Important notes: You **MUST** use this template. Do **NOT** enter author and affiliation on this form, you will be able to enter this information online when you submit the abstract. Do **NOT** write outside the boxes or alter this form by deleting parts of it (including this text). Please cut and paste abstract in the box below including tables. The abstract should consist of: **Focal Points, Introduction, Methods, Results, Discussion** and **References**. No more than two references may be cited and references must be typed in Times New Roman 9 point.

Title:

Use of unlicensed medicines by prescribers, pharmacists and patients across primary and secondary care: A qualitative study

Abstract: (Please refer to instructions to authors and example abstract)

Focal Points:

- This study aimed to explore perceptions of healthcare professionals and patients about the use of unlicensed medicines (ULMs)
- Education and training of healthcare professionals is likely to be a key enabler in improving use of ULMs
- This study revealed differences in perceptions between patients and professionals, and across care settings

Introduction:

An unlicensed medicine (ULM) is a product which does not have a marketing authorisation from the MHRA[1]. Areas that have not previously been explored include; how and why prescribers choose to initiate them, how and where pharmacists source them, patient use and awareness of ULMs. This research study aimed to explore the perceptions of healthcare professionals and patients on the use of ULMs.

Methods:

Semi-structured face-to-face interviews were conducted with prescribers (n=11), pharmacists (n=10) and patients (n=7) from primary and secondary care. A theoretical sampling approach was used; grounded theory analysis led to the development of themes and informed participant selection. Interviews were audio recorded and transcribed verbatim. Themes were presented back to participants (n=8) using two focus groups (healthcare professionals and patients separately). Ethical approvals from the NHS and University were obtained prior to completion of this research.

Results:

All interviewees had experience of either; prescribing, reviewing, dispensing or taking unlicensed medicines. Participants discussed several ULM scenarios including imported medicines, 'Specials', food supplements, 'off-label' use of medicines and investigational medicinal products. Several themes were identified across the data by healthcare professionals and patients in primary and secondary care, including:

- Healthcare professionals' awareness of when they were using an ULM and their definition of an ULM
- Perceptions of safety of ULMs was elicited, including the lack of safety and efficacy data compared to licensed products and the perceived under-reporting of adverse effects
- Provision of information and whether patients were likely to be informed about the unlicensed status of their medicines, who the person to inform them should be and what information patients would want
- The place of unlicensed medicine use in the clinical management of a patient, including whether licensed alternatives were tried first
- Trust as an important aspect in the use of unlicensed medicines, this was apparent throughout the interviews and between all actors

Lack of education and training for healthcare professionals around what an ULM is and the associated implications of their use, coupled with a lack of information seems to perpetuate problems identified in the use of ULM. Cost implications associated with ULMs was a strong theme among primary care participants, however, many secondary care participants lacked an awareness of the associated costs which could lead to under-utilisation of viable alternatives. Costly and burdensome regulatory processes for medicines licensing were often cited for the use of ULMs and seemed to legitimise their routine use in practice.

Discussion:

The lack of marketing authorisation creates many issues in the use of ULMs, including a lack of access to information and reduced intelligence around their safety and efficacy. Despite this they are generally perceived as safe. The regulatory implications of using ULMs and the potential variability between products, does not seem to be well understood. Consideration of how the patient will use the medication and the provision of suitable written information seems to be inconsistently considered. There is a need for training and the development of mutually agreed standards on the use of ULMs to inform a more consistent approach to their use by both healthcare professionals and patients. The study was limited by only being able to include those who were willing to participate.

References:

1.MHRA. Guidance note 14: The supply of unlicensed medicinal products ("specials"). 2014. http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con413520.pdf (Accessed 21 March 2016)