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**Committee of Experts on the Transport of Dangerous Goods  
and on the Globally Harmonized System of Classification  
and Labelling of Chemicals****Sub-Committee of Experts on the Globally Harmonized  
System of Classification and Labelling of Chemicals****Thirty-sixth session**

Geneva, 5-7 December 2018

Item 4 (b) of the provisional agenda

**Hazard communication:****improvement of annexes 1 to 3 and further  
rationalization of precautionary statements****Proposed changes to Annex 3 to improve medical response  
precautionary statements (P310 to P315)****Transmitted by the expert from the United Kingdom on behalf of the  
informal working group on improving annexes 1, 2 and 3 of the GHS\*****Background**

1. In line with its mandate for the 2017-2018 biennium the informal working group has taken forward work under its Workstream 1: “to develop proposals to rationalise and improve the comprehensibility of hazard and precautionary statements for users, while taking into account usability for labelling practitioners. This may include proposals to rationalise and clarify ambiguous or unhelpful instructional precautionary statements (PS), such as statements relating to medical response and disposal.”
2. This document presents the outcome of work on item 1 in the Group’s workplan (informal document INF.12/Rev.1 (thirty-second session)) where the issue is summarised as: “The precise meaning of the medical response statements (P310-P315) is not clear and manufacturers/suppliers have encountered difficulties in choosing the appropriate wording

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\* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, para. 98 and ST/SG/AC.10/44, para. 14).

from the two options. Translation of the Precautionary Statement and conditions for use has also resulted in discrepancies.”.

3. Specific issues arising from the existing medical response PS include:
  - There are too many;
  - Providing options using a forward slash “/” or three dots “...” has not been successful, as often no choice is made and these notations appear on labels;
  - Access to poison centres (where they exist) varies in different jurisdictions. In some jurisdictions access is restricted to medical staff only whilst in others they are also available to the general public;
  - Although “medical advice” and “medical attention” can be distinguished<sup>1</sup>, in practice the distinction is subtle and not always helpful in providing clear messages for medical response in the event of an incident. Furthermore, translation of these terms into other languages can be problematic<sup>2</sup>.

## Discussion

### Medical response precautionary statements

4. In undertaking its work on medical response statements, the informal working group decided to start with a blank sheet and adopted the following general principles:
  - Keep it simple;
  - Look at a simple matrix of urgency versus seriousness, and consider possible medical response for the four possible combinations of high and low (High High (HH); High Low (HL); Low High (LH); and Low Low (LL));
  - Focus high urgency/high seriousness (HH) response on situations where immediate medical help is needed (acute high hazard), i.e. potentially life-threatening situations;
  - To keep it simple, use the same medical response statement for hazard classes/categories within the three other quadrants (HL, LH and LL) if possible;
  - Consider the following qualifiers for low urgency situations, where appropriate: **if you feel unwell**, or **if exposed or concerned**;
  - Avoid choices or additions for suppliers by not using ‘/’ or ‘...’ (c.f. Poison Centre/doctor/...), where possible;
  - Aim for simple, succinct, translatable and universally understood PS, applicable in all jurisdictions that distinguish the hazard classes and categories requiring immediate/urgent medical help from those requiring less urgent medical help.
5. Figure 1 below brings together the informal working group’s considerations for the new medical response PS and the proposed allocation of the hazard classes and categories.
6. The informal working group agreed that the PS for the chemicals in hazard classes and categories allocated in the High-High (HH) quadrant, i.e. potentially life-threatening, should clearly signal the need for emergency medical help. For many jurisdictions the PS “**Get emergency medical help immediately**” will be sufficient. A challenge was to find a

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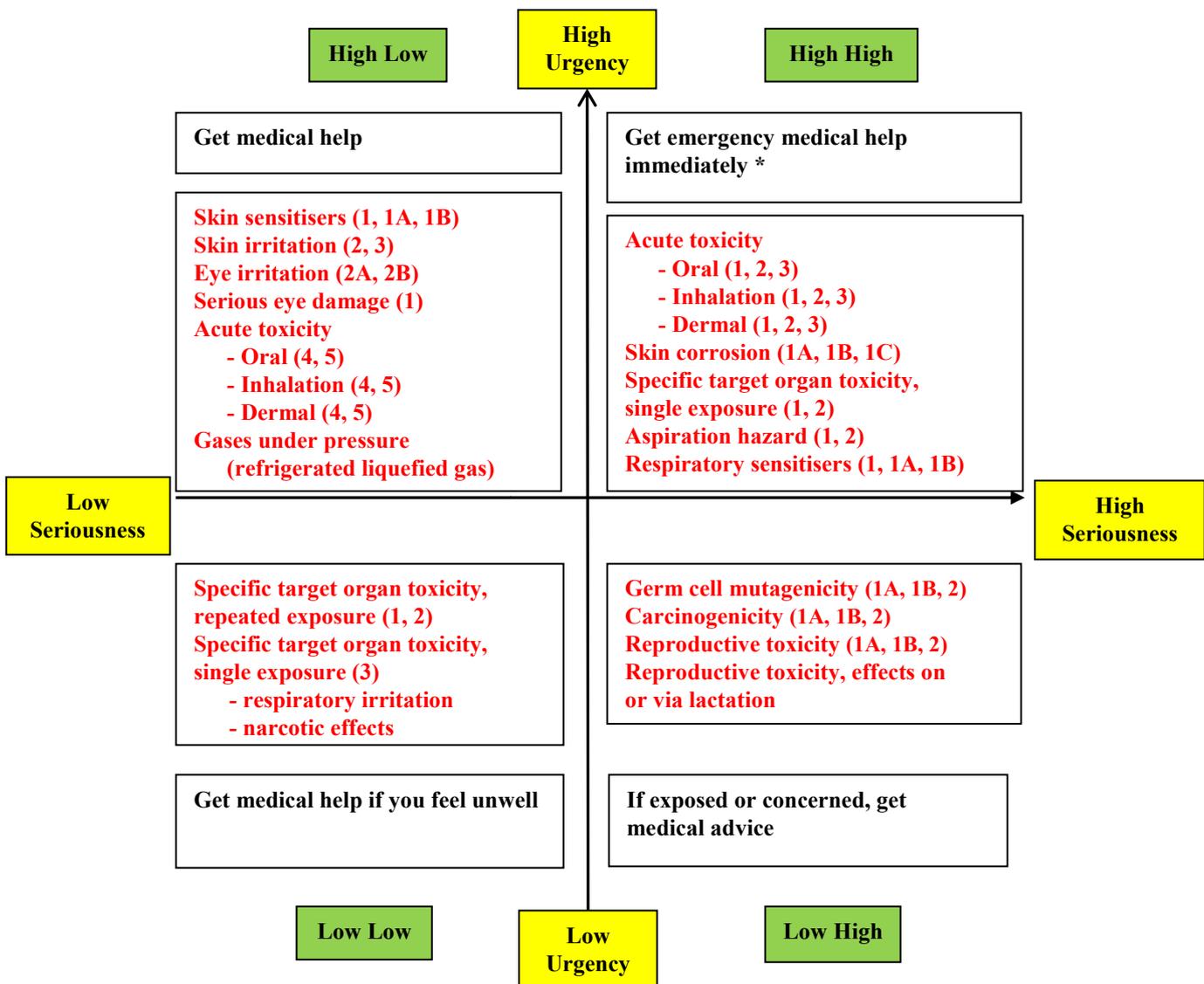
<sup>1</sup> Informal document INF.13 (thirty-second session) – “Medical advice and medical attention”.

<sup>2</sup> Document ST/SG/AC.10/C.4/2016/20 – “Precautionary statements on medical advice/attention: correction of linguistic discrepancies”.

way to indicate more precisely what to do in the emergency situation where this is considered necessary. Noting that in the past providing options using a forward slash “/” or three dots “...” has not been successful in the context of medical response, the informal working group proposes a new approach in Column 5 to permit the use of additional information. This enables the competent authority or manufacturer / supplier to add ‘Call’, followed by the appropriate emergency telephone number for the country or region concerned (e.g. 911, 111 or 999), or by the appropriate provider of emergency medical help, which could be a poison centre, emergency centre, doctor or alternative, in line with the arrangements and organisation of the health services in the country or region concerned.

7. To help ensure that the emergency response services worldwide are focussed where they are most needed, this additional information is applicable to the HH quadrant only.

Figure 1



\* Competent Authority or manufacturer / supplier may add “Call” followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a poison centre, emergency centre or doctor.

8. The informal working group is not aware of any significant problems in translating the four proposed PS for medical response into other languages.
9. Consistent with the current approach, the new PS would always follow the relevant **IF...** PS (P301-P306), sometimes in conjunction with one or more specific actions. Some examples of possible combination statements with the new PS for medical response that suppliers could use in practice are in the Annex of this document.
10. The proposed new PS with the hazard classes/categories to which they are assigned are also shown in the Annex to this paper. The advantages of the proposed PS compared to the existing P310 to P315 are:
- (a) The number of medical response PS is reduced from 6 to 4;
  - (b) The action to take is conveyed more clearly and the potential confusion between ‘medical advice’ and medical attention’ is avoided;
  - (c) The new PS don’t use “/” or “...” and so manufacturers and suppliers don’t have to make difficult choices between options;
  - (d) Where emergency medical help is needed provision has been made to allow competent authorities or manufacturers / suppliers to add additional information specifying the appropriate number to call or the emergency provider to contact.
11. In considering the new medical response PS the informal working group agreed that in the event of accidental exposure to substances and mixtures classified as gases under pressure (refrigerated liquefied gas) or serious eye damage the situation would not generally be potentially life-threatening, and the appropriate response was **“Get medical help”** rather than **“Get emergency medical help immediately”**. The group also agreed that the appropriate response for skin corrosion was **“Get emergency medical help immediately”**. However, to communicate the urgency of appropriate initial action following accidental exposure to substances or mixtures in these hazard classes, a minor change is proposed to P336 for gases under pressure (refrigerated liquefied gas), and a new P354 (a variation of P351) is proposed for serious eye damage (1) and skin corrosion (1, 1A, 1B, 1C). See paragraphs 16 and 17 below.

### **Presentation of the new medical response precautionary statements**

12. In line with advice from the secretariat, to avoid confusion between the existing medical response PS (P310 to P315) in versions of the GHS up to and including the seventh revised edition, it is proposed to delete the current codes P310 to P315 and assign new codes P316 to P319 to the four proposed new medical response PS. For clarity “deleted” is inserted into column 1 of Table A3.2.3 beneath the codes that become obsolete. In addition, some explanatory text is inserted in Annex 3, section 2 (see informal document INF.7).

### **Further changes and rationalisation of precautionary statements**

13. In the proposed new PS for medical response the existing P308, **“If exposed or concerned:”** is incorporated in P318 **“If exposed or concerned get medical advice”** in a similar way to **“... if you feel unwell”** (now part of P314). The proposed new PS P318 is applied to the hazard classes carcinogenic, mutagenic and reprotoxic (CMRs) in line with P308 now. However, P308 is also currently applied to substances or mixtures classified as specific target organ toxicity, single exposure (STOT SE) (1, 2). The informal working group considered that in these cases **“Get emergency medical help immediately”** is the appropriate medical response. As the routes of exposure for classification as STOT SE (1, 2)

are often not known or available, P308 is retained for this hazard class and categories. However, P308 + P313, which applies only to CMRs, can be deleted.

14. P308 is also needed to retain the existing provision to replace three or more routes of exposure (P301 to 306) in combination with the same medical response statement with **“IF exposed or concerned:”**.

15. P302 **“IF ON SKIN”** and P303 **“IF ON SKIN (or hair)”** are also rationalised. P303 currently applies to substances or mixtures classified as flammable liquids (1 - 3) and skin corrosion (1, 1A, 1B, 1C). For increased clarity of the action required in the event of accidental exposure to substances and mixtures with these hazard classes and categories, the informal working group considered that it would be more appropriate for skin corrosion (1, 1A, 1B, 1C) to be added to P302 and flammable liquids (1 - 3) to be retained under P303. It was noted that the three response PS which refer to rinse or wash with water (P351, P352 and P353), none refer to hair and only P353 mentions skin, even though P353 is linked to P303 in the combination statement **“IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]”** (P303 + P361 + P353). The informal working group considered it necessary to amend P353 so it applies to any region of the body that may be affected. The proposed amended P353 is: **‘Rinse affected areas with water [or shower]’**.

16. To communicate the urgency of appropriate initial action following accidental exposure to substances or mixtures classified as gases under pressure (refrigerated liquefied gas), a minor change is proposed to add ‘Immediately’ at the start of P336 so the PS reads: **“Immediately thaw frosted parts with lukewarm water. Do not rub affected area”**.

17. Finally, and again to communicate the urgency of appropriate initial action following accidental exposure to substances or mixtures classified as serious eye damage (category 1) or skin corrosion (1, 1A, 1B, 1C), the informal working group also proposes to remove these hazard classes/categories currently assigned to P351 and create a new P354 applicable only to serious eye damage (category 1) and skin corrosion (1, 1A, 1B, 1C). The proposed new P354 is **‘Immediately rinse with water for several minutes’**.

## Proposal

18. The Annex to this paper sets out the proposed new PS for medical response, and illustrates how they would typically appear in combination with other PS on labels.

19. Other changes in the proposal are to:

- (a) Make the conforming changes in Table A3.2.3 to combination PS including medical response;
- (b) Delete the response precautionary statements, hazard classes, hazard categories and associated column 5 entries for the following PS from Table A3.2.3, and insert **“deleted”** in column 1 below each of the codes: P310, P311, P312, P313, P314, P315;
- (c) Delete the following combined PS entry from Table A3.2.3: P308 + P313;
- (d) Delete the hazard classes / categories for carcinogenic, mutagenic and reprotoxic (CMRs) as listed under P308 in Table A3.2.3;
- (e) Move the hazard classes / categories for skin corrosion (1, 1A, 1B, 1C) as listed under P303 to P302 in Table A3.2.3;
- (f) Make the conforming changes to combination PS including P303;

- (g) Amend the PS entries in Table A3.2.3 for P336 and P353 (new text underlined and text is shown in ~~striketrough~~) as follows:
- i. For P336: **Immediately thaw**~~Thaw~~ **frosted parts with lukewarm water. Do deleted not rub affected area.**
  - ii. For P353: **Rinse affected areas** ~~skin~~ **with water [or shower].**
- (h) Make the conforming changes to combination PS that include P336 or P353;
- (i) Amend the PS entry for P351 in Table A3.2.3 to remove the entries for serious eye damage (category 1) and skin corrosion (1, 1A, 1B, 1C);
- (j) Introduce a new PS entry ‘P354’ in Table A3.2.3 for serious eye damage (category 1) and skin corrosion (1, 1A, 1B, 1C): **‘Immediately rinse with water for several minutes’**;
- (k) Introduce a new combination statement in Table A3.2.3 for P305+P354+P338: **‘IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.’**;
- (l) Amend A3.2.3.5 of Annex 3, section 2 to cover provision of additional information as appropriate (new text underlined):
- “A3.2.3.5 In cases where additional information is required, or information either has to be or may be specified, this is indicated by a relevant entry in column (5) in plain text.”
- (m) Insert a new paragraph A.3.2.3.9 in Annex 3, Section 2 on deleted codes:
- “A3.2.3.9 Where precautionary statements become obsolete, **“deleted”** is inserted under the existing code in column 1 of the tables in this Section to avoid potential confusion between codes used in different editions of the GHS.”
- (n) Replace A3.3.2.4 in Annex 3, Section 3, “Application of precautionary statements concerning medical response” with the corresponding text in informal document INF.7;
- (o) Make the necessary conforming amendments to the matrix of PS by hazard class/category in Annex 3, Section 3.
20. Informal document INF.7 sets out the changes in full. New text is shown in red. Deleted text is shown in ~~striketrough~~.

## Action requested

21. The Sub-Committee is invited to agree to the proposed changes to Annex 3, sections 2 and 3 as set out in paragraphs 18 to 19 above and in informal document INF.7.

## Annex

### Proposed new medical response statements, hazard classes/categories allocation and conditions for use

Code (1)	Response precautionary statements (2)	Hazard class (3)	Hazard category (4)	Conditions for use (5)
P316	<b>Get emergency medical help immediately.</b>	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Competent Authority or manufacturer / supplier may add, 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.
		Acute toxicity, dermal (chapter 3.1)	1, 2, 3	
		Acute toxicity, inhalation (chapter 3.1)	1, 2, 3	
		Skin corrosion (chapter 3.2)	1, 1A, 1B, 1C	
		Respiratory sensitization (chapter 3.4)	1, 1A, 1B	
		Specific target organ toxicity, single exposure; (chapter 3.8)	1, 2	
		Aspiration hazard (chapter 3.10)	1, 2	
P317	<b>Get medical help.</b>	Gases under pressure (chapter 2.5)	Refrigerated liquefied gas	
		Acute toxicity, oral (chapter 3.1)	4, 5	
		Acute toxicity, dermal (chapter 3.1)	4, 5	
		Acute toxicity, inhalation (chapter 3.1)	4, 5	
		Skin irritation (chapter 3.2)	2, 3	
		Serious eye damage (chapter 3.3)	1	
		Eye irritation (chapter 3.3)	2/2A, 2B	
P318	<b>If exposed or concerned, get medical advice.</b>	Skin sensitization (chapter 3.4)	1, 1A, 1B	
		Germ cell mutagenicity (chapter 3.5)	1, 1A, 1B, 2	
		Carcinogenicity (chapter 3.6)	1, 1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1, 1A, 1B, 2	
P319	<b>Get medical help if you feel unwell.</b>	Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	
		Specific target organ toxicity, single exposure; respiratory tract irritation (chapter 3.8)	3	
		Specific target organ toxicity, single exposure; narcotic effects (chapter 3.8)	3	
		Specific target organ toxicity, repeated exposure (chapter 3.9)	1, 2	

## Examples of how the proposed new medical response statements would appear in practice on labels

1. For substances or mixtures classified as aspiration hazard, categories 1 or 2:

**IF SWALLOWED: Get emergency medical help immediately\*. (P301 + P316)**

\* Provision to add 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.

2. For substances or mixtures classified as acute toxicity, inhalation, category 5:

**IF INHALED: Get medical help. (P304 + P317)**

3. For substances or mixtures classified as skin sensitiser, category 1, 1A or 1B:

**If skin irritation or rash occurs: Get medical help. (P333 + P317)**

4. For substances or mixtures classified as serious eye damage, category 1:

**IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help. (P305 + P354 + P338 + P317)**

5. For substances or mixtures classified as skin corrosive, category 1, 1A, 1B or 1C:

**IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get emergency medical help immediately\*. (P301 + P330 + P331 + P316)**

\* Provision to add 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.

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