I. Answer the following questions:

1. Give the generic name and therapeutic uses for each of the following products: (2 points each)

   A. Diprivan B. Klaricid C. Burinex D. Betaloc
   E. Diovan F. Taxotere G. Coumadin H. Avandia

2. Give the active ingredients contained in the following preparations: (2 points each)

   A. Rifater B. Unasyn C. Tienam D. Cafergot

3. The following medications should not be triturated or chewed when taken orally. Give the reason for each preparation: (2 points each)

   A. Losec B. Coracten spansule C. Uroprin
   D. Plendil E. Nitrostat

4. Interpret the meaning of the following abbreviations using English: (2 points each)

   A. ad lib B. a.s. C. gtt D. pulv.
   E. stat. F. BSA G. BUN H. IBW
   I. OTC J. TPN K. MRSA L. GDP

5. The directions intended for the patient on a prescription read"1 tbsp ac and hs for 10 days." What is the minimum volume the pharmacist should dispense? (3 points)

6. The adult dose of a drug is 250 mg. What is an appropriate dose for a child shoes BSA is calculated to be 0.75 m^2? (3 points)

7. A vial of a lyophilized drug is labeled "10,000 units: to reconstitute, add 17 ml of Sterile Water for Injection (SWFI) to obtain 500 units per mL." How many mL of SWFI must a pharmacist add if a 1000 U/mL concentration is needed? (3 points)

(背面仍有題目,請繼續作答)

8. Dopamine 200 mg in 500 mL of normal saline at 5 μg/kg/min is ordered for a 154-lb patient. At what rate (mL/min) should the solution be infused to deliver the desired dose of 5 μg/kg/min? (3 points)

II. After reading the following article, describe

1. The difference between expiration date and beyond-use date. (5 points)
2. How to assign beyond-use dates to manufactured drug products dispensed by the pharmacist? (15 points)

The label of an official drug product or nutritional supplement shall bear an expiration date. All products shall display the expiration date so that it can be read by an ordinary individual under customary conditions of purchases and use. The expiration date identifies the time during which the product may be expected to meet the requirements of the Pharmacopeial monograph provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the product may be dispensed or used. Where an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month.

The labeling of all solid, oral dosage forms intended for sale pursuant to a prescription (other than those packaged by the manufacturer in containers that are labeled for dispensing directly to the patient) shall provide sufficient packaging and beyond-use dating information to permit the dispenser to select a suitable container for dispensing and to place a meaningful beyond-use date on the label of the prescription container when stored as directed. Based on the information supplied by the manufacturer, the dispenser shall place on the label of the prescription container a suitable beyond-use date to limit the patient's use of the product. The beyond-use date is the date after which an product must not be used. The beyond-use date placed on the label shall be not later than the expiration date of the manufacturer's container.

The recommended beyond-use date for manufactured drug products depends on whether the drug is dispensed in a multi-dose or unit-dose package.

1. Multi-dose containers
   a. As stated in the definitions given previously, for prescription drug products dispensed in multi-dose containers, the *USP* allows use of the manufacturer's expiration date or 1 year from the date the drug product is dispensed, whichever is earlier.

(1) Remember that this is **maximum** length allowed and that you must consider the drug, the dispensing container, and storage conditions.
(2) Dispensing software packages that automatically label prescriptions with expiration dates of 1 year from the date dispensed should be used with discretion; the manufacturer's expiration date should always be consulted and a shorter dating should be printed on the prescription label when this is warranted.

b. You usually can feel comfortable about using the maximum allowable time when drug products are dispensed in their **original** containers **if** you are confident that the patient will store the product as directed. An exception to this would be a volatile drug like nitroglycerin. Even though this drug is dispensed in its original glass container, it will lose potency over time as the patient opens and closes the bottle to remove doses.

c. A shorter dating may also be appropriate when you are required, as is usually the case, to transfer a product from its original container to a dispensing container. Expiration dates assigned by manufacturers are determined using the original container. Manufacturers do considerable research in container design to give a product maximum protection at a reasonable cost. Many tablets and capsules are sensitive to moisture, and dispensing them in a prescription vial, even though it is classified as a tight container, can decrease their shelf-life. Furthermore, the patient will be opening and closing the dispensing container often as doses are taken, thus exposing the drug product to the atmosphere.

d. The pharmacist should also be conscious of the recommended storage conditions for a drug product. Many products require storage at controlled room temperature. Therefore, it is prudent to be conservative with beyond-use dates when a product is dispensed in hot, humid weather, especially when you cannot be sure that the product will be stored under controlled conditions.

2. Single-unit and unit-dose containers for nonsterile dosage forms

a. If a prescription medication is transferred to a unit-dose package, USP regulations are more strict because most unit-dose packages do not provide as secure a moisture barrier as multi-dose packages.

b. For these, it is stated in the *USP* 23 that: "In the absence of stability data to the contrary, such date (i.e., expiration date) should not exceed: (i) 25% of the remaining time between the date of repackaging and the expiration date on the original manufacturer's bulk container; or (ii) a six-month period from the date the drug is repackaged, whichever is earlier". For a more complete discussion of these standards, consult the *USP* 23, Section <661> Containers, Single-Unit Containers and Unit-Dose Containers for Nonsterile Solid and Liquid Dosage Forms, pp. 1786-1787.

c. The above recommendation assumes that the product is being stored at

(背面仍有題目,請繼續作答)

controlled room temperature with relative humidity not exceeding 75% at 23℃, and that the drug being repackaged is not one with known stability problems . Repackagers are required to use unit-dose containers that comply with *USP* specifications for Class A or B containers, so it is recommended that pharmacists use packaging materials that meet these standards.

3. Customized patient medication packages
   a. A customized patient medication package is a package prepared by a pharmacist for a specific patient. It is comprised of a series of packets or containers that contain two or more prescribed solid oral dosage forms. It is intended as a compliance aid for the patient so that each packet or container is labeled with the day and time that the contents of that container are to be taken.
   b. The *USP* has separate recommendations for labeling of patient medication packages. These can be found in their entirety in the *USP* 23, Section <661> Container, Customized Patient Medication Packages. The section on expiration or beyond-use dates recommends using a maximum of 60 days from the date of preparation, provided that it does not exceed the shortest expiration date on the original manufacturer's bulk container for the dosage forms in the pack.

III. 依優良藥品調劑作業規範第四十四條所記：藥事人員應依藥師法規定，於藥品容器包裝上記明下列事項－〈一〉藥局之名稱、地址、電話號碼；〈二〉處方編號及調劑日期；〈三〉病患姓名、性別；〈四〉藥品商品名；〈五〉藥品單位含量與數量；〈六〉清楚的劑量、頻次、途徑與簡短的用藥指示；〈七〉藥品使用期限；〈八〉調劑者姓名。
請參閱下列剪報後，就藥袋標示的現況提出您的見解。(10 points)

藥袋統一標示 三月實施

內容包括調劑者姓名等十二項 藥物副作用仍由醫師告知

〔記者王維菁／台北報導〕藥袋標示項目參差不齊的現象即將成爲過去式，行政院衛生署昨開會決議，三月起藥袋標示內容將統一爲十二個項目，包括：藥物商品名、用法、用量、調劑處等，並首度將用藥諮詢電話納入，不過民眾關心的藥物適應症、主要副作用與必要的服藥指示均未列入罹標示項目，僅建議爲醫師口頭告知事項。

衛生署副署長楊漢溾指出，未來藥袋（包括：藥局藥袋）需統一標示的十二個項目包括：病人姓名、性別、藥品商品名、藥物單位、含量、適用量、建議用法、用量、調劑處名稱、地址、電話與調劑者姓名等，病人將不再有看到藥袋卻霧煞煞的困擾，有問題也可藉由電話諮詢得到解答。

至於民眾經常詢問的主要適應症、藥物副作用以及必要用藥指示等爲何不列入標示中？

楊漢溾表示，以美國而言，適應症、副作用與用藥指示都屬於醫師諮詢項目，由於藥物一般均有多種適應症與副作用，在藥劑師無法完全分得知患者病情狀況下，廣泛列出適應症恐會失焦。

至於特殊、必要的用藥指示，如部分藥物無法與酸性食品併用、服用抗組織胺藥物後不適合開車、部分藥物有特殊保存方式等，因不屬於全面性的藥物現象，因此衛生署也建議醫師以口頭方式告知患者即可。

而部分醫界建議加列項目如：藥物中文標示、藥品保存期限、處方編號、病人年齡等，楊漢溾指出，部分項目不符患者醫求（如：處方編號），部分標示不甚必要（如：患者年齡、藥品保存期限），而藥品中文標示目前很難達成，因此該建議衛生署不予採納。

衛生署表示，十二項統一標示項目由於法源散佈於藥師法、醫師法、健保相關規定及優良藥品調劑規範中，部分規定目前缺乏罰則，諮詢電話標示項目則缺乏法源，所以衛生署未來除將推動修法外，現階段將先以行政命令的方式協調醫院、診所與藥局共同執行藥袋標示統一的政策。

副作用不標示 醫改會：失望

〔記者洪素珊／台北報導〕衛生署即將公告藥袋標示標準項目，對此近來推動藥袋標示不遺餘力的醫療改革基金會昨日間訊表示「肯定其立意良善」。

但獲知衛生署將包括：「藥物副作用、適應症以及藥物保存方式」二項資訊列爲醫師告知事項，而非藥袋標示事項，醫改會表示「失望」，並指衛生署「不了解現階段醫療環境」，沒有活在現實生活中。醫改會董事長張苙雯說，醫改會不認爲現今「三長兩短」現實醫療環境中，醫師有可能花時間向患者詳細說明藥品適應症與副作用或保存方式。

張苙雯表示，現在很多患者拿著藥包回去，根本不知道有些藥品不能被光線直接照射、必須保存在室溫等，放在車上讓陽光一路曬回去，藥品品質早就走了樣。張苙雯更直指，即使以目前藥師人數與病患人數比百來，換點也不可能有能力負荷這項新增任務可能帶來的龐大工作量。

而即使醫師有心力，有時間與患者溝通上述項目，張苙雯認爲以我國民眾對於藥品「薄弱」的知識，能否充分掌握專業醫事人員所傳達訊息，也是一大問題。張苙雯表示，望外研究顯示，在醫師交代完用關事項後，充分鐘，就有近半數的人會遺忘部分資訊，原應患者到家後，還能記得多少，恐滋令人質疑。

至於這次也沒有被訂定在標準項目中的「藥廠名稱」與批號，張苙雯表示，這項標示便於日後責任歸屬認定，對於藥廠應該沒有什麼不妥，她不了解爲什麼衛生署將這項資訊排除在外。