Extemporaneously compounded oral medicines in UK hospital pharmacies

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Background

Pharmaceutical compounding in the UK corresponds to the extemporaneous preparation of medicines in community and hospital pharmacies and also to the manufacture of specials by licensed hospital manufacturing units and pharmaceutical industries. The extemporaneous preparation of medicines is becoming less common in the UK (Marriott et al., 2010) and it has been considerably replaced by the use of specials (Tuleu et al., 2003). SPECIALS are manufactured in accordance to GMP whereas EXTEMPORANEOUS PREPARATIONS may be prepared in accordance to less strict standards and, therefore, specials are regarded as a quality-assured alternative to extemporaneous preparations. Both specials and extemporaneous preparations are known as UNLICENSED MEDICINES in the UK (Carvalho, 2012).

Methods

In order to identify and characterise the oral compounded medicines (extemporaneous preparations and specials) most frequently dispensed in the UK hospital pharmacies, a self-completion questionnaire was developed and distributed to a purposive sample of 36 hospitals (including 7 paediatric hospitals and 25 licensed hospital manufacturing units). The questionnaire included 2 Excel tables, for both extemporaneous preparations and specials, in which data regarding the active substance(s), strength(s), dosage form, pack size and number of times dispensed, were collected for the most frequently dispensed oral compounded medicines. All hospitals were contacted by email during 2007 and data collection referred to the previous year (Carvalho, 2012).

Results and Discussion

A total of 20 hospitals, located across England and Wales, responded to the request for collaboration (Figure 1). The oral specials reported were produced in the manufacturing units of the hospital pharmacies and/or bought from other specials manufacturers. Almost all unlicensed medicines dispensed included only one active substance (single drug). The most frequently dispensed dosage form was oral liquids, in a total of 50,571 units, which represented over 95% of all unlicensed medicines dispensed (both extemporaneous preparations and specials) (Figure 2). Oral liquids were dispensed by all hospitals and included solutions, suspensions, mixtures and syrups. The top 5 oral liquids are displayed in Table 1. Overall, specials were dispensed in much larger quantities than extemporaneous preparations but these were reported in a greater range of strengths. This was expected since specials are produced in batches and, therefore, in order to optimise costs, specials manufacturers are interested in producing selected strengths only (Carvalho, 2012).

Conclusions

Although extemporaneous preparations are associated with more risks than specials, the evident large scale production of specials is of concern since these medicines are unlicensed and, therefore, their quality, safety and efficacy has not been accessed by the MHRA. Further research is necessary to identify and characterise the specials prepared at specials manufacturers in the UK so that the most frequently dispensed specials are prioritised for standardisation in the British Pharmacopoeia or encouraged for licensing in the authorities (Carvalho, 2012).

Reference


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