language (22 EU-languages). Providing a rigid template to cover a large variation of practical situations inevitable reduces the appropriateness in specific situations. It also surpasses the idea that different people require different formats which match their personal cognitive style. These differences must be taken into account if appropriate information needs to be provided. A single rigid template obstructs this.

### b. The template does not follow 'best practice'

The template contains unhelpfully obscure language and does not use visual variables to clarify the structure of the contents. The template is therefore unnecessarily difficult to access. The EMEA website states that the QRD templates 'Define the format and layout for summary of product characteristics (SPC); labelling and package leaflet'. Although there is clear guidance on the format and layout in which the documents must be submitted to the EMEA, there is very little guidance on the format and layout in which information must be presented to 'users' (patients, pharmacists, doctors, nurses, ...). The format and layout of the template are inappropriate for users. The template itself, and its translations, should be a good example of best practice.

### c. The template stifles developments

Both the development of new package leaflets, and the development of new approaches to provide users with appropriate information are hampered by the current template. It is unlikely that a novel approach, such as for example used in the US by Target Pharmacies (figure 2), would be tried in Europe. Developments using digital technology, in combination with the supply of information in different modes, cannot be considered within the current template.



**Figure 2. Alternative designs.**

Medicine packaging for Target Pharmacies (US). Innovative solutions to provide patients with information are unlikely to be developed if rigid templates must be applied. (source: <http://newyorkmetro.com/nymetro/health/features/11700/index.html>) (April 18, 2005. Photo credit: Davies + Starr)

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**Figure 3. Considering users in context**  
Two front-sides of boxes for inhalers for an asthma patient. Which inhaler must be used in case of an asthma attack? (Netherlands, 2004)

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**d. The template does not help applicants**

The EMEA website states: *‘The information contained in these documents is non-exhaustive; applicants should also refer to all relevant EU legislation and guidelines when drawing up their application. It is the applicant’s responsibility to ensure that the product information complies with all such requirements.’* This statements diminishes the practical value of the template for applicants. Using the template does not guarantee that product information is compliant. In practice, each applicant must compare the templates with all other documents. Unfortunately, some of these other documents provide conflicting advice. For example, information in the template conflicts with information in the Readability guideline in many details. There is no guidance which of these two document should prevail. If applicants really need to consult all other documents anyway, then the template just adds another level in the process.

**e. The template implies that information can be developed without users**

Using the template and writing a text is only a very small part of the development process of suitable information. The real value of information can only be established by actual users in context. Involving users before (observation), during (diagnostic tests) an afterwards (evaluation) are essential to measure the quality of information and prove that modifications are real improvements. The template is not integrated into an ‘information development process’, and does not provide any guidance or references to such a process.

**f. The template implies that package leaflets can be developed on their own**

People do not use package leaflets on their own. Package leaflets are used in combination with other information, such as the information appearing on the medicine itself, and information on the outer packaging. The use of these three sources depends on the context.

The template does not consider the combination of these sources. For example, the purpose of an inhaler for asthma patients should be mentioned on the outer box (‘Use in case of an asthma attack’) to distinguish it from an identical inhaler which should state (‘Use regularly to control asthma’). This would make it easier for patients to select either ‘Salbutamol’ or ‘Beclometason’ (Figure 3, Netherlands, 2004). Both package leaflets accurately and clearly mention the different indications. However, the package leaflet does not take a serious asthma attack into account, and it is very likely that the wrong inhaler is selected and used. Investigating the readability of the package leaflets only would not have revealed this problem.

It’s necessary to consider that users will consult several sources simultaneously, and ignore others. Interviewing users will not only reveal issues related to package inserts, but also issues related to the combination of package leaflet, medicine pack and outer packaging. The template needs to allow for this.

### **g. The template makes compliance with article 61(1) more time consuming**

Article 61(1) of Directive 2004/27/EC states that ‘*The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority*’. The template has not been subjected to diagnostic user testing, not in English nor in any other EU-language. Package leaflets that followed the template have always failed such tests. In practice, the template needs to be substantially modified in order to pass any assessment with target patient groups. Applying the template frequently adds at least one unnecessary test-round to the development process. This takes time and puts additional pressure on applicants, because a patient-assessment test failure could delay the registration process.

### **h. Standardized information is less likely to be read**

The use of a single template for all medicines results in package leaflets that look and feel similar. Patients who use several medicines at the same time, and use medicines for a longer period will therefore receive many similar looking package leaflets. This makes it likely that package leaflets are ignored, even though they might contain new and relevant information. Even if the information in a package leaflet is optimally clear, understandable, applicable, relevant and suitable, it becomes less likely to be noticed if it is presented in a format that is difficult to distinguish. The template does not allow for alternatives to focus the attention of patient to modified information.

### **i. Instructions must be tested**

The EMEA website states: ‘*The templates are intended to provide applicants with practical advice on how to draw up the product information, ...*’ and ‘*Provide useful guidance as to the content of the information to be supplied*’. However, just like the legal obligation to test package leaflets to establish if they really ‘enable users to act appropriately’, it would be beneficial if the EMEA and EU-guidelines would be tested to determine if they ‘enable applicants to submit appropriately’. In other words, it would be beneficial to find out if the instructions really ‘provide practical advice’ and ‘provide useful guidance’ before these claims are made. Providing untested guidance is like supplying untested medicines. It might do more harm than good.

## **Concluding**

The templates cannot guarantee that obligatory requirements are met. The templates are inappropriate for users (patients, pharmacists, doctors, nurses, ...) in contents, format and layout. The template is very difficult to use by applicants. The benefits of a template, such as consistency and comparability, are insignificant and not relevant for users nor applicants.

The abovementioned arguments make it necessary to reconsider the role of templates in relation to Directive 2004/27/EC.

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## Considering alternatives: future perspective?

The supply of information about medicines should not only be related to the direct use of specific medicines in a particular context. The following three developments show an increasingly worrying situation. It is clear that the supply of information can only alleviate parts of these developments, but substantial improvement could be made.

### a. Poor compliance

The actual use of medicines can be described as adherence, concordance, compliance or persistence. These figures indicate what proportion of medicine is taken in such a way that optimum benefit is achieved. The Cochrane Collaboration and the World Health Organization have published figures about compliance, which suggest that 50 per cent of medicines for chronic conditions are not taken according to the instructions (Haynes, McDonald, Garg, 2002). It is likely that suitable and relevant information would enhance appropriate behaviour.

### b. Worrying error-rates

The report *To err is human* has once more focused the attention on medication errors (Institute of Medicine, 2000). It mentions that between 44,000 and 98,000 people in the USA die every year because of such errors. Although these extrapolated figures must be verified, they clearly indicate that medication errors are fairly common and can be very costly. It is likely that suitable and relevant information would reduce the number of errors (see also figure 4).

### c. Increasing medicine budgets

Expenditure on medicines as a percentage of the health budget varies from 7.8 per cent in Norway to 25.0 per cent in Portugal (Tinke and Griens, 2003). It is expected that these costs will increase by about 9 per cent per year. It is likely that suitable and relevant information would balance the costs-benefit ratio.

Information about medicines should ultimately be judged against criteria related to these developments:

- are medicines taken more correctly?
- is the number of errors lower than before?
- are medicines used in a more cost-effective manner?



**Figure 4: Testing packaging.**

Ask a number of pharmacists to handle prototypes and give a personal opinion about their 'confusability'. The question 'Are you afraid that you might confuse these boxes and dispense the wrong one to patients?' provides a wealth of information about pharmaceutical packaging design. 'Readability' is not a suitable criteria in this situation. For this test, a user (dispensing pharmacist), appropriate action (selecting correct box) and criteria (confusability) are defined. Rigid templates do not detect problematic practice.

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It is necessary to consider the current template-approach in relation to these developments as well. Focusing on human actions - taking medicines, handling medicines, trading medicines - is likely to be most beneficial. The statement in paragraph 63(b)2 of Directive 2004/27/EC - enable users to act appropriately - is now only applicable to package leaflets. It would be beneficial if it is applied to all information about medicines.

## Conclusions

### 1. The EU-Directives do not make clear for whom information is intended

The people who should read the information about medicines are described in the EU-Directives as 'users', 'patients', 'consumers', and 'health professionals'. The confusion in terminology makes the development and evaluation of information difficult, because it is not clear who needs to be addressed.

### 2. EU-Directive 2004/27/EC provides unequivocal and measurable criteria

Directive 2004/27/EC makes it obligatory to provide information in package leaflets which 'enables users to act appropriately'. This clarifies and enforces the statement in Directive 2001/83/EC: 'information supplied to users ... in order that medicinal products may be used correctly'. Both these criteria - 'act appropriately' and 'used correctly' can be accurately measured. In contrast, the other criteria mentioned in the Directives and guidelines, such as 'readability', 'clear and understandable', and 'easily comprehensible' have proven to be difficult to quantify.

### 3. It is obligatory to investigate and describe 'acts' and 'users'

In order to 'enable users to act appropriately', it is essential to describe 'users' and 'act' first. There are different users of medical information, such as patients, nurses, doctors, pharmacists, and there are different actions related to medicine handling and use. Examples of actions are identifying, taking, storing, remembering, learning, deciding, recognizing, and reacting to name but a few. Describing practice and developing 'user experience diagrams' will be necessary.

### 4. It is obligatory to define criteria and suitable thresholds

In order to find out if users are able to 'act appropriately', it is necessary to develop criteria for each activity and to decide on an exact level of necessary achievement. The threshold what is considered 'appropriate' for each of the actions needs to be discussed and tested, in relation to a specific user and a specific context. As an example: '100% of nurses must be able to identify the correct route of administration for prepared intravenous infusions within 5 seconds.' In this example, both the user (nurse) and act (identify) are clear. The level of appropriateness of both values '100%' and '5 seconds' need to be discussed and validated in tests.

### 5. 'Information Design' provides proven and practical method

Performance centered information design offers an effective method to approach to these issues. The information design method has been applied in Australia and now forms the basis of legislation for information about medicines. The same approach is used in fields as diverse as signage systems, financial information, website usability and software interfaces.

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## **6. A single template does not help users**

The legal requirement of ‘enabling users’ is in conflict with the use of a template for the provision of information. A single template cannot optimally present information that will be used by different users in different contexts in different languages for different medicines to enable different actions. Secondly, people look at different information sources simultaneously. A template cannot look at combinations of different documents. A third issue is related to standardized information, which reduces the likelihood that it is consulted.

## **7. A single template does not help applicants**

A template gives the incorrect impression that information can be developed without the involvement of people who use the information. The template is not integrated into a process, which makes it for example unclear how and when the ‘assessment in cooperation with target patient groups’ needs to be undertaken. Furthermore, the template does not guarantee legal compliance. All applicants are still advised to read and apply all other EU-legislation and guidance as well. This substantially reduces the practical value of the template.

## **8. The template does not follow best practice and has not been tested**

The format, contents and layout of the current template are inappropriate for both ‘users’ and ‘applicants’. The template and accompanying guidance must be tested in order to prove its practical value.

## **9. A single template does not focus on longer term**

The use of a single template is unlikely to contribute to longer term issues, such as a reduction in medication errors, an improvement in medicine taking behaviour (compliance/concordance), and a better balanced benefit-cost ratio. Information needs to be suitable, appropriate and relevant to make it possible to use medicines effectively. This requires a close analysis of all activities related to the use of medicines and its supporting information. A single template hampers the developments of alternatives that might be effective in specific circumstances. And a template provides a false sense of security because it does not detect any practical problems with the use of information.

## **10. Reconsider the role of templates for package leaflets**

Referring to the abovementioned nine conclusions, it would be advisable to reconsider the use of templates. It would be beneficial if the phrase ‘enable users to act appropriately’ would be applied to all information about medicines.

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