PHAR9101
Introduction to the Therapeutics Industry

Course Outline
Term 1, 2023

School of Biomedical Sciences
Faculty of Medicine & Health
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<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Affiliation</th>
<th>Email</th>
<th>Phone</th>
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</thead>
<tbody>
<tr>
<td>Course Convener</td>
<td>Dr Johnson Liu</td>
<td>Senior Lecturer, School of Biomedical Sciences, UNSW Sydney</td>
<td><a href="mailto:johnson.liu@unsw.edu.au">johnson.liu@unsw.edu.au</a></td>
<td>02-9385 9086</td>
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<td>Lecturer</td>
<td>Dr Lindsay Wu</td>
<td>Senior Lecturer, School of Biomedical Sciences, UNSW</td>
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<td></td>
<td>Dr David Brown</td>
<td>Director, Heaton-Brown Life Sciences; Conjoint Lecturer, UNSW</td>
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<tr>
<td></td>
<td>Dr Brendan Shaw</td>
<td>Shawview Consulting, London, UK and Australia</td>
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<td></td>
<td>Mr Bob Kramer</td>
<td>Special Counsel, Finnegan</td>
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<td></td>
<td>A/Prof Orin Chisholm</td>
<td>Academic Lead, University of Sydney</td>
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<tr>
<td></td>
<td>Candy Braithwaite</td>
<td>Managing Director, Biopharmax, Singapore</td>
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<tr>
<td></td>
<td>Prof Eugene Salole</td>
<td>Principal, Value-based Access and Conjoint Professor, UNSW</td>
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<tr>
<td></td>
<td>Dr Jessica Pace</td>
<td>Sydney Pharmacy School, University of Sydney</td>
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<tr>
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<td>Education Support Team</td>
<td>School of Biomedical Sciences, UNSW Sydney</td>
<td><a href="mailto:pharm.med@unsw.edu.au">pharm.med@unsw.edu.au</a></td>
<td>02-9385 2464</td>
</tr>
</tbody>
</table>

All inquiries and study questions should be directed in the first instance to the course convener who, if required, will direct your matters to an appropriate tutor or UNSW department.

2. **Course information**

Units of credit: 6

Pre-requisite(s): Enrolment in 3831 Science (Medicine) Honours

**Credit points:** This course has 6 Units of Credit. The course has been planned so that the average student should study for approximately 15 hours per week throughout the 10-week course. These hours cover all aspects of the workload including reading set material, watching pre-recorded videos, doing assignment work, preparing for and participating in online classes and participating in groupwork and discussion forums. Students differ in background; consequently, the amount of work will vary greatly between individuals, and, for particular students, it will vary between courses.
2.1 Course summary

This course begins with an introduction to the milestones of pharmaceutical product development, including a case study. This is followed by an introduction to the history of the therapeutics industries and how companies are created and structured. After that it explores current and future strategies for therapeutics development and the role of trade, global harmonisation and the evolution of new funding models in future therapeutics development. It then examines the role of therapeutics in improving health outcomes. The course finishes with an introduction to pharma image and ethics as well as examining the roles of the people who work in the industry.

The course site in Moodle has been organised around the following Sections:

Section 1 – Milestones in pharmaceutical product development
Section 2 – History and structure of therapeutics companies
Section 3 – Future strategies for therapeutics industry
Section 4 – Role of therapeutics in improving health outcomes
Section 5 – Pharma image/ethics
Section 6 – Roles of therapeutics industry employees

2.2 Course aims

The course introduces students to the global therapeutics industry (pharmaceuticals, biotechnology, medical devices and diagnostics); the role of therapeutics in improving health outcomes; the history of the therapeutics industry; how companies are created and structured; current and future strategies for development of therapeutic technologies; the role of global trade agreements, regulatory harmonisation and the evolution of new models for funding innovation in future therapeutics development.

2.3 Course learning outcomes (CLO)

At the conclusion of this course the student will be able to:

1. Describe the major milestones involved in the lifecycle of a therapeutic product and the role of that product in improving health outcomes.
2. Identify the functions of various roles in the therapeutics industry and how they contribute to the overall business of a company.
3. Critique the financial drivers of current and future models of therapeutics development.
4. Debate the reputation of the therapeutics industry and explore opportunities to enhance its reputation.
5. Develop active and reflective learning strategies.
2.4 Relationship between course learning outcomes and assessments

Using the table below specify clearly how the course contributes to the course learning outcomes. Complete the table with your own course and learning outcomes, tasks and assessments. These should match to those approved in ECLIPS for this course https://eclips.unsw.edu.au

<table>
<thead>
<tr>
<th>Course Learning Outcome (CLO)</th>
<th>LO Statement</th>
<th>Related Tasks &amp; Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLO 1</td>
<td>Describe the major milestones involved in the lifecycle of a therapeutic product and the role of that product in improving health outcomes.</td>
<td>1, 2, 3, 4</td>
</tr>
<tr>
<td>CLO 2</td>
<td>Identify the functions of various roles in the therapeutics industry and how they contribute to the overall business of a company.</td>
<td>1, 2, 3, 4</td>
</tr>
<tr>
<td>CLO 3</td>
<td>Critique the financial drivers of current and future models of therapeutics development.</td>
<td>1, 2, 3, 4</td>
</tr>
<tr>
<td>CLO 4</td>
<td>Debate the reputation of the therapeutics industry and explore opportunities to enhance its reputation.</td>
<td>1, 2, 3, 4</td>
</tr>
<tr>
<td>CLO 5</td>
<td>Develop active and reflective learning strategies</td>
<td>2, 4</td>
</tr>
</tbody>
</table>

3. Strategies and approaches to learning

3.1 Learning and teaching activities

The course is delivered fully online.

Reading materials are accessible via the Moodle Learning Management System. Resources to help you learn the course topics include course notes, websites, videos, lecture recordings, relevant books and journal articles. Many of the resources are accessible in Moodle or via the UNSW Library (UNSW VPN and Student credentials required).

Weekly online classes are held via Blackboard with presentations on relevant topics by guest lecturers.
Online discussion forums are set up for individual course sections and facilitated by guest lecturers and the course convenor.

### 3.2 Expectations of students

Students are reminded that UNSW recommends that a 6 unit-of-credit course should involve about 150 hours of study and learning activities. The formal learning activities total approximately 50 hours throughout the term and students are expected (and strongly recommended) to do at least the same number of hours of additional study.

Students are expected to join synchronous online classes delivered via the Blackboard system and contribute to online discussion forums asynchronously. Please notify the Course Convenor if you are unable to attend the online class with a legitimate reason.

Participation and contribution to online discussion forums are required and assessed as an assessment of the course.

Students are required to participate actively in group tasks and group activities.

### 4. Course schedule and structure

Online classes are scheduled weekly on Mondays at 8:00pm to 9:30pm (Sydney time) (See course timetable for detail). Guest lecturers will present on specific topics and run class discussions of case studies and tutorials for assessment tasks. Students are encouraged to complete prereading if required. Online sessions are conducted via the Blackboard Collaborate system accessible through the course site on Moodle. Google Chrome or Firefox are the preferred browser. Class recording is available overnight in Blackboard.

Asynchronous online discussion forums are set up for individual course sections. Students can post on set topics or put forward your own topics if they are relevant to the Section. Course lecturers and convenor will facilitate the discussion forums on a weekly basis.

Exam Period: 28 April – 11 May
Supplementary Exam Period: 22 May – 26 May

### 5. Assessment

#### 5.1 Assessment tasks

The course is assessed by completion of a mixture of assignments, online discussion forums, groupwork, participation in and leading online class discussions and a self-reflection journal.
<table>
<thead>
<tr>
<th>Assessment task</th>
<th>Task length</th>
<th>Weight</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task 1 Therapeutic Product Development</td>
<td>4000 words</td>
<td>40%</td>
<td>Wed 22 Mar (23:59)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Peer reviews: Wed 29 Mar (11:59pm)</td>
</tr>
<tr>
<td>Task 2 Models for Therapeutics development</td>
<td>2000 words</td>
<td>30%</td>
<td>Wed 26 Apr (23:59)</td>
</tr>
</tbody>
</table>
| Task 3 Online Discussion Forums                     | • 6 posts (200 words/post)  
• Top 3 posts plus justification (1000 words) | 15%    | Weekly throughout the Term. Final submission: Mon 1 May (23:59) |
| Task 4 Reflective Journal                           | 1500 words (6 entries) | 15%    | Weekly throughout the Term. Final submission: Mon 1 May (23:59) |

**Assessment Task 1 – Groupwork Wiki project (40%) – Therapeutic product development**

Weighting: 40%

Due Date:
- 12 Mar: Wiki draft for feedback (optional)
- 22 Mar (23:59): Wiki
- 29 Mar: Peer review

Task length: 4000 words (excluding table, figure and references)

This is a collaborative assessment task which involves exploring the development of a therapeutic product as part of a collaborative team. This task is conducted using the sharing platform Wiki that is available on Moodle.

Students will be allocated to groups for this task. Group list will be available on Moodle in Week 2.

Each group needs to choose one of the following therapeutic products (Table 1) for their Wiki task. There will be a choice selection tool on the Moodle site. The topics will be available on Moodle from **9am on Mon 20 Feb (Week 2)**. You may only choose one product and if it is already taken you must choose a different one. Nominate one person from your
group to make the product choice for your group. Please note the indication as some products are registered for multiple indications.

**Table 1 Assessment Task 1 Wiki project – Topic list**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic name</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluad paediatric</td>
<td>trivalent seasonal influenza vaccine</td>
<td>Influenza</td>
</tr>
<tr>
<td>Zavicefta</td>
<td>ceftazidime and avibactam</td>
<td>Antibiotic</td>
</tr>
<tr>
<td>Rekovelle</td>
<td>follitropin delta</td>
<td>Controlled ovarian stimulation for Assisted Reproductive Technology (ART)</td>
</tr>
<tr>
<td>Aimovig</td>
<td>erenumab (rch)</td>
<td>Migraine</td>
</tr>
<tr>
<td>Kymriah</td>
<td>tisagenlecleucel</td>
<td>Diffuse large B-cell lymphoma (DLBCL)</td>
</tr>
<tr>
<td>Idevion</td>
<td>albutrepenonacog alfa</td>
<td>Factor IX for Hemophilia B</td>
</tr>
<tr>
<td>Velphoro</td>
<td>sucriferric oxyhydroxide</td>
<td>hyperphosphataemia</td>
</tr>
<tr>
<td>Alunbrig</td>
<td>brigatinib</td>
<td>Anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)</td>
</tr>
<tr>
<td>Signifor</td>
<td>pasireotide diaspantate</td>
<td>Cushing’s syndrome</td>
</tr>
<tr>
<td>Elelyso</td>
<td>taliglucerase alfa</td>
<td>Gaucher’s disease</td>
</tr>
<tr>
<td>Cabometyx</td>
<td>caboazatinib</td>
<td>Renal cell carcinoma</td>
</tr>
<tr>
<td>Staquis</td>
<td>crisaborole</td>
<td>Atopic dermatitis</td>
</tr>
<tr>
<td>Zinbryta</td>
<td>daclizumab</td>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>Takhzyro</td>
<td>lanadelumab (rch)</td>
<td>Hereditary angioedema</td>
</tr>
<tr>
<td>Stelara</td>
<td>ustekinumab</td>
<td>Crohn’s disease</td>
</tr>
<tr>
<td>Fycompa</td>
<td>perampanel</td>
<td>Partial seizures epilepsy</td>
</tr>
<tr>
<td>Xiidra</td>
<td>lifitegrast</td>
<td>Dry eye disease</td>
</tr>
<tr>
<td>Stivarga</td>
<td>regorafenib</td>
<td>Gastro-Intestinal Stomach Cancer (GIST)</td>
</tr>
<tr>
<td>Nucala</td>
<td>mepolizumab</td>
<td>Asthma</td>
</tr>
<tr>
<td>FluMist</td>
<td>quadrivalent influenza virus nasal spray applicator</td>
<td>Influenza</td>
</tr>
<tr>
<td>KRAS mutation</td>
<td>In Vitro Diagnostic (IVD), class 3</td>
<td><strong>See <a href="#">here</a></strong> for TGA registered example</td>
</tr>
</tbody>
</table>

In this assessment task, you need to investigate the history and development of the product you have chosen. Start with the early-stage research and development of the product, then move through pre-clinical testing and the clinical research results. Then provide some details about the registration of the product – where and when was it registered? (You should at least cover the EMA, USA and Australia). Are there any post-approval commitments or further developments of the product since registration (new indications or safety monitoring)? Has the product been reimbursed in Australia? If known, please provide reimbursement dates and conditions. Please include a timeline of the key developmental milestones for the product in your Wiki. The final section should cover how this particular product contributes to improved health outcomes in patients.
For your reference, an example of a wiki that students completed in a previous year is available on the Moodle site, as an example of the type of information to include in your wiki. Please note that the requirements have changed slightly this year – so please follow the instructions here and not just the example wiki.

Various databases are helpful to gather information for your product, which are accessible via UNSW library (https://subjectguides.library.unsw.edu.au/medicine), especially under the sub-category of Pharmacy & pharmaceutical medicine.

**Peer marking:**

The final marks of this task include marks by lecturers (75%) and peer marking (25%). Peer marking includes marks from group member (10%), peer marks on your Wiki project (10%) and your participation of peer marking (5%). Different marking rubrics are provided for member contribution and Wiki project. Please Do NOT just give all colleagues full marks for their participation or Wiki project, but review them carefully and come to a decision based on the assessment criteria provided in the marking rubrics.

**Submission:**

- Final submission via Turnitin: You need to download a PDF of your Wiki and submit it on Moodle. Each student needs to submit a copy on Moodle.
- Peer marking results: Send your marking results to the pharm.med@unsw.edu.au (with a subject line “PHAR9101 peer marking”).
- Each student needs to submit a copy of your group slides to Turnitin.

Detailed task instructions are available at the course Moodle site.

**Assessment Task 2 – Individual Assignment (30%) – Drivers of pharma development**

**Weighting:** 30%

**Due Date:**

- Draft outline for feedback: Wed 12 April (Email to Course Convenor) (Optional)
- Final submission: Wed 26 April (23:59)

**Task Length:** 2000 words (excluding figure, table and references)

The aim of the Task is to evaluate the drivers of current and future models of therapeutics development.

In this essay, you are required to evaluate the current pharmaceutical industry, both globally and locally, and discuss the drivers for future developments in the industry. You should examine the societal, legal and technological issues facing the industry and how these issues might lead to changes in the industry in the future. What future do you see for the industry and what obstacles does it need to overcome to get there? You should support your opinions with evidence from the literature, government reports, industry reports, etc, and use case studies where appropriate to support your perspective. There is no right or wrong
answer; this is an opportunity for you to develop your analytical skills in researching future trends and justifying your choices with supportive evidence.

Why are you required to complete this assessment task?

This essay is a personal reflection on your opinions of the future development of the industry in which you have chosen to work. This essay is designed to get you thinking about the industry as a whole in both a local and global context and to start looking at a wider view of where the industry fits and how it evolves. It will also give you skills in learning how to support your perspective with evidence – a critical skill in business intelligence.

Further information will be provided on the course Moodle site.

Assessment task 3 – Discussion Forums (15%)

Due Date:

• Weekly throughout the Term for individual forums by the due dates indicated on Moodle
• Final submission of selected posts: Mon 1 May (23:59)

Task length: 200 words/post; 1000 words for Turnitin submission (3 selected posts plus justification)

There are 6 Section-specific discussion forums for this course. Students are required to contribute at least ONE post to each of these 6 discussion forums regularly throughout the Term. Please see individual due dates for posting to the forums listed in the as the Course Timetable and Moodle site.

Your posts should contribute a body of knowledge to the Discussion Forum topic (250 words per post excluding references). You can include supportive references. You may contribute a link to an article you have read with your critical review of the article, a link to a video resource you have viewed with a critical review of the video, substantive answers to any questions that lecturers post in the Discussion Forums, etc.

You should complete your posts regularly in line with the course progress and select your top 3 posts to submit through Turnitin as a single MS Word or pdf document. You must also include a paragraph outlining your justification on the selection of those particular 3 posts that you consider them to be your best ones (300 words).

Marking:

To be eligible for marking, you must post at least one post online to the discussion forum. The record of all your online posts on Moodle will be assessed in addition to your Turnitin submission. The total number and timing of your posts will be considered and highly weighted when marking (see the marking rubric for detail), as posting regularly and timely is
essential to achieving the objectives of this task, i.e., to promote self-learning, peer learning and peer engagement.

Submission via Turnitin:

In addition to the regular posting to the forums as required above, you need to select your top 3 posts and submit it through Turnitin as a single MS Word or pdf document. You must also include a justification on why you have chosen those 3 posts and why you consider them to be your best ones. Your justification should be around 200 words.

Why are you required to complete this assessment task?

Participating in online discussion forums will develop your communication skills, which are critical in the pharmaceutical industry. I strongly believe that you can all contribute and support each other’s learning through participating in these Discussion Forums. It is also a way of developing your relationships with each other, which you can maintain throughout your careers.

Assessment Task 4 – Reflective journal (15%)

Due Date:

- Throughout the term on weekly basis.
- Final submission: Mon 1 May (23:59)

Length: 1500 words excluding references (at least 6 entries)

The Reflective Journal is a core component to the development of your personal and professional skills and involves a reflective online learning process. You are required to create a reflective journal. Note: You cannot submit the same journal that you may have created for other courses or the program.

Students are required to write at least 6 entries for your journal on a regular basis. You can reflect on weekly learning, completing assessment tasks and other personal development as appropriate, but your entry should be focused on the weekly learning in this course.

The purpose of reflective writing is to review:

- **What?** – What have I learned this [week, fortnight]? What most surprised you? What did you relate to the most? Or the least?
- **So what?** - How does my learning relate to my program and professional/career goals? What am I confused about? What links can I make between my learning and my career? What areas of my personal growth do I need to focus on? What skills do I need to focus on? Are there any gaps in my knowledge and skills in the subject area?
- **Now what?** What do I need to do to achieve my learning/career goals? What are my next steps? How can I integrate what I have learnt into my professional life? How has feedback on my performance influenced my career choices? What actions does your reflection lead you to implementing? How do you address the gaps identified?
In writing a reflection you can:

- write brief notes or point form phrases
- write about yourself, for example, your feelings and attitudes, values and reactions
- observe others (fellow students or employees) and describe what you can learn from them eg, presentation skills, expressing your point of view with evidence
- see every situation as providing material for reflection and new learning
- listen/read what your peer/colleagues have to say and use the different perspectives given to deepen your personal reflection
- cover the various assessment tasks you are undertaking (group work, individual essays, discussion forums) and discuss skills you have gained or want to develop as a result of your studies

Submission:
The reflective journal will be submitted and assessed specifically for this course. If you use a public blogging site for your journal, please download a pdf or word version of your reflection for this course for submission. You must conduct self-check of your similarity score in your originality report in Turnitin before submission to ensure the compliance and avoid plagiarism.

Why am I asking you to complete this assessment task?
This assessment task is designed to demonstrate an ability to integrate your course learning with your work environment, knowledge of the pharmaceutical industry and self-development. Self-reflection is a powerful learning tool and you can use it throughout your career to discern your own performance and where you would like to make improvements. Keeping a record of your achievements and areas for improvement will prepare you for job interviews and promotions.

Further information
UNSW grading system: https://student.unsw.edu.au/grades
UNSW assessment policy: https://student.unsw.edu.au/assessment

5.2 Assessment criteria and standards
The assessment criteria and standards for individual tasks are available as marking rubrics in the Assessment section on Moodle course site. It is highly recommended to preview the marking rubrics when completing the tasks.
5.3 Submission of assessment tasks

Late Submission
UNSW has standard late submission penalties as outlined in the UNSW Assessment Implementation Procedure, with no permitted variation. All late assignments (unless extension or exemption previously agreed) will be penalised by 5% of the maximum mark per day (including Saturday, Sunday and public holidays). For example, if an assessment task is worth 30 marks, then 1.5 marks will be lost per day (5% of 30) for each day it is late. So, if the grade earned is 24/30 and the task is two days late the student receives a grade of 24 – 3 marks = 21 marks.

Late submissions will be penalized at 5% per day capped at five days (120 hours). Students will not be permitted to submit their assessments after this date.

Special Consideration
If you experience a short-term event beyond your control (exceptional circumstances) that impacts your performance in a particular assessment task, you can apply for Special Considerations.

You must apply for Special Consideration before the start of your exam or due date for your assessment, except where your circumstances of illness or misadventure stop you from doing so.

If your circumstances stop you from applying before your exam or assessment due date, you must apply within 3 working days of the assessment, or the period covered by your supporting documentation.

More information can be found on the Special Consideration website.

Turnitin and plagiarism check
All assignments must be submitted through Turnitin via the Moodle course site. Submission via Email attachment to the Course Convenor is not acceptable unless specifically instructed otherwise. Assignments submitted on Moodle are automatically scanned using Turnitin to check for plagiarism against known articles submitted by other students, your own previous submissions (self-plagiarism), literature and articles from the internet.

You must self-check your originality report including the similarity score to ensure your compliance before your final submission. As a rule, the Turnitin system allows for unlimited times of resubmission and it can produce the originality report immediately after each submission before the due date, but it will take 24 hours to generate the report after 3 resubmissions. The pass threshold of your originally report will be discussed in the class and at Moodle site.

Students should always retain a copy of each assessment task (including posts in Discussion forums) for their own records. Please review the guidelines on academic integrity in the following sections of the course outline.

5.4 Feedback on assessment
You can submit a draft outline of Assessment Task 1 and Assessment Task 2 to the Course Convenor by the specified due date for feedback, but this is optional.

Student submissions in Turnitin will be marked online. Once the marks and comments of your assessment are available, students should log back into Turnitin and download their marked assignment and review comments. Students should include their thoughts on the feedback in their reflective journals, including plans for future assignments to address any deficiencies.

Final result for the course will be emailed to student email address on the UNSW’s Release of Results date. Results can also be viewed online by logging into myUNSW and selecting “View Results” under “My Student Profile”.

Definitions of grades used at UNSW are available here: https://student.unsw.edu.au/grades.

6. Academic integrity, referencing and plagiarism

Referencing is a way of acknowledging the sources of information that you use to research your assignments. You need to provide a reference whenever you draw on someone else’s words, ideas or research. Not referencing other people’s work can constitute plagiarism.

Further information about referencing styles can be found at https://student.unsw.edu.au/referencing.

References should be cited in the text and referenced at the end of the assignment. Vancouver referencing style is recommended for this course. An example can be found in Nature Medicine. Briefly, in-text citations are numbered and the bibliography at the end of the assignment are numbered correspondingly.

Note: The exact formatting is flexible, but you must keep consistency across your references.

A general guide can be found here for citing sources using Vancouver referencing style, including journal article, book chapter, newspaper article, industry report or websites.

Academic integrity is fundamental to success at university. Academic integrity can be defined as a commitment to six fundamental values in academic pursuits: honesty, trust, fairness, respect, responsibility and courage ¹. At UNSW, this means that your work must be your own, and others’ ideas should be appropriately acknowledged. If you don’t follow these rules, plagiarism may be detected in your work.

Further information about academic integrity and plagiarism can be located at:

- The Current Students site https://student.unsw.edu.au/plagiarism, and
- The ELISE training site https://subjectguides.library.unsw.edu.au/elise

The Conduct and Integrity Unit provides further resources to assist you to understand your conduct obligations as a student: https://student.unsw.edu.au/conduct


The University will not tolerate plagiarism in submitted written work and regard this as an academic misconduct. Evidence of plagiarism in submitted assignments will be thoroughly investigated by the Conduct and Integrity Office. Evidence of plagiarism may result in disciplinary outcomes and a record being made in the Central Plagiarism Register, and the Faculty Student Integrity Advisor being notified. Please note that employers have the right to ask the University for evidence of student misconduct.

7. Readings and resources

In addition to the materials provided on Moodle course site, including course notes, references and book chapters, students will need to consult the following websites when completing learning activities and assessment tasks during their course study.

**Regulatory authorities:** For most assessments, you will need to check information posted on the websites of various regulatory bodies; the following will help you start:

- Food and Drug Administration (FDA): [http://www.fda.gov](http://www.fda.gov)

**Governmental and industrial websites:**

- Australian Government Department of Health: [http://www.health.gov.au](http://www.health.gov.au). This site will lead you to many types of useful information, for example, Australian statistics on medicine (useful if you want to state the health burden of a particular disease)
- International Standards Organisation: [http://www.iso.ch](http://www.iso.ch)

**The Product Information (PI)** is the Therapeutic Goods Administration (TGA) approved information supplied by Sponsors of pharmaceutical products. It is written for healthcare professionals. The consumer-focused document is called the Consumer Medicine Information (CMI). The PI is essential reading for assignments dealing with specific therapeutics. PIs and CMIs are available on the TGA website ([https://www.ebs.tga.gov.au/](https://www.ebs.tga.gov.au/)). Reformatted versions of approved PIs are available in MIMS. It is important to emphasise that MIMS may not have the latest PI updates and that they have been subject to editorial modification (usually minor). You should contact the sponsor if you want the latest PI. If you quote the information in MIMS, you should state this as your source.

Numerous relevant databases are available through UNSW Library under the Subject Guides for Pharmacy & pharmaceutical medicine ([https://subjectguides.library.unsw.edu.au/medicine/pharmacy](https://subjectguides.library.unsw.edu.au/medicine/pharmacy)), such as:

- **MIMS online**: The web version of MIMS - an Australian pharmaceutical database. Incorporating information from both MIMS Bi-Monthly and MIMS Annual Online, it
offers access to essential information on over 2,300 prescription and non-prescription drugs. Includes the Don’t Rush to Crush module.

- **MedicinesComplete** contains online versions of major pharmacy handbooks including Pharmaceutical excipients and Martindale: The Complete Drug Reference.
- **Australian medicines handbook** is an evidence-based resource for drugs currently marketed in Australia.
- **MedDRA: medical dictionary for regulatory activities** is the clinically-validated international medical terminology that is being implemented by the U.S. Food and Drug Administration (FDA) as well as by the regulatory authorities in the European Union (EMEA) and the Japanese Ministry of Health and Welfare (MHW).
- **British pharmacopoeia** is a six-volume leading reference tool for medicines and healthcare research & development and contains an extensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products.
- **US Pharmacopoeia and National Formulary (USP-NF)** is a combination of the United States Pharmacopeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics.

**Note:** All databases need your UNSW credentials to access. Some databases require pop-up username and password for login. Please allow pop-ups on our browser.

**8. Administrative matters**

General student enquiries should be submitted via student portal [https://portal.insight.unsw.edu.au/web-forms/](https://portal.insight.unsw.edu.au/web-forms/)

**Official communication**

UNSW student email and Moodle announcements are the main tools for course-related communications. Please include the course code in the subject line of all emails. If you use non-UNSW email, you must arrange redirection from your student email.

**Course- and program-related matters**

For course-related matters please contact your Course Convenor. For other matters please contact the Admin Team first at pharm.med@unsw.edu.au for advice.

**Grievance resolution officer**

If you have any problem or grievance about the course, you should try to resolve it with the coordinator (Dr Johnson Liu- Tel: 02 9385 9086; johnson.liu@unsw.edu.au) or the Head of Pharmacology/Program Authority (Professor Margaret Morris - Tel: 02 9385 1560; m.morris@unsw.edu.au). If the grievance cannot be resolved in this way, you should contact the School of Medical Sciences Grievance Officer, Professor Nick Di Girolamo (Tel: 02 9385 2538; n.digirolamo@unsw.edu.au).
9. **Additional support for students**

- The Current Students Gateway: [https://student.unsw.edu.au/](https://student.unsw.edu.au/)
- Academic Skills: [https://student.unsw.edu.au/academic-skills](https://student.unsw.edu.au/academic-skills)
- Student Wellbeing and Health: [https://www.student.unsw.edu.au/wellbeing](https://www.student.unsw.edu.au/wellbeing)
- UNSW IT Service Centre: [https://www.myit.unsw.edu.au/services/students](https://www.myit.unsw.edu.au/services/students)
- UNSW Student Life Hub: [https://student.unsw.edu.au/hub#main-content](https://student.unsw.edu.au/hub#main-content)
- Student Support and Development: [https://student.unsw.edu.au/support](https://student.unsw.edu.au/support)
- eLearning and IT Apps: [https://student.unsw.edu.au/elearning](https://student.unsw.edu.au/elearning)
- Student Support Advisors: [https://student.unsw.edu.au/advisors](https://student.unsw.edu.au/advisors)
- Equitable Learning Services (Formerly Disability Support Unit): [https://student.unsw.edu.au/els](https://student.unsw.edu.au/els)
- Transitioning to Online Learning: [https://www.covid19studyonline.unsw.edu.au/](https://www.covid19studyonline.unsw.edu.au/)
- Guide to Online Study: [https://student.unsw.edu.au/online-study](https://student.unsw.edu.au/online-study)
- UNSW Student complaints: [https://student.unsw.edu.au/complaints](https://student.unsw.edu.au/complaints)
- Postgraduate coursework student support: [https://student.unsw.edu.au/postgrad](https://student.unsw.edu.au/postgrad)
- Special Consideration: [https://student.unsw.edu.au/special-consideration](https://student.unsw.edu.au/special-consideration)
- Student Wellness Counselling: [https://student.unsw.edu.au/counselling](https://student.unsw.edu.au/counselling)
- Academic Standing for postgraduates: [https://student.unsw.edu.au/academic-standing-postgrad](https://student.unsw.edu.au/academic-standing-postgrad)
- English language support: [https://student.unsw.edu.au/english](https://student.unsw.edu.au/english)