



Statement on Off-label use of medicines by anaesthesiologists

“Off-label” use of a medicine can be defined as the use of the medicine:

- For an indication not specified in the product information (PI) supplied by the manufacturer
- In a different population to that intended by the manufacturer (e.g. children)
- At a different dose or in a different population to that recommended in the PI
- Via a different route of administration to that specified in the PI

In many countries, product information, which includes recommendations on indications, dosage, routes of administration and intended recipient populations, are subject to an approval process by regulatory bodies (e.g. governments, health services), often at great expense. There may be impediments to producing up to date product information on the safe use of all medicines, as the body of knowledge of particular drug uses is always evolving.

The World Federation of Societies of Anaesthesiologists (WFSA) supports the statement of the United States Food and Drug Administration on “Off-label Use of Drugs” which states “If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects” (1).

The WFSA maintains that the term “off-label” does not imply improper, illegal or contraindicated use.

The WFSA calls on national therapeutic regulatory bodies and hospital administrations to work with drug manufacturers to provide up to date product information wherever possible.

A decision to use a medicine off label should be based on the risks and benefits for each patient, after considering evidence and expert opinion, anaesthesiologists should document any adverse events.

This statement was developed by the WFSA's Safety & Quality and Paediatric Anaesthesia Committees in February 2016.

References

- (1) "Off-Label" and Investigational Use Off Marketed Drugs, Biologics, and Medical Devices - Information Sheet. U.S. FDA 2014.
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>