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Evaluation of the overdosage section in summaries of the product characteristics for medicines responsible for exposure calls to the Belgian Poison Centre

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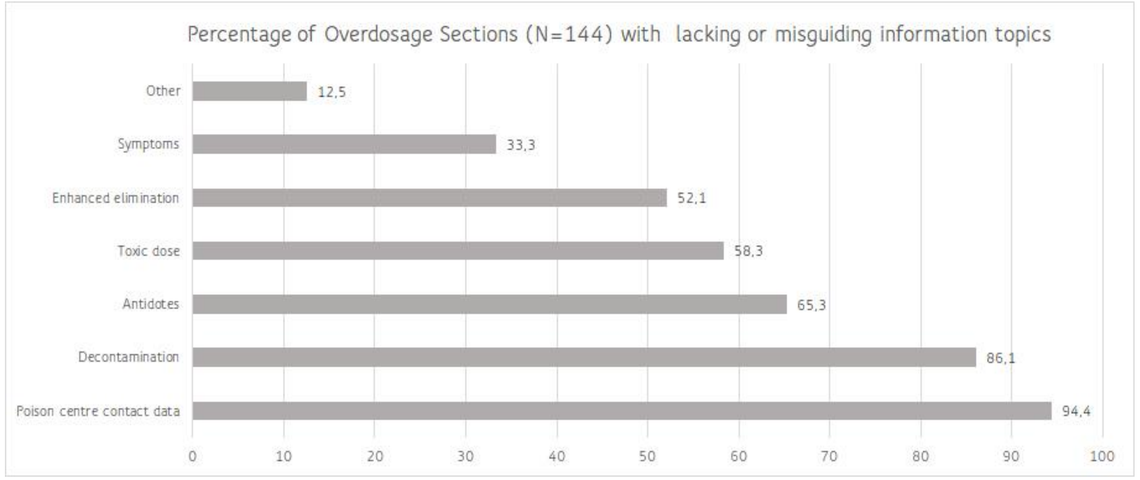
Objective

To evaluate the overdosage sections (OS) in the summaries of the product characteristics (SmPC) from all medicines containing one of the 25 active pharmaceutical ingredients (API) most responsible for medication exposure calls to the Belgian Poison Centre (BPC) in 2019.

Methods

SmPC were retrieved from the national competent authority's website. Then the information in its OS about decontamination, antidotes, enhanced elimination, symptoms to expect, toxic dose, poison centres contact data or other relevant issues was evaluated for presence and consistency with up-to-date clinical toxicology practice guidelines.



Results

The BPC received 9,764 medication exposure calls for the 25 API on a total of 21,077 in 2019. These API were present in 144 officially authorised medicines.

In the 144 corresponding SmPC, 86.1 % (N=124) of the OS had no or misguiding information about decontamination techniques as induce vomiting, gastric lavage or activated charcoal. Additionally, 65.3 % (N=94) lacked or had incomplete information about antidotes like the use of insulin/glucose and L-carnitine or the contraindications of flumazenil. Similarly 52.1 % (N=75) had absent information about enhanced elimination techniques or suggested to apply them despite they are ineffective.

Though 66.7 % (N= 96) cited the correct symptoms to expect, 33.3% (N=48) did not mention toxidromes like serotoninergic syndrome or neuroleptic malignant syndrome or lacked important symptoms like hyperthermia, hepatitis or hyperammonaemia. Furthermore 12.5 % (N=18) had misguiding information about blood analyses, half-life or treatment options. Correct information about the toxic dose was cited by 41.7 % (N=60) of the OS.

Finally 94.4% (N=136) did not suggest to contact the BPC in case of overdosage. Complete contact data for the BPC were given in 2.8 % (N=4) of all the OS.

Conclusion

Important information was found to be lacking, incomplete or misguiding in the OS of the SmPC from medicines containing one of the 25 API most responsible for medication exposure calls to the BPC in 2019. Lacking or misguiding information can influence the management of overdosages by healthcare professionals. The marketing authorisation holders should thus revise their OS accordingly. Poison centres or clinical toxicologist can thereby have an advisory role.

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