

## Specials prescribing briefing

### Key recommendations

- Before prescribing a special consider if a medicine is needed at all.
- If a medicine is required, a stepped approach is suggested to choose an appropriate preparation, especially where an adult has difficulties swallowing:
  1. Licensed medicines administered as intended.
  2. Licensed medicines administered in an unlicensed manner.
  3. Imported products.
  4. Special-order products.
- A special should only be prescribed when there is no available licensed medicine which fully meets the patient's clinical needs.
- Decisions about the prescribing of specials should be based on professional judgment and an understanding of individual patient need as accountability for prescribing a special rests with the prescriber.
- Review patient's prescribed specials to ensure that a special is (and remains) the most appropriate option.

### Background

A special is an unlicensed medicine that does not have a UK Marketing Authorisation (MA).<sup>1</sup> Medicines used outside the terms of their MA are also an unlicensed ('off-label') use.<sup>1,2</sup> Imported products are unlicensed medicinal products sourced from outside the UK under an importers licence issued by the Medicines and Healthcare products Regulatory Agency (MHRA).<sup>3</sup> A special may only be supplied when there is no available licensed medicine which fully meets the patient's clinical needs. They can be prescribed when it is judged by the prescriber and agreed with the patient or carer that, on the basis of available information, a special is the most appropriate option for the patient.<sup>1</sup>

### Savings

In England, £49 million is spent annually on prescribing specials (NHSBSA (June to August 2022)).

A 10% reduction in spend on specials across England **could result in annual savings of £4.9 million. This equates to £7,974 per 100,000 population.**

### Considerations when prescribing specials

- The prescriber should be able to justify and feel competent in using such medicines.<sup>2</sup> However, with unlicensed specials there are additional considerations for prescribers and supplying pharmacists in any care setting:
  - » Licensing – Unlicensed specials are not assessed through the MHRA MA process and so they have not been assessed as meeting appropriate standards of quality, safety and efficacy. Only holders of Manufacturer (Specials) (MS) licence may manufacture specials. The MHRA inspects MS licence holders' premises and processes to ensure they are fully compliant with Good Manufacturing Practice (GMP). However, there is no formal assessment and approval of the formulation, manufacturing method or stability of individual specials.<sup>1</sup>
  - » Legal - The responsibility for prescribing rests with the prescriber who signs the prescription- this is shared with the supplying pharmacist. Good practice guidance to support prescribers is available from the GMC in prescribing unlicensed medicines.<sup>4</sup> The Royal Pharmaceutical Society (RPS) outlines what pharmacists should consider when supplying a UK special manufactured by an MS licence holder.<sup>1</sup>
  - » Patient information – Patient and/or carers need to be provided with information either written or verbal to support shared decision making. However, patient information leaflets are not routinely available for specials.<sup>5</sup> Examples of resources to support information sharing include:
    - o The Royal College of Paediatrics and Child Health - Medicines for Children.
    - o The British Pain Society published - Use of medicines outside of their UK marketing authorisation in pain management and palliative medicine.
  - » Quality – As specials can be obtained from a range of suppliers and are not all manufactured in the same way, the quality, bioavailability and consistency of specials can vary even where the same product is prescribed.<sup>5</sup>
  - » Identifying a special - It can be difficult to identify a special at the point of prescribing.<sup>5</sup> Pharmacists have a professional responsibility to liaise with the prescriber and the patient or carer to ensure that a special is (and remains) the most appropriate choice.<sup>1</sup>
- The RPS describe five principles for the prescribing, procurement and supply of specials: Establish the optimal treatment for the patient; Understand the patient's experience and make a shared decision; Identify a preparation and a supplier; Monitor the patient and review the need for a special; Ensure effective governance is in place.<sup>1,5</sup>

## References

1. Royal Pharmaceutical Society of Great Britain. Professional Guidance for the Procurement and Supply of Specials. December 2015. <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf>
2. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. October 2022. <https://www.medicinescomplete.com/>.
3. NHS Business Services Authority. Drug Tariff. October 2022. <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>
4. General Medical Council. Prescribing unlicensed medicines. April 2021. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>
5. Royal Pharmaceutical Society of Great Britain. Prescribing specials. April 2016. <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/professional-standards---prescribing-specials.pdf>

Additional resources available	Bulletin	<a href="https://www.prescqipp.info/our-resources/bulletins/bulletin-301-specials-prescribing/">https://www.prescqipp.info/our-resources/bulletins/bulletin-301-specials-prescribing/</a>
	Tools	
	Data pack	<a href="https://data.prescqipp.info/views/B301_Specialsprescribing/FrontPage?%3Aembed=y&amp;%3Aiid=1&amp;%3AisGuestRedirectFromVizportal=y">https://data.prescqipp.info/views/B301_Specialsprescribing/FrontPage?%3Aembed=y&amp;%3Aiid=1&amp;%3AisGuestRedirectFromVizportal=y</a>

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