

SUPPLEMENTARY DATA: ONLINE RESOURCE 1

Development and preliminary evaluation of an assessment of the age-appropriateness/age-inappropriateness of formulations used in children

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Table S1. Age-appropriate assessment outcome categories

Top Level Assessment Outcome	AaF Assessment Code
Product Unassessable	U
Medical Device (includes any manipulations needed)	MD
Age-Appropriate Formulation (including permitted manipulations)	AaF
Maybe Age-Appropriate Formulation (Off-label including permitted manipulations)	M (OL)
Maybe Age-Appropriate Formulation (Unlicensed including permitted manipulations)	M (UL)
Age-inappropriate Formulation (Off-label with unauthorised manipulations)	AiF (OL)
Age-inappropriate Formulation (Unlicensed with unauthorised manipulations)	AiF (UL)

Table S2. Detailed age-appropriate assessment outcome sub-categories

Detailed Assessment Outcome Result
Product Unassessable (U) - Manufacturer Unknown
Product Unassessable (U) - Missing Information
Product Unassessable (U) - Other (Specify) >>> SEND TO PANEL
Medical Device (MD) - Suitable Product (No issues)
Medical Device (MD) - Product Required Manipulation
Medical Device (MD) - Other (Specify) >>> SEND TO PANEL
AaF - Authorised Medicine (Paediatric Indication covered by MA)
AaF - Authorised Medicine (Paediatric Indication covered by MA using Permitted Manipulation)
AaF - Authorised Medicine (OK once issue resolved + Paediatric Indication covered by MA)
AaF - Authorised Medicine (OK once issue resolved + Paediatric Indication covered by MA using Permitted Manipulation)
M (OL) - DF OK / No Manipulation Required
M (OL) - DF OK / Permitted Manipulation Used (<i>Record source used - Manufacturer only</i>)
M (OL) - DF OK / Added to Milk Feed (Neonate/Infants)
M (OL) - Other (Specify) >>> SEND TO PANEL
M (UL) - DF OK / No Manipulation Required
M (UL) - DF OK / Permitted Manipulation Used (<i>Record source used - Manufacturer only</i>)
M (UL) - DF OK / Added to Milk Feed (Neonate/Infants)
M (UL) - Other (Specify) >>> SEND TO PANEL

Detailed Assessment Outcome Result
AiF (OL) - DF Issue
AiF (OL) - DF Issue + Added to Milk Feed (Neonate/Infants)
AiF (OL) - DF Issue (via Enteral Tube)
AiF (OL) - DF Issue (via Enteral Tube) + Added to Milk Feed (Neonate/Infants)
AiF (OL) - DF Issue + Added to Food (Ease of Administration)
AiF (OL) - DF Issue + Added to Food (Palatability Issue / Taste Masking)
AiF (OL) - DF Issue + Added to Food (Reason Unknown)
AiF (OL) - DF Issue + Added to Drink (Ease of Administration)
AiF (OL) - DF Issue + Added to Drink (Palatability Issue / Taste Masking)
AiF (OL) - DF Issue + Added to Drink (Reason Unknown)
AiF (OL) - DF Issue + Addition to Thickener (Swallowing Issue)
AiF (OL) - DF Issue + Addition to Thickener (Swallowing Issue) + Added to Drink (Ease of administration)
AiF (OL) - Patient Preference
AiF (OL) - Medicine Refused
AiF (OL) - Added to Food (Ease of Administration)
AiF (OL) - Added to Food (Palatability Issue / Taste Masking)
AiF (OL) - Added to Food (Reason Unknown)
AiF (OL) - Added to Drink (Ease of Administration)
AiF (OL) - Added to Drink (Palatability Issue / Taste Masking)
AiF (OL) - Added to Drink (Reason Unknown)
AiF (OL) - Mixed with other medicine(s)
AiF (OL) - Addition to Thickener (Swallowing Issue)
AiF (OL) - Convenience
AiF (OL) - Compliance / Adherence Issue
AiF (OL) - Standard Practice / Policy Manipulation
AiF (OL) - Other (Specify) >>> SEND TO PANEL
AiF (UL) - DF Issue
AiF (UL) - DF Issue + Added to Milk Feed (Neonate/Infants)
AiF (UL) - DF Issue (via Enteral Tube)
AiF (UL) - DF Issue (via Enteral Tube) + Added to Milk Feed (Neonate/Infants)
AiF (UL) - DF Issue + Added to Food (Ease of Administration)
AiF (UL) - DF Issue + Added to Food (Palatability Issue / Taste Masking)
AiF (UL) - DF Issue + Added to Food (Reason Unknown)
AiF (UL) - DF Issue + Added to Drink (Ease of Administration)
AiF (UL) - DF Issue + Added to Drink (Palatability Issue / Taste Masking)
AiF (UL) - DF Issue + Added to Drink (Reason Unknown)
AiF (UL) - DF Issue + Addition to Thickener (Swallowing Issue)
AiF (UL) - DF Issue + Addition to Thickener (Swallowing Issue) + Added to Drink (Ease of administration)
AiF (UL) - Patient Preference
AiF (UL) - Medicine Refused
AiF (UL) - Added to Food (Ease of Administration)
AiF (UL) - Added to Food (Palatability Issue / Taste Masking)
AiF (UL) - Added to Food (Reason Unknown)

Detailed Assessment Outcome Result
AiF (UL) - Added to Drink (Ease of Administration)
AiF (UL) - Added to Drink (Palatability Issue / Taste Masking)
AiF (UL) - Added to Drink (Reason Unknown)
AiF (UL) - Mixed with Other Medicine(s)
AiF (UL) - Addition to Thickener (Swallowing Issue)
AiF (UL) - Convenience
AiF (UL) - Compliance / Adherence Issue
AiF (UL) - Standard Practice / Policy Manipulation
AiF (UL) - Other (Specify) >>> SEND TO PANEL
UNCLEAR - Send to Panel (For Discussion)