

# EXEMPLAR

## EPA- 2 Compounding Pharmaceutical Products

**Key themes** Compounding workflow, dosage form modification, extemporaneous dispensing, quality assurance

### Scenario in prose

Doris Roberts, presents a prescription for her daughter Marika (13 months old, 9kg) for omeprazole, prescribed for suspected acid reflux. The intern and preceptor agree this would be a good opportunity for a Short Practice Observation (SPO) of compounding.

### History of presentation

Marika has a history of colic, and her parents say she is a 'fussy eater'. Recently Marika appears to have a sore stomach and has been grumpy in the evening. Her parents have been trialling *Gaviscon Infant* sachets for the last couple of weeks following advice from a doctor, which has improved some of the symptoms, but the effect is short-lived. The symptoms last night were 'particularly bad'.

Doris and Marika have just seen a doctor, who has prescribed omeprazole daily for 2 to 4 weeks before the next review. The doctor counselled about the medicine in detail, but did not describe the formulation or how to administer it. Doris plans to collect the product later today.

### Medications

\* *Gaviscon Infant* (sodium alginate 225mg & magnesium alginate 87.5mg) sachets - 2 sachets mixed in water after dinner

### Patient information

- Marika Roberts
- 13 months old
- 9kg, weighed this morning

### Medical history, including allergies and adverse drug reactions

- Reflux. Suspected Gastro-oesophageal Reflux Disease (GORD)
- No known drug allergies.

## Prescription order received

<p>Dr Kirk McSwain (Medical Practitioner) Suite 111 The Boulevard Pharmville NSW 2300 Prescriber no. 444XXX</p>	<p>Dr Kirk McSwain (Medical Practitioner) Suite 111 The Boulevard Pharmville NSW 2300 Prescriber no. 444XXX</p>
<p>Patient's Medicare no. _____</p> <p>Pharmaceutical benefits entitlement no. _____</p> <p><input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box) <input type="checkbox"/> Concessional or dependent RPBS beneficiary or PBS Safety Net concession cardholder</p>	<p>Patient's Medicare no. _____</p> <p>Pharmaceutical benefits entitlement no. _____</p> <p><input type="checkbox"/> PBS Safety Net entitlement cardholder (cross relevant box) <input type="checkbox"/> Concessional or dependent RPBS beneficiary or PBS Safety Net concession cardholder</p>
<p>Patient's name Address Marika Roberts 17 Stanley Ave Bolton Point NSW 2283</p>	<p>Patient's name Address Marika Roberts 17 Stanley Ave Bolton Point NSW 2283</p>
<p>Date PBS <input type="checkbox"/> RPBS <input type="checkbox"/> Brand substitution not permitted</p>	<p>Date PBS <input type="checkbox"/> RPBS <input type="checkbox"/> Brand substitution not permitted</p>
<p><b>Pharmacist patient COPY</b></p> <p>Omeprazole tablets 10mg (30) f/h suspension 5mg nocte. Review in one month KMcSwain</p> <p>If not a Medical Practitioner, tick your prescriber type: Dentist <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Midwife <input type="checkbox"/> Optometrist <input type="checkbox"/></p> <p>Prescriber to sign original and duplicate</p>	<p><b>Medicare / DVA</b></p> <p>Omeprazole tablets 10mg (30) f/h suspension 5mg nocte. Review in one month KMcSwain</p> <p>I declare that I have received this/these medicine(s) and the information relating to any entitlement to a pharmaceutical benefit is correct.</p> <p>Patient's or agent's signature _____ Date of supply _____</p> <p>Agent's address _____</p> <p>PB023.1711</p>

Performance Outcomes (PO)<sup>1</sup> to be demonstrated

Performance outcome(s)	Description
3.15	Preparing and supplying extemporaneously compounded medications safely and accurately in accordance with current legislation, scope of practice, PharmBA Guidelines and other relevant jurisdictional requirements.
4.2	Identifying and acknowledging professional limitations and seeking appropriate support where necessary, including additional professional education and/or referral of patients to other health care professionals.
5.3	Recognising and responding to the inherent complexity, ambiguity and uncertainty of contemporary and future professional practice.

<sup>1</sup>The activity may also provide evidence relating to other performance outcomes and this should be recorded in the 'Intern assessment and feedback form'

Key activities undertaken during short practice observation

<p><b>Decision making phase</b></p> <p><i>Intern discusses their thought process as they determine the safety/appropriateness of the prescription with the preceptor.</i></p>	<p>The intern:</p> <ul style="list-style-type: none"> <li>• Checks the prescription for legality, validity and completeness – the administration instructions are unclear.</li> <li>• Confirms the suitability of the indication and dose in the Australian Medicines Handbook (AMH).</li> <li>• Checks no suitable proprietary product is available.</li> <li>• Checks the <i> Losec </i> product information and <i> Don't Rush to Crush </i> for guidance about dosage form modification. The intern identifies two possible options: dispensing omeprazole tablets and instructing the parents in how to suspend and administer, or compounding the medicine into a stable oral suspension.</li> <li>• Discusses these options with preceptor, and then with Doris. All agree that compounding the medicine would be easier to administer and worth the additional time and cost. Doris chooses Marika's preferred flavour, provides a contact number, and plans to return later.</li> <li>• Searches the Australian Pharmaceutical Formulary (APF), and then the specialty compounding provider formulae, for a suitable formula.</li> <li>• Listens to the preceptor contact the prescriber by telephone as they recommend the prescription be re-written to state "compounded omeprazole suspension 5mg/mL 50mL". The prescriber gives verbal consent so the intern can proceed.</li> <li>• Prints out a new Compounding worksheet for omeprazole suspension, and completes the blank fields (including checking all required ingredients are available and not expired). The preceptor reviews it, and asks the intern to explain the compounding process.</li> </ul>
<p><b>Technical dispensing process phase</b></p> <p><i>Intern performs procedural aspects of preparing medicine for supply</i></p>	<p>The intern:</p> <ul style="list-style-type: none"> <li>• Dispenses prescription and prepares dispensing label.</li> <li>• Dresses in appropriate Personal Protective Equipment – chooses to wear a laboratory coat, bouffant cap, safety goggles and respirator mask.</li> <li>• Cleans and prepares compounding area and required equipment, including mortar and pestle, conical flask, weighing scales, etc.</li> <li>• Weighs out the active ingredient and flavouring agent; the preceptor checks each one and signs off the appropriate lines on the worksheet.</li> <li>• Triturates the omeprazole powder in a mortar and pestle before adding a small volume of <i> Base for Omeprazole Suspension (O-Base) </i> to make a paste.</li> </ul>

	<ul style="list-style-type: none"> <li>• Transfers to a conical flask adding more <i>O-Base</i> as required, scraping and ensuring there is no omeprazole remaining in the mortar.</li> <li>• Stirs while adding the flavouring, then makes up to final volume with <i>O-Base</i> under direct supervision by the preceptor (and at times by the laboratory technician)</li> <li>• Checks the pH of the final solution with pH paper (&gt;8 is satisfactory); attaches the pH paper to the Batch Sheet.</li> <li>• Transfers to a 50mL smooth amber plastic bottle with a screw-top lid.</li> <li>• Labels the final container with the dispensing label, and CALs: Label 6 (“REFRIGERATE Do not Freeze”, Label 7a with 180-day expiry, and Label 23; the intern forgets to add “Shake the Bottle”.</li> <li>• Takes the bottle to the supervisor for the final product check for quality and completeness, who then signs off on the prescription and worksheet. Supervisor asks the intern to attach a Medicine Bottle Syringe Adaptor with 1mL Oral Syringe instead of the screw-top lid and adds the CAL “Shake the Bottle”.</li> <li>• Realises the technician has already cleaned and cleared the equipment, says thank you, and checks the steps involved in the clean-up.</li> <li>• Telephones the patient’s mother to advise the script is ready for collection, and describes the storage conditions, noting the importance of taking it straight home to be refrigerated.</li> </ul>
<p><b>Entrustment discussion</b></p>	<p>A few days later, the preceptor collects feedback from the technician, and then meets with the intern for an Entrustment discussion.</p> <p>Key elements of discussion</p> <ul style="list-style-type: none"> <li>• The intern’s decision-making process was excellent, understanding the practical limitations of suspending and administering medicines to children, and involving the mother after the options were clear.</li> <li>• The intern’s technical skills were satisfactory and will become more efficient with practice.</li> <li>• The main suggestions for improvement are around the final product presentation: providing a syringe adaptor and “Shake the Bottle”.</li> <li>• That prescribers can be unsure about how to write a compounding prescription (particularly because most prescription software won’t facilitate it easily), and how pharmacists need to be very clear about the legal requirements.</li> </ul> <p>Some What-If questions were asked during the entrustment discussion including:</p> <ul style="list-style-type: none"> <li>• What if you were working in a pharmacy without a compounding laboratory – could you make any non-sterile product e.g., omeprazole suspension?</li> <li>• What if this script were presented on a weekend, when there is no one rostered to work in the compounding laboratory, but you know it is needed ASAP?</li> <li>• What if the prescriber was on leave and couldn’t be contacted for a few weeks to re-write the prescription to make it suitable for compounding?</li> </ul>
<p><b>Feedback and assessment of EPA</b></p>	<p>The intern’s performance was to a standard that the preceptor would feel confident the intern could complete this without direct supervision in the future.</p> <p>For any future prescription for omeprazole suspension, the preceptor would like to sign off on the product label and worksheet both before and after anything is done in the laboratory, but the intern is allowed to perform all other compounding steps without close supervision (although must ask for assistance any time the intern is unsure). This is the same level of Entrustment as discussed in past EPAs for simple creams and ointments, T3 capsules and diclofenac gel.</p> <p>For any type of compounding product the intern has not made before in this laboratory (i.e. excepting those listed above), the intern still requires direct supervision by a combination of the preceptor and the laboratory technician. This is partly because the intern has not yet completed a specialty compounding training course.</p> <p>The intern is now Entrustment Level 3 for compounding omeprazole suspension. The intern remains at Entrustment Level 2 for compounding any specialty product that the intern has not previously compounded at this pharmacy.</p>

Performance outcome(s)	Preceptor feedback and expectations of Intern**
3.15	See above: "Entrustment discussion" & "Feedback and assessment of EPA" – entirely competent for this stage of the internship, but ensure appropriate final container and labelling.
4.2	See above: "Feedback and assessment of EPA"
5.3	Be ready to make the phone call to a prescriber next time we need to clarify or alter a compounding prescription, keeping in mind the limitations of prescribers' knowledge about how to write these prescriptions.

*\*\*Note that the feedback and expectations of the Intern should consider and be tailored to the stage of training of the Intern.*