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**APPENDICES**

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**Appendix A Table A.1:** Data extraction form - Systematic Review

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**Appendix B Table B.1** Summary of the assessment of bias in the Systematic Review



## Appendix C: Study Information Sheet



Dr Mea van Huyssteen  
Pharmacy building, First floor Room F6  
School of Pharmacy, University of the Western  
Cape  
Robert Sobukwe Road, Bellville, 7535  
Tel: (021) 959 2864

Ms Jeanne Heyns  
39 Hawkins Avenue  
Epping Industria 1, 7460  
Tel: (021) 507 4844

### *The effectiveness of using pictograms and text on medication labels at primary healthcare facilities in Cape Town*

#### **Invitation**

You are being asked to take part in a research study on the understanding that patients have of the medicine label. The study will be conducted by Jeanne Heyns, a Master's Degree student at the School of Pharmacy at the University of the Western Cape. The supervisor of the study is Dr Mea van Huyssteen.

Before you make a decision on whether you would like to take part in this study, I would like to tell you a bit more about this study and answer all the questions that you may have. If you would like to participate in the study, I will ask you to sign a consent form. A copy of this study information sheet will be given to you for your own records. You may decide to stop being a part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn / destroyed. There are no negative consequences if you choose not to take part in this study.

## **Purpose**

The aim of the study is to evaluate the use of pictograms on medication labels in CHCs of the Cape Metropole, and establish how well the pictogram conveys its meaning and if there is any benefit for the patient to use pictograms. The study is for patients with no education or patients who have completed some or all 7 grades of primary school education. I would also like to compile recommendations or ways to improve medication labels for patients.

## **Procedures**

Interviews will be conducted at the CHCs by the research pharmacist. Participant will be asked specific questions about the medicine label to determine their understanding of the instructions on the medicine label.

## **Participants' Rights**

You will not be identified in any way. You have the right to withdraw from the study at any time without an explanation. You have the right to have all your questions about this study material answered.

## **Risks and Benefits**

There is no risk for you in this study. You may experience the benefit of better understanding of how to take your medication.

## **Confidentiality**

The data I collect will not contain any personal information. Your name will not be mentioned in any of the study reports. Study material will be kept in a secure location under lock and key. Only the research team will have access to this material and it will be destroyed after the research output has been published.

## **Voluntary Participations**

If you would like to take part in the study you will be asked to sign the consent form. Participating in this study will not cost you any money and you will not be paid for your participation. We will only take about 10 minutes of your time.

## **Contact Information**

I will be glad to answer your questions about this research study at any time. If you have any questions now, you may ask them. Alternatively you can contact me at:

39 Hawkins Avenue  
Epping Industria 1, 7460  
Tel: (021) 507 4844  
E-mail: [jeanne.a.heyns@gsk.com](mailto:jeanne.a.heyns@gsk.com)

or

Dr Mea van Huyssteen  
Pharmacy building, First floor Room F6  
School of Pharmacy, University of the Western Cape  
Robert Sobukwe Road, Bellville, 7535  
Tel: (021) 959 2864  
Email: [mvanhuyssteen@uwc.ac.za](mailto:mvanhuyssteen@uwc.ac.za)

The committees giving ethical approval for this study is the UWC Faculty board Research and Ethics Committee and the UWC Senate Research Committee. If you have any problems or questions about this study you can also contact the Ethics committee directly at telephone number 021 959 3170.

## Appendix D: Informed Consent Form



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Tel: (021) 959 2864

Ms Jeanne Heyns  
39 Hawkins Avenue,  
Epping Industria 1, 7460  
Tel: (021) 507 4844

**Informed consent for patients who are invited to participate in the research project titled:**

*The effectiveness of using pictograms and text on medication labels at primary healthcare facilities in Cape Town*

Date: \_\_\_\_\_

Name of participant: \_\_\_\_\_

Unique identifier assigned to participant: \_\_\_\_\_

Name of person taking consent: \_\_\_\_\_

I have been invited to participate in research about understanding of the medicine label, by patients.

I have read the information that follows / the information that follows has been read to me in a language that I understand and I understand the objectives of the study.

I have been provided with a study information sheet and I was given the opportunity to ask questions about it. The questions I asked have been answered to my satisfaction.

I understand that I can withdraw from the study at any time.

I understand that the information that I provide will not be a test of how clever I am, but will be valuable to the researcher to understand where improvements can be made on how to provide information regarding the medication.

I understand that my name will not be mentioned with any of the information I provide.

I understand that all information I provide will be kept secure by the researchers.

I hereby give voluntarily consent to be a participant in this study.

Print Name of Participant: \_\_\_\_\_

Signature of Participant: \_\_\_\_\_

Date: \_\_\_\_\_ dd/mm/yyyy

Statement by the researcher / person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the information sheet. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher / person taking the consent: \_\_\_\_\_

Signature of Researcher / person taking the consent: \_\_\_\_\_

Date: \_\_\_\_\_ dd/mm/yyyy



## Appendix E: Individual Interview Outline



Dr Mea van Huyssteen  
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Ms Jeanne Heyns  
39 Hawkins Avenue  
Epping Industria 1, 7460  
Tel: (021) 507 4844

*The effectiveness of using pictograms and text on medication labels at primary healthcare facilities in Cape Town*

Unique Identifier: \_\_\_\_\_

Name of interviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Location (facility name): \_\_\_\_\_

Duration of interview (in minutes): \_\_\_\_\_

### **Introduction**

Good day, my name is [\_\_\_\_\_]. I would like to find out more about your understanding of how to take your medication. Your name will not be mentioned with any of the information that you share with me. The results of all the interviews will be used to learn more about what patients understand on how to use their medication and will be recorded in the write-

up of a research study. The information that you provide will not be a test of how clever you are, but will be valuable to us for understanding where we can improve on how we provide information regarding your medication.

### Interviewer instructions

- Provided informed consent and other background information.
- Asked interviewee for permission to record the interview.
- Collected the following relevant information during the introduction phase.

Gender: Male

Female

Marital status: Married

Single

Divorced

Residence: Formal dwelling

Informal Dwelling / shack in backyard

Informal Dwelling / shack NOT in backyard

Other

Age: \_\_\_\_\_

Home language: Afrikaans

English

Educational level: No Schooling

Grade 1 - 3

Grade 1 - 6

Grade 7 - 12

Tertiary

Reason for visiting the CHC: \_\_\_\_\_

Are you able to tell me what the time is by looking at this watch: Yes

No

Are you employed: Yes

No

Monthly income: No income

R 1 to R 3 200

More than R 3 200

Access to running water from a tap inside your house: Yes

No

Access to running water from a tap outside your house: Yes

No

Refuse removal: Never

Yes

If the answer to any of the below questions was “yes” except for the last question, the patient will not be able to take part in the study:

- Do you have problems with your eye sight so that you have difficulty seeing pictures on a paper?  
Yes  No
- Do you have trouble hearing?  
Yes  No
- Do you feel that you are too ill take part in this study?  
Yes  No
- Can you speak English / Afrikaans / isiXhosa?  
Yes  No

### Research Questions

Allocate participant to: Control group (‘routine instructions’)

Experimental group (‘text and pictogram’)

Present the allocated medication label to the patient and ask the following questions:

- What is the name of the medication?
- Model answer: Oral Rehydration Mixture
- What should the medicine be used for?
- Model answer: diarrhoea

- How should this medication be prepared for use?
- Model answer: boil and cool one liter of water, add the contents of the packet to the cooled water and mix until all crystals are dissolved.
- How much of the medicine should be taken?
- Model answer: Half a cup after each loose stool
- When/how often and for how long should the medicine be taken?
- Model answer: Half a cup of the solution after each loose stool until diarrhea resolves, or if 24 hours elapse after making up the solution
- When should this medication be thrown away?
- Model answer: Within 24 hours of the time it was made up

The responses are recorded and on the basis of the answers the patient is categorized according to the Likert Scale as follows:

1. Not aligned with intended message (way off the model answer, not even close)
2. Partially aligned with intended message (some aspects of the model answer)
3. Fully aligned with intended message (the model answer)

Explain to the patient the intended message of the medication label. The following set of questions is asked to establish the patients' perception of the labeling practices and their opinion of the respective medication label:

- Which instructions were easy to understand?
- Which instructions were difficult to understand?

- What do you think could be the reason why you did not understand the instructions?
- (Only for those in the experimental group). Were the pictograms on the label helpful or hindering to your understanding of the medication instructions?
- (Only for those in the control group). What do you think might help you interpret medication labels better?

The patient is asked for any suggestions that could help him/her understand the medicine label better:

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#### **Interviewer script**

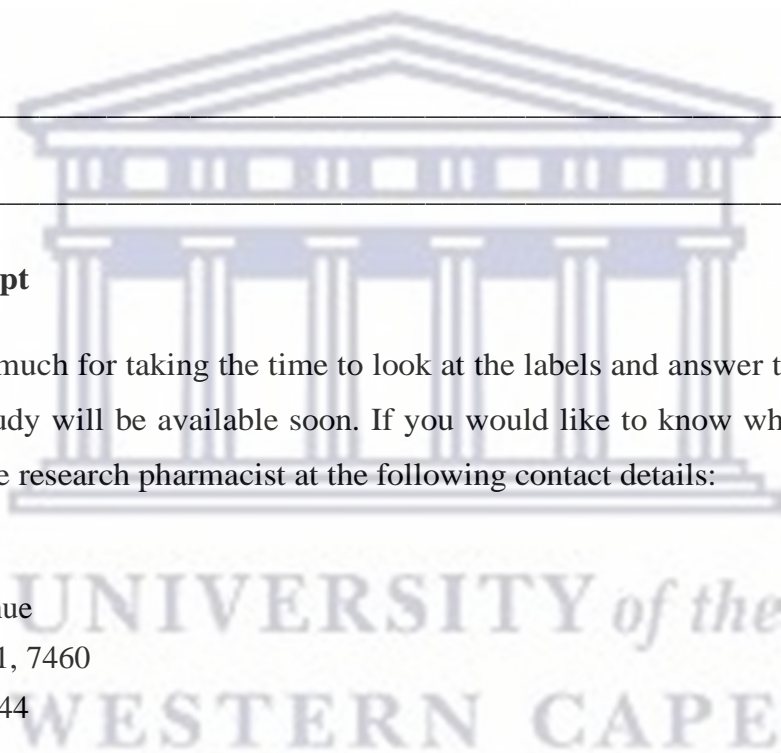
Thank you very much for taking the time to look at the labels and answer the questions. The results of this study will be available soon. If you would like to know what the results are, please contact the research pharmacist at the following contact details:

Jeanne Heyns

39 Hawkins Avenue

Epping Industria 1, 7460

Tel: (021) 507 4844



**Appendix F Table F.1:** Participant responses to Question 1 to 6, scored according to a Likert scale in relation to the intended therapeutic message on the medication label

Questions	Model answer: experimental group	Scoring* on Likert scale: experimental group	Model answer: control group	Scoring* on Likert scale: control group
Question 1: What is the name of the medicine?	Oral Rehydration Mixture.	3: “Oral Rehydration Mixture”.	Name of medication** for rehydration / powder for oral rehydration therapy, for the treatment of electrolyte and fluid depletion associated with diarrhoea.	3: “Name of the medication**” / “name of the medication** for rehydration”.
		2: E.g. “mix for rehydration”.		2: E.g. “electrolyte powder”/ “for rehydration”.
		1: E.g. “I don’t know” / “diarrhoea”.		1: E.g. “glucose water”.

Questions	Model answer: experimental group	Scoring* on Likert scale: experimental group	Model answer: control group	Scoring* on Likert scale: control group
Question 2: What should the medicine be used for?	For prevention of dehydration during diarrhoea.	3: E.g. “For prevention of dehydration during diarrhoea” / “for diarrhoea” / “for dehydration”.	For rehydration / powder for oral rehydration therapy/for the treatment of electrolyte and fluid depletion associated with diarrhoea.	3: “Oral rehydration therapy” / “for rehydration” / “for diarrhoea”.
		2: E.g. “for prevention of diarrhoea”.		2. E.g. “for the stomach”.
		1: E.g. “to keep the blood and body clean”.		1: E.g. “if the child cannot take in food”.

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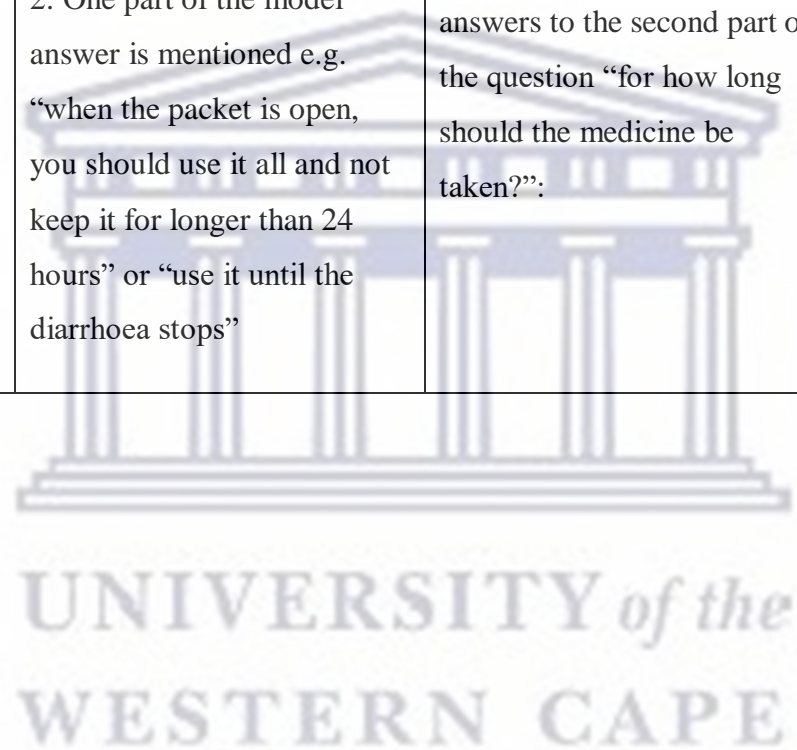


Questions	Model answer: experimental group	Scoring* on Likert scale: experimental group	Model answer: control group	Scoring* on Likert scale: control group
Question 3: How should this medicine be prepared for use?	Boil 2 liters of water and cool, pour water in a clean 1-liter bottle and add dry ingredients to clean water.	3: All four elements of the model answer is mentioned, “boil the water, cool the water, use 1 liter of water and add dry ingredients/content of sachet to the water”.	Dissolve one sachet in a liter of previously boiled and cooled water.	3: All four elements of the model answer is mentioned, e.g. “boil the water, cool the water, use 1 liter of water and dissolve one sachet in water”.
		2: At least three of the elements of the model answer is mentioned, e.g. “boil 2 liters of water and cool, pour water in a clean bottle and add this powder to clean water”.		2: At least three of the elements of the model answer is mentioned, e.g. “use a liter of boiled and cooled water”.

Questions	Model answer: experimental group	Scoring* on Likert scale: experimental group	Model answer: control group	Scoring* on Likert scale: control group
		1: One or two elements of the model answer is mentioned e.g. “boil water and add mixture”, or “throw in a bottle”.		1: One or two elements of the model answer is mentioned e.g. “boil a liter of water” or “use one scoop”.
Question 4: How much of the medicine should be taken?	Drink half a cup after every watery stool.	3: E.g. “half a cup after each loose stool” / ”half a cup”	Administer the solution in frequent small volumes.	3: E.g. “frequent small volumes”/”small volumes”.
		2: E.g. “half a cup daily”		2: E.g. “the contents of the sachet”.
		1: E.g. “two cups”.		1: E.g. “a glass two times an hour”.

	<p>There are two possible answers to the first part of the question “when/how often should the medicine be taken?”:</p> <ul style="list-style-type: none"> <li>- Drink after every watery stool.</li> </ul> <p>Or</p> <ul style="list-style-type: none"> <li>- Take when you have diarrhoea (derived from “for prevention of dehydration during diarrhoea”).</li> </ul> <p>There are two possible answers to the second</p>	<p>3: Both parts of the model answer is mentioned e.g. “take after every loose stool and discard unused solution after 24 hours” or “take after diarrhoea and stop when the stool is not watery”.</p>	<p>There are two possible answers to the first part of the question “when/how often should the medicine be taken?”:</p> <ul style="list-style-type: none"> <li>- Administer the solution in frequent small volumes.</li> </ul> <p>Or</p> <ul style="list-style-type: none"> <li>- Take when you have diarrhoea (derived from the indication for use, “for the treatment of electrolyte and fluid depletion associated with diarrhoea”).</li> </ul>	<p>3: Both parts of the model answer is mentioned e.g. “take frequently and discard unused solution after 24 hours” or “take after diarrhoea until diarrhoea has stopped”.</p>
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Questions	Model answer: experimental group	Scoring* on Likert scale: experimental group	Model answer: control group	Scoring* on Likert scale: control group
	part of the question for how long should the medicine be taken?": If interpreted as "how long to take the medicine for intended	2: One part of the model answer is mentioned e.g. "when the packet is open, you should use it all and not keep it for longer than 24 hours" or "use it until the diarrhoea stops"	There are two possible answers to the second part of the question "for how long should the medicine be taken?":	2: One part of the model answer is mentioned e.g. "discard unused solution after 24 hours" or take "until the diarrhoea has cleared up".



<p>Question 5: When / how often and for how long should the medicine be taken?</p>	<p>use”, the answer would be:</p> <ul style="list-style-type: none"> <li>- Take until diarrhoea has cleared up (derived from the indication for use “for prevention of dehydration during diarrhoea”).</li> </ul> <p>If interpreted as “how long to take the medicine before it should be discarded?”:</p> <ul style="list-style-type: none"> <li>- Take for no longer than 24 hours (derived from instruction “do not</li> </ul>	<p>1: E.g. “use for one week”.</p>	<p>If interpreted as “how long to take medicine for intended use”, the answer would be:</p> <ul style="list-style-type: none"> <li>- Take until the diarrhoea has cleared up (derived from the indication for use, “for the treatment of electrolyte and fluid depletion associated with diarrhoea”).</li> </ul> <p>If interpreted as “how long to take the medicine before it should be discarded?”:</p> <ul style="list-style-type: none"> <li>- Take for no longer than 24 hours (derived from the instruction “discard</li> </ul>	<p>1: E.g. “take a spoon 3 times a day until you finish it”.</p>
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Questions	Model answer: experimental group	Scoring* on Likert scale: experimental group	Model answer: control group	Scoring* on Likert scale: control group
	keep mixture for more than 24 hours”).		unused solution after 24 hours”).	
Question 6: When should this medicine be thrown away?	Do not keep mixture for more than 24 hours.	3: E.g. “24 hours” or “1 day”.	Discard unused solution after 24 hours.	3: E.g. “24 hours” or “1 day”.
		2: E.g. “when the diarrhoea has cleared up”.		2: E.g. “a day or two”.
		1: E.g. “2 – 3 weeks”.		1: E.g. “7 days”.

\*A score of 3 was allocated for the model answer, a score of 2 was allocated for part of the model answer and a score of 1 was allocated if the participant did not know the answer or the answer was not in line with the intended message.

\*\*For protection of the third party, the name of the product is not mentioned.

**Appendix G Table G.1:** Summary of statistical analyses for font size (control group)

<b>Question</b>	<b>Possible answer to questions</b>	<b>Font size* and position</b>	<b>Font type</b>	<b>White space Y / N</b>	<b>Median and Range</b>	<b>Font size legibility score and statistical significance (P-value**)</b>
<b><u>Question 1:</u></b> <b>What is the name*** of the medication? (Name of the product).</b>	1. Trade name	1. 55 pt (FP) and / or 35 pt (BP)	1. Bold	1. Y	3 (1 to 3)	<u>Between Q 1 and Q 2</u> Not significant (P = 0,414) <u>Between Q 1 and Q 3</u> Significant (P = 0,015)
<b><u>Question 2:</u></b> <b>What should the medicine be used for? (Indication for use).</b>	1. For rehydration 2. Powder for oral rehydration therapy	1. 18 pt (FP) 2. 7 pt (BP) 3. 7 pt (BP)	1. Bold 2. Bold 3. Not bold	1. Y 2. N 3. N	3 (1 to 3)	<u>Between Q 1 and Q 4</u> Significant (P = 0,000) <u>Between Q 1 and Q 5</u> Significant (P = 0,000)

	3. For the treatment of electrolyte and fluid depletion associated with diarrhoea					<u>Between Q 1 and Q 6</u> Significant (P = 0,000) <u>Between Q 2 and Q 3</u> Not significant (P = 0,120) <u>Between Q 2 and Q 4</u> Significant (P = 0,000)
<b><u>Question 3:</u></b> <b>How should this medication be prepared for use?</b> <b>(Preparation of medication for use).</b>	1. Dissolve one sachet in previously boiled and cooled water	1. 7 pt (BP)	1. Not bold	1. N	3 (1 to 3)	<u>Between Q 2 and Q 5</u> Significant (P = 0,000) <u>Between Q 2 and Q 6</u> Significant (P = 0,002) <u>Between Q 3 and Q 4</u>



<p><b><u>Question 4:</u></b>  <b>How much of the medicine should be taken? (Medication dosage).</b></p>	<p>1. Frequent small volumes</p>	<p>1. 7 pt (BP)</p>	<p>1. Not bold</p>	<p>1. N</p>	<p>1 (1 to 3)</p>	<p>Significant  (P = 0,000)  <u>Between Q 3 and Q 5</u>  Significant  (P = 0,000)  <u>Between Q 3 and Q 6</u>  Significant  (P = 0,049)</p>
<p><b><u>Question 5:</u></b>  <b>When / how often and for how long should the medicine be taken? (Frequency and duration of use).</b></p>	<p>• When / how often should the medicine be taken?  1. Administer the solution in frequent small volumes  2. Take when you have</p>	<p>1. 7 pt (BP)  2. 7 pt (BP)  3. 7 pt (BP)  4. 7 pt (BP)</p>	<p>1. Not bold  2. Not bold  3. Not bold  4. Bold</p>	<p>1. N  2. N  3. N  4. N</p>	<p>2 (1 to 3)</p>	<p><u>Between Q 4 and Q 5</u>  Not significant  (P = 0,060)  <u>Between Q 4 and Q 6</u>  Significant  (P = 0,000)  <u>Between Q 5 and Q 6</u>  Significant  (P = 0,001)</p>

	<p>diarrhoea (derived from "for the treatment of electrolyte and fluid depletion associated with diarrhoea")</p> <ul style="list-style-type: none"> <li>• How long should the medicine be taken?</li> </ul> <p>3. Take until the diarrhoea has cleared up (derived from</p>					
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	<p>"for the treatment of electrolyte and fluid depletion associated with diarrhoea")</p> <p>4. Take for no longer than 24 hours (derived from "discard unused solution after 24 hours")</p>					
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<p><b><u>Question 6:</u></b> <b>When should this medicine be thrown away? (Expiry of medication).</b></p>	<p>1. Discard unused solution after 24 hours.</p>	<p>1. 7 pt (BP)</p>	<p>1. Bold</p>	<p>2. N</p>	<p>3 (1 to 3)</p>	
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\* The font sizes are estimates in font type Arial

\*\* P-values calculated from the Mann-Whitney test

\*\*\* For protection of the third party, the name of the product is not mentioned

