

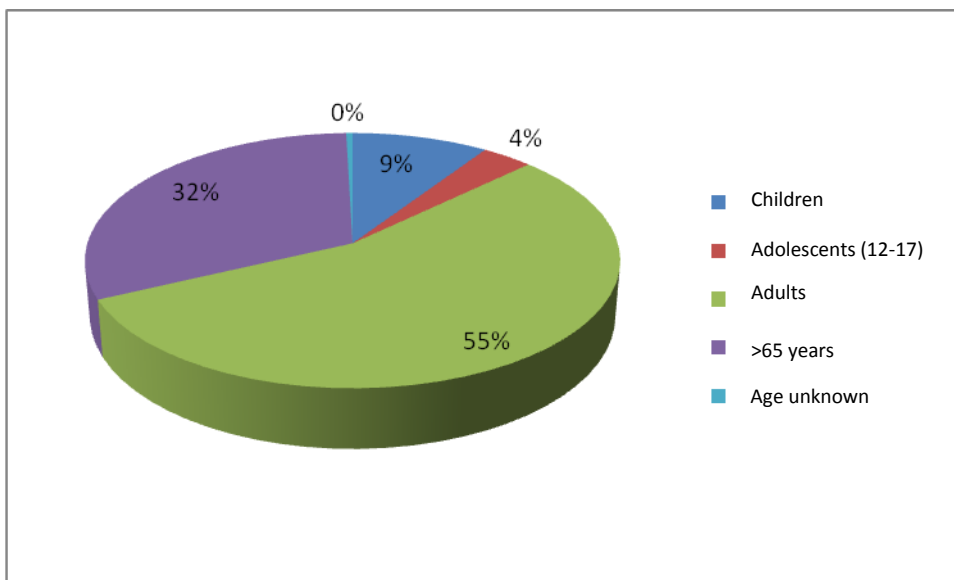
VOLUNTARY REPORTING OF SUSPECTED ANTIBIOTIC ADVERSE EVENTS FROM 2001 TO 2008

From 1 January 2001 to 6 November 2008, 6411 reported events have been inserted in the Drug Surveillance of the adverse reactions from systematic use of different classes of antibiotics from a total of 61 273 entries.

Graphic 1: Distribution by age

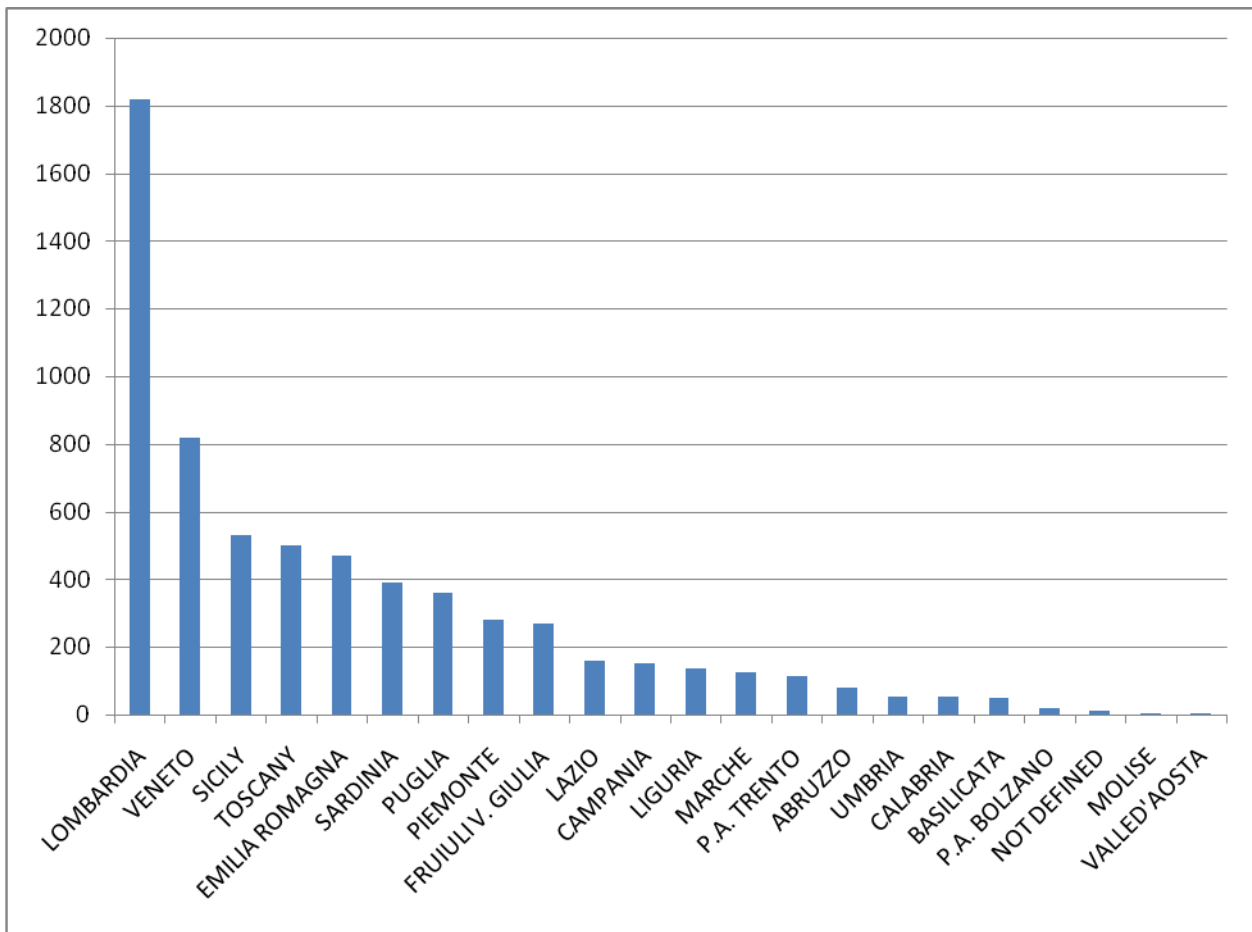
Year	Total Entries
2001	902
2002	969
2003	747
2004	625
2005	563
2006	659
2007	1090
2008	856

Graphic 2: Distribution by age.



In regards to the reporting, more than half, namely 54%, originate from hospital physicians and 29% from General Practitioners, with a minor number from other health specialists (6.6%), pharmacists (5.4%), pediatricians (1.7%), and nurses (1.5%). The remaining 2% of the cases are from other health care operators, with a minimal number from patients and pharmaceutical companies.

Graphic 3: Number of adverse events by region



2375 cases have been defined serious and 2937 as non-serious, the remaining 1099 not being defined. The reporting the most common types of administration, 70% were oral, 15% by intravenous injection and 7% intramuscular.

The drugs principally reported were the beta-lactam antibiotics followed by quinolones. In terms of action typologies, cutaneous and/or allergic were the most frequently reported.

The below table reports the principal adverse reactions for the considered period that were in excess of 100 cases.

Condition	Reported Total
Urticaria	1 342
Erythema	622
Cutaneous exanthema	494
Pruritus	424
Angioedema	241
Dyspnea	233
Maculo-papular rashes	212
Vomiting	195
Anaphylactic Shock	192
Dermatitis	189
Diarrhoea	184
Erythematous eczema	180
Tendinitis	165
Nausea	139
Generalised pruritus	132
Hypotension	111