实用药学英语

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前　言

随着我国“一带一路”倡议和“走出去”战略的提出，国家对复合型技能型人才的需求与日俱增。与此同时，2019 年国务院印发的《国家职业教育改革实施方案》提出了“三教”（教师、教材、教法）改革的任务，指出“三教”改革落脚点是培养适应行业企业需求的复合型、创新型高素质技术技能人才，目的是提升学生的综合职业能力。基于此背景，本书编者编写了这本针对我国高职高专及应用型本科药学及相关专业学生，突出实用性、应用性，同时符合职业院校学生的英语水平和认知特点的《实用药学英语》教材。

本教材包括药品研发、药品生产、药品使用、用药安全、药品行业相关职业技能和拓展阅读六个模块，每个模块由四至六篇课文组成，每篇课文后都精心设计了词汇、阅读和口语练习。在“课程思政”理念的指导下，选材与任务设计实现了知识性、实用性和育人性的有机统一。编者精心选取教材内容，设计形式各异的练习，旨在让学生熟悉和了解药学领域相关岗位职责和中医药文化，提高学生的英语综合应用能力和分析解决问题的能力，培养学生的批判性思维，涵养他们的文化自信和制度自信，为我国培养具有良好职业素养的复合型、创新型高素质技术技能人才。

本书由酒泉职业技术学院易建红主编并负责全书统稿，范佩芳任副主编。本书在编写过程中，得到了西南交通大学出版社和酒泉职业技术学院的大力支持和帮助，在此表示衷心的感谢。

鉴于编者水平有限，本书不妥之处在所难免，恳请各位读者提出宝贵意见，使本教材能进一步完善。

Contents

Module One

The R&D of Drug

- Mastering vocabularies and expressions related to the R&D of drug.
- Understanding the definition of patented drug and generic drug.
- Knowing the history of TCM.

- Skimming and scanning.
- Identifying each phrases in the R&D of drug.
- Introducing TCM in English.
- Sharing one’s opinion with others.

- Understanding the connotation of scientific spirit.
- Knowing the importance of inheritance and innovation.
- Developing confidence in TCM.
- Knowing the importance of protecting patent rights.

Lesson One　Drug Discovery

It is the mission of pharmaceutical research companies to take the path from understanding a disease to bringing a safe and effective new treatment to patients. Scientists work to piece together the basic causes of disease at the level of genes, proteins and cells. Out of this understanding emerge “targets,” which potential new drugs might be able to affect. Researchers work to:

• validate these targets

• discover the right molecule (potential drug) to interact with the target chosen

• test the new compound in the lab and clinic for safety and efficacy and gain approval and get the new drug into the hands of doctors and patients.

It takes about 10 – 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. The average cost to research and develop each successful drug is estimated to be $800 million to $1 billion. This number includes the cost of the thousands of failures: For every 5,000–10,000 compounds that enter the research and development (R&D) pipeline, ultimately only one receives approval. These numbers defy imagination, but a deeper understanding of the R&D process can explain why so many compounds don’t make it and why it takes such a large, lengthy effort to get one medicine to patients. Success requires immense resources – the best scientific minds, highly sophisticated technology and complex project management. It also takes persistence and, sometimes, luck.

1. Pre-discovery

Understand the Disease

Before any potential new medicine can be discovered, scientists work to understand the disease to be treated as well as possible, and to unravel the underlying cause of the condition. They try to understand how the genes are altered, how that affects the proteins they encode and how those proteins interact with each other in living cells, how those affected cells change the specific tissue they are in and finally how the disease affects the entire patient. This knowledge is the basis for treating the problem. Researchers from government, academia

and industry all contribute to this knowledge base. However, even with new tools and insights, this research takes many years of work and, too often, leads to frustrating dead ends. And even if the research is successful, it will take many more years of work to turn this basic understanding of what causes a disease into a new treatment.

Target Identification

Choose a molecule to target with a drug. Once they have enough understanding of the underlying cause of a disease, pharmaceutical researchers select a “target” for a potential new medicine. A target is generally a single molecule, such as a gene or protein, which is involved in a particular disease. Even at this early stage in drug discovery it is critical that researchers pick a target that is “drugable,” i.e., one that can potentially interact with and be affected by a drug molecule. Target validation test the target and confirm its role in the disease After choosing a potential target, scientists must show that it actually is involved in the disease and can be acted upon by a drug. Target validation is crucial to help scientists avoid research paths that look promising, but ultimately lead to dead ends. Researchers demonstrate that a particular target is relevant to the disease being studied through complicated experiments in both living cells and in animal models of disease.

2. Drug Discovery

Find a promising molecule (a “lead compound”) that could become a drug. Armed with their understanding of the disease, scientists are ready to begin looking for a drug. They search for a molecule, or “lead compound,” that may act on their target to alter the disease course. If successful over long odds and years of testing, the lead compound can ultimately become a new medicine. There are a few ways to find a lead compound. Nature: Until recently, scientists usually turned to nature to find interesting compounds for fighting disease. Bacteria found in soil and moldy plants both led to important new treatments, for example. Nature still offers many useful substances, but now there are other ways to approach drug discovery. De novo: Thanks to advances in chemistry, scientists can also create molecules from scratch. They can use sophisticated computer modeling to predict what type of molecule may work. High-throughput Screening: This process is the most common way that leads are usually found. Advances in

robotics and computational power allow researchers to test hundreds of thousands of compounds against the target to identify any that might be promising. Based on the results, several lead compounds are usually selected for further study. Biotechnology: Scientists can also genetically engineer living systems to produce disease-fighting biological molecules.

Early Safety Tests

Perform initial tests on promising compounds lead compounds go through a series of tests to provide an early assessment of the safety of the lead compound. Scientists test absorption, distribution, metabolism, excretion and toxicological (ADME/Tox) properties, or "pharmacokinetics," of each lead. Successful drugs must be:

absorbed into the bloodstream,

distributed to the proper site of action in the body,

metabolized efficiently and effectively,

successfully excreted from the body,

demonstrated to be not toxic.

These studies help researchers prioritize lead compounds early in the discovery process. ADME/Tox studies are performed in living cells, in animals and via computational models.

Lead Optimization

Alter the structure of lead candidates to improve properties. Lead compounds that survive the initial screening are then "optimized," or altered to make them more effective and safer. By changing the structure of a compound, scientists can give it different properties. For example, they can make it less likely to interact with other chemical pathways in the body, thus reducing the potential for side effects. Hundreds of different variations or "analogues" of the initial leads are made and tested. Teams of biologists and chemists work together closely: The biologists test the effects of analogues on biological systems while the chemists take this information to make additional alterations that are then retested by the biologists. The resulting compound is the candidate drug. Even at this early stage, researchers begin to think about how the drug will be made, considering formulation (the recipe for making a drug, including inactive ingredients used to hold it together and allow it to dissolve at the right time), delivery mechanism (the way the drug is taken – by mouth, injection, inhaler) and large-scale manufacturing (how you make the drug in large quantities).

Preclinical Testing

Lab and animal testing to determine if the drug is safe enough for human testing. With one or more optimized compounds in hand, researchers turn their attention to testing them extensively to determine if they should move on to testing in humans. Scientists carry out in vitro and in vivo tests. In vitro tests are experiments conducted in the lab, usually carried out in test tubes and beakers ("vitro" is "glass" in Latin) and in vivo studies are those in living cell cultures and animal models ("vivo" is "life" in Latin). Scientists try to understand how the drug works and what its safety profile looks like. The U.S. Food and Drug Administration (FDA) requires extremely thorough testing before the candidate drug can be studied in humans. During this stage researchers also must work out how to make large enough quantities of the drug for clinical trials. Techniques for making a drug in the lab on a small scale do not translate easily to larger production. This is the first scale up. The drug will need to be scaled up even more if it is approved for use in the general patient population. At the end of several years of intensive work, the discovery phase concludes. After starting with approximately 5,000 to 10,000 compounds, scientists now have winnowed the group down to between one and five molecules, "candidate drugs," which will be studied in clinical trials.

validate	[ˈvælɪˌdeɪt]	*vt.* 使生效
candidate	[ˈkændɪˌdeɪt]	*n.* 候选
efficacy	[ˈefɪkəsɪ]	*n.* 功效
alter	[ˈɔːltə]	*vi.* 改变；更改
approval	[əˈpruːvl]	*n.*（正式的）批准
identification	[aɪˌdentɪfɪˈkeɪʃən]	*n.* 认同
compound	[ˈkɒmpaʊnd]	*n.* 化合物
absorption	[əbˈzɔːpʃən]	*n.* 吸收
defy	[dɪˈfaɪ]	*vt.* 公然违抗
distribution	[ˌdɪstrɪˈbjuːʃən]	*n.* 分布

lengthy	[ˈleŋθɪ]	*adj*. 漫长的
excretion	[ɪkˈskriːʃən]	*n*. 排泄；排出
properties	[ˈprɒpətɪz]	*n*. 性能
toxicological	[tɒksɪkəˈlɒdʒɪkl]	*adj*. 毒理学的

vitro test　体外试验
vivo tests　活体试验
interact with　与……相互作用
lead optimization　先导化合物的优化
be scaled up　扩大规模
armed with　以……为武器

1. Read the text and finish the quiz.

1. On average, it takes _____ years to do the discovery research and testing to bring a new drug to the market.

A. 6 – 9

B. 9 – 12

C. 12 – 15

D. 15 – 18

2. Which one is NOT a reason promising compounds might be abandoned?

A. Safety/toxicity issues.

B. Poor absorption or ineffectiveness.

C. Manufacturing difficulties.

D. Limited market potential.

3. What is the purpose of pre-clinical testing?

A. Verify that a drug is sufficiently safe and effective to be tested in humans.

B. Undergo preliminary testing in healthy humans to monitor the effects of the drug.

C. Create a basic outline for the larger scale future tests on a widespread population.

D. A and B.

4. Which is the primary goal/major milestone of preclinical development?

A. Filing an IND application with the FDA.

B. Identifying the target population for the lead compound that is being developed.

C. To determine anticipated revenue.

2. Rank the order of discovering a new drug.

A. understand the disease　B. target identification　G. preclinical test

C. early safety test　D. target validation　F. drug discovery

E. lead optimization

Step1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7

Read the story *Chinese scientist Tu Youyou and Artemisinin* and share with your partners on what you've learned from this story.

中国故事——屠呦呦和青蒿素

2015 年 10 月 5 日，从瑞典斯德哥尔摩传来令人振奋的消息:中国女科学家屠呦呦获得 2015 年诺贝尔生理学或医学奖。理由是她发现了青蒿素，这种药品可以有效降低疟疾患者的死亡率。屠呦呦是第一位获得诺贝尔科学奖项的中国本土科学家、第一位获得诺贝尔生理医学奖的华人科学家。

屠呦呦获得了诺贝尔生理学或医学奖，填补了我国无诺贝尔科学奖的空白。她将中医中药推向了世界，她将民族的变成世界的。过去，包括很多中国人在内的国内外学者专家，都批评中医中药为伪科学。屠呦呦用诺贝尔医学奖粉碎了他们对中医中药的攻击，奠定了中医中药在世界医学领域的地位。

屠呦呦是民族的功勋、佼佼者，她对科学的贡献是卓著的。

40年前的科研条件和环境可想而知，屠呦呦要从医药中寻找抗疟新药谈何容易？屠呦呦和她的团队，克服重重困难，可谓历经千辛万苦。失败了，推掉重来，经历了无数次的实验。在失败面前，他们不言弃，始终执着地追求。屠呦呦被称为“三无教授”，她毫不在乎，兢兢业业，对科学执着追求，锲而不舍。为了检验药物的效果，屠呦呦甚至亲自口服药物，尝试药物在自己身上的反应，以做到保证药物的万无一失，屠呦呦的肝脏因此受到了损伤，牺牲了自己的健康，目的就是换来大家的健康，换来人类的科学进步。屠呦呦与青蒿素之间充满了许多精彩传奇故事，表现了科学家的态度、品质和精神，屠呦呦的精彩故事是一本极好的励志书。必须用好这本书，教育我们的下一代，学习科学家的精神特质，“攻城不怕坚，攻书莫畏难。科学有险阻，苦战能过关。”在困难面前不低头，在荣誉待遇面前不伸手，为着祖国的科学事业默默无闻无私奉献。

Lesson Two　Drug Development Process

Before any clinical trial can begin, the researchers must file an Investigational New Drug (IND) application with the FDA. The application includes the results of the preclinical work, the candidate drug's chemical structure and how it is thought to work in the body, a listing of any side effects and manufacturing information. The IND also provides a detailed clinical trial plan that outlines how, where and by whom the studies will be performed. The FDA reviews the application to make sure people participating in the clinical trials will not be exposed to unreasonable risks.

FDA IND Review Team

The review team consists of a group of specialists in different scientific fields. Each member has different responsibilities.

Members	Responsibilities
Project Manager	Coordinates the team's activities throughout the review process, and is the primary contact for the sponsor.
Medical Officer	Reviews all clinical study information and data before, during, and after the trial is complete.
Statistician	Interprets clinical trial designs and data, and works closely with the medical officer to evaluate protocols and safety and efficacy data.
Pharmacologist	Reviews preclinical studies.
Pharmacokineticist	Focuses on the drug's absorption, distribution, metabolism, and excretion processes. Interprets blood-level data at different time intervals from clinical trials, as a way to assess drug dosages and administration schedules.
Chemist	Evaluates a drug's chemical compounds. Analyzes how a drug was made and its stability, quality control, continuity, the presence of impurities, etc.
Microbiologist	Reviews the data submitted, if the product is an antimicrobial product, to assess response across different classes of microbes.

Approval

The FDA review team has 30 days to review the original IND submission. The process protects volunteers who participate in clinical trials from unreasonable and significant risk in clinical trials. FDA responds to IND applications in one of two ways:

Approval to begin clinical trials.

Clinical hold to delay or stop the investigation. FDA can place a clinical hold for specific reasons, including: Participants are exposed to unreasonable or significant risk; Investigators are not qualified; Materials for the volunteer participants are misleading; The IND application does not include enough information about the trial's risks.

A clinical hold is rare. Instead, FDA often provides comments intended to improve the quality of a clinical trial. In most cases, if FDA is satisfied that the trial meets Federal standards, the applicant is allowed to proceed with the proposed study.

The developer is responsible for informing the review team about new protocols, as well as serious side effects seen during the trial. This information ensures that the team can monitor the trials carefully for signs of any problems. After the trial ends, researchers must submit study reports. This process continues until the developer decides to end clinical trials or files a marketing application. Before filing a marketing application, a developer must have adequate data from two large, controlled clinical trials.

Phase 1　Clinical Trial Perform initial human testing in a small group of healthy volunteers

The candidate drug is tested in people for the first time. These studies are usually conducted with about 20 to 100 healthy volunteers. The main goal of a Phase 1 trial is to discover if the drug is safe in humans. Researchers look at the pharmacokinetics of a drug: How is it absorbed? How is it metabolized and eliminated from the body? They also study the drug's pharmacodynamics: Does it cause side effects? Does it produce desired effects? These closely monitored trials are designed to help researchers determine what the safe dosing range is and if it should move on to further development.

Phase 2　Clinical Trial Test in a small group of patients

The researchers evaluate the candidate drug's effectiveness in about 100 to

500 patients with the disease or condition under study, and examine the possible short-term side effects (adverse events) and risks associated with the drug. They also strive to answer these questions: Is the drug working by the expected mechanism? Does it improve the condition in question? Researchers also analyze optimal dose strength and schedules for using the drug. If the drug continues to show promise, they prepare for the much larger Phase 3 trials.

Phase 3 Clinical Trial Test in a large group of patients to show safety and efficacy

The researchers study the drug candidate in a larger number (about 1,000 – 5,000) of patients to generate statistically significant data about safety, efficacy and the overall benefit-risk relationship of the drug. This phase of research is key in determining whether the drug is safe and effective. It also provides the basis for labeling instructions to help ensure proper use of the drug (e.g., information on potential interactions with other medicines). Phase 3 trials are both the costliest and longest trials. Hundreds of sites around the United States and the world participate in the study to get a large and diverse group of patients. Coordinating all the sites and the data coming from them is a monumental task. During the Phase 3 trial (and even in Phases 1 and 2), researchers are also conducting many other critical studies, including plans for full scale production and preparation of the complex application required for FDA approval.

New Drug Application (NDA) submit application for approval to FDA

Once all three phases of the clinical trials are complete, the sponsoring company analyzes all of the data. If the findings demonstrate that the experimental medicine is both safe and effective, the company files a New Drug Application (NDA) – which can run 100,000 pages or more – with the FDA requesting approval to market the drug. The NDA includes all of the information from the previous years of work, as well as the proposals for manufacturing and labeling of the new medicine.

Once FDA receives an NDA, the review team decides if it is complete. If it is not complete, the review team can refuse to file the NDA. If it is complete, the review team has 6 to 10 months to make a decision on whether to approve the drug. The process includes the following:

Each member of the review team conducts a full review of his or her section

of the application. For example, the medical officer and the statistician review clinical data, while a pharmacologist reviews the data from animal studies. Within each technical discipline represented on the team, there is also a supervisory review.

FDA inspectors travel to clinical study sites to conduct a routine inspection. The Agency looks for evidence of fabrication, manipulation, or withholding of data.

The project manager assembles all individual reviews and other documents, such as the inspection report, into an "action package." This document becomes the record for FDA review. The review team issues a recommendation, and a senior FDA official makes a decision.

Following rigorous review, the FDA can either 1) approve the medicine, 2) send the company an "approvable" letter requesting more information or studies before approval can be given, or 3) deny approval.

Review of an NDA may include an evaluation by an advisory committee, an independent panel of FDA-appointed experts who consider data presented by company representatives and FDA reviewers. Committees then vote on whether the FDA should approve an application, and under what conditions. The FDA is not required to follow the commendations of the advisory committees, but often does

Manufacturing

Going from small-scale to large-scale manufacturing is a major undertaking. In many cases, companies must build a new manufacturing facility or reconstruct an old one because the manufacturing process is different from drug to drug. Each facility must meet strict FDA guidelines for Good Manufacturing Practices (GMP). Making a high-quality drug compound on a large scale takes great care. Imagine trying to make a cake, for example, on a large scale – making sure the ingredients are evenly distributed in the mix, ensuring that it heats evenly. The process to manufacture most drugs is even more complicated than this. There are few, if any, other businesses that require this level of skill in manufacturing. Ongoing Studies and Phase 4 Trials Research on a new medicine continues even after approval. As a much larger number of patients begin to use the drug, companies must continue to monitor it carefully and submit periodic reports, including cases of adverse events, to the FDA. In addition, the FDA sometimes

requires a company to conduct additional studies on an approved drug in “Phase 4” studies. These trials can be set up to evaluate long-term safety or how the new medicine affects a specific subgroup of patients.

The discovery and development of new medicines is a long, complicated process. Each success is built on many, many prior failures. Advances in understanding human biology and disease are opening up exciting new possibilities for breakthrough medicines. At the same time, researchers face great challenges in understanding and applying these advances to the treatment of disease. These possibilities will grow as our scientific knowledge expands and becomes increasingly complex. Research-based pharmaceutical companies are committed to advancing science and bringing new medicines to patients.

Ongoing Studies and Phase 4 Trials

Even though clinical trials provide important information on a drug’s efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval. Despite the rigorous steps in the process of drug development, limitations exist. Therefore, the true picture of a product’s safety actually evolves over the months and even years that make up a product’s lifetime in the marketplace. FDA reviews reports of problems with prescription and over-the-counter drugs, and can decide to add cautions to the dosage or usage information, as well as other measures for more serious issues.

Supplemental Applications

Developers must file a supplemental application if they wish to make any significant changes from the original NDA. Generally, any changes in formulation, labeling, or dosage strength must be approved by FDA before they can be made.

INDs for Marketed Drugs

If sponsors want to further develop an approved drug for a new use, dosage strength, new form, or different form (such as an injectable or oral liquid, as opposed to tablet form), or if they want to conduct other clinical research or a post-market safety study, they would do so under an IND.

Manufacturer Inspections

FDA officials conduct routine inspections of drug manufacturing facilities across the United States, and abroad if approved products are manufactured overseas. Manufacturers may be informed of inspections in advance, or the

inspections may be unannounced. Inspections may be routine or caused by a particular problem or concern. The purpose of these inspections is to make sure that developers are following good manufacturer practice. FDA can shut down a facility if minimum standards are not met.

Drug Advertising

FDA regulates prescription drug advertisements and promotional labeling. By law, a developer is prohibited from advertising unapproved uses of their product.

All advertisements cannot be false or misleading. They must contain truthful information about a drug's effectiveness, side effects, and prescribing information. These advertisements can be found in medical journals, newspapers, and magazines, and on the Internet, television, or radio.

Promotional labeling differs from drug advertisements in the way it is distributed. Pharmaceutical companies give out brochures or other promotional materials to physicians or consumers. The drug's prescribing information must accompany promotional labeling.

Generic Drugs

New drugs are patent protected when they are approved for marketing. This means that only the sponsor has the right to market the drug exclusively. Once the patent expires, other drug manufacturers can develop the drug, which will be known as a generic version of the drug. Generic drugs are comparable to brand name drugs and must have the same dosage form, strength, safety, quality, performance and characteristics. Because generic drugs are comparable to drugs already on the market, generic drug manufacturers do not have to conduct clinical trials to demonstrate that their product is safe and effective. Instead, they conduct bio-equivalence studies and file an Abbreviated New Drug Application.

Reporting Problems

FDA has several programs that allow manufacturers, health professionals, and consumers to report problems associated with approved drugs.

Active Surveillance

Under the Sentinel Initiative, FDA is developing a new national system to more quickly spot possible safety issues. The system will use very large existing electronic health databases – like electronic health records systems, administrative and insurance claims databases, and registries – to keep an eye on the safety of

approved medical products in real time. This tool will add to, but not replace, FDA's existing post-market safety assessment tools.

clinical	[ˈklɪnɪkl]	*adj*. 临床的
metabolize	[mɪˈtæbəˌlaɪz]	*v*. 使代谢
optimal	[ˈɒptɪml]	*adj*. 最佳的
sponsor	[ˈspɒnsə]	*n*. 赞助方
generic	[dʒɪˈnerɪk]	*n*. 非专利商品
surveillance	[səˈveɪləns]	*v*. 监管

1. Read the text and fill in the form.

Phase	Subject	Purpose	Time of Length
1	20 – 100 Healthy people	To discover if the drug is safe in human	Several month
2			
3			
4			

2. Read the text and finish the quiz.

1. On what does Phase 1 clinical testing test?

A. Animal subjects.

B. Healthy human volunteers.

C. Widespread differentiated population.

D. People with the target disease/condition.

E. Large-scale tests in people with the target disease/population.

2. On what does Phase 2 clinical trials test?

A. Animals.

B. Healthy human volunteers.

C. Widespread differentiated population.

D. 100 – 500 people with the target disease/condition.

3. On what does Phase 3 trials test?

A. Animals.

B. Healthy human volunteers.

C. 1,000 – 5,000 people with the target disease/condition.

4. What is the approximate ratio of potential compounds the beginning of development to number of products that ultimately get FDA approval?

A. 1∶10　　B. 1∶100　　C. 1∶1,000　　D. 1∶10,000

5. What is the purpose of Phase 1 clinical trials?

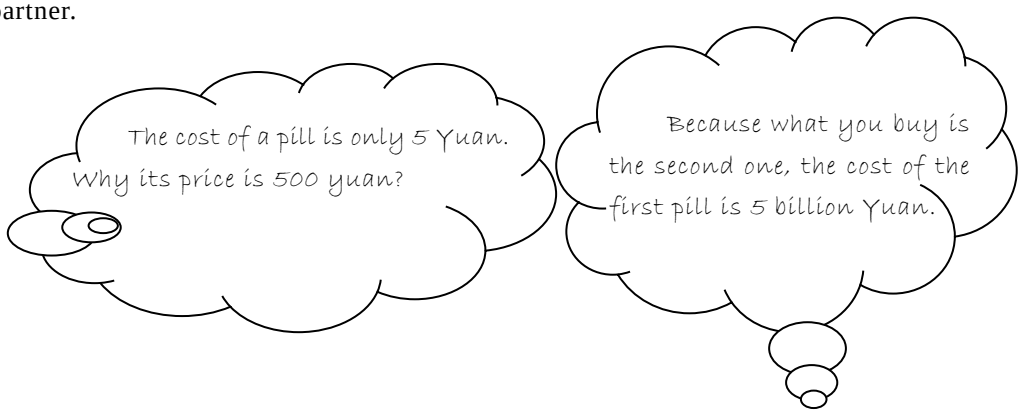
A. To select a lead compound from a lead series.

B. To identify a target population.

C. To establish the safety of administration to humans.

D. To test whether the proposed drug actually works.

1. How should we understand the dialogue? Share your opinion with your partner.



2. What is the connotation of craftsman spirit? Read the story and share your opinion with your partners.

中国故事——医药研发战线上的工匠精神

张冬梅，鲁抗医药研发中心合成室主任。张冬梅天生对于科学与未知世界怀有探索的执着与热忱，1995 年 7 月，年仅 22 岁的张冬梅从华东理工大学化学制药专业毕业后，便一头扎入科研的海洋中——山东鲁抗医药股份有限公司研发中心。在 21 年的科研生涯中，张冬梅曾获得多项发明专利，论文曾多次刊登在医药化工刊物当中。科研工作很苦很累很寂寞，当问及是什么让她在这 20 多年里日复一日年复一年地坚持着，张冬梅眼睛里闪现着孩童般的光芒：“可能是热爱吧！”在实验室里，她乐此不疲地探索着未知的世界；在她的书架上总是放满了各种各样的关于药物研究的书籍，以便随时查阅。桌上一本《中华人民共和国药典》也因为张冬梅的执着增添了很多“伤疤”和“补丁”。面对这些“伤疤”，张冬梅表示她很享受实验室里的生活，她说：“研发是一个具有挑战性的积累的过程，更是一项长期战斗的过程。研究的东西往往是之前不存在的，优秀的科研成果来自广泛阅读后的厚积薄发，来自实验室日复一日的长期积累，每天生活都是在实验室度过，进入攻关的时候，实验会从早上 8 点一直持续到晚上 10 点。做实验是一件让人享受的活儿，有很多实验改变一个变量，就可能有不同的结果，为了得到想要的数据，每个实验都是一次探索和历险，这个过程是值得我们去享受的。”

张冬梅告诉我们，科研人员不仅要有常人难以企及的执着和毅力，更要具有颠覆常规的创新力。张冬梅回忆：实验中曾经用到过一种催化剂——正丁基锂，它是一种化学反应活性很高，且极不稳定的物质。在使用或者运输过程中很容易发生燃烧或者爆炸，也不容易购买储存。在此种情况下，张冬

梅提出由鲁抗研发人员自己合成正丁基锂。在试生产过程中，由于初次进行该项操作，引发剂的加入需要摸索，与中试不同，张冬梅发现温度突然急剧上升，一想到封闭的罐体里面装满了低沸点的乙醚，一旦温度失控将会发生剧烈的爆炸，后果不堪设想，所有人都害怕了。正当其他人都一筹莫展的时候，她当机立断迅速关闭普通降温系统打开液氮系统，温度这才渐渐稳了下来。没错，研究工作虽然枯燥单调，遇到的困难数不胜数，但解决问题的喜悦吸引着她，困难无法阻止她追寻真理的步伐，反而激发了她更强大的战斗力。

张冬梅带领着实验室里的博士、硕士研究生们，日复一日对新药品的研发进行着实验，目前有两个精制方法的发明专利正在公示阶段中。科研是一个非常艰苦枯燥的过程，你不奉献你的玩乐时间、休息时间是做不成科研的。就学生的培养过程而言，张冬梅首先要求学生能正确认识到什么是科研。科研绝不是每天坐在实验室里，而是要就现实问题去分析，把握其问题的影响因素，然后拿出一个可行的方案。不光对研究生们，对自己也一样，她所要求的最基本的就是要耐得住寂寞、能够吃苦、勤于动手。事实上，这种苦中作乐的情怀贯穿了张冬梅的整个科研生涯，但她觉得这是一种对科学技术的信仰。

Lesson Three Patented Drugs, Original Drugs and Generic Drugs

From the perspective of R & D, drugs can be divided into patented drugs, original drugs and generic drugs.

Patented drugs and originally developed drugs are actually the same thing. They are used to being called “patented drugs” during the patent period. After the patent period, they are called “originally developed drugs”.

1. Patented Drug / Original Drug

Patented drug or original drug is an original new drug. The whole process needs to go through a long R & D process: start from finding the target of disease control, studying the receptor, then select the leading compound and optimize the prevalent compound. The following process are technical drug R & D, preparation R & D, small-scale, pilot scale and large-scale production. It also needs to do experiments on animals, and finally clinical trials, and apply for listing after passing the full test. The whole process normally takes more than ten years and more than $1 billion. So enterprise must apply for patents long before listing.

In most cases, the drug patent is awarded for around twenty years in the United States. The lifetime of the patent varies between countries and also between drugs. Since the company applies for a patent long before the clinical trial to assess a drug’s safety and efficacy has commenced, the effective patent period after the drug has finally received approval is often around seven to twelve years.

Once the patent has expired, the drug can be manufactured and sold by other companies. At this point, the drug is referred to as a generic drug.

2. Generic Drug

Generic drug is a medicinal product that contains the same amount of active substance and affords the same bioavailability as a proprietary medicine whose patent has expired. Proprietary medicinal products are protected by patent for a number of years in order to facilitate the pharmaceutical company that funded

the lengthy research and product launch process. At the end of this “protected” period, the medicinal product may be manufactured by other pharmaceutical companies and sold at lower prices. According to guidelines in most countries, including those from the US FDA, generic drugs have to be identical to the branded drug in terms of efficacy, safety, usage, route of drug administration, pharmacokinetics and pharmacodynamics. In all medicines there are both active and inactive ingredients. The inactive ingredients in the medicine are called excipients. Generic medicines may have different inactive ingredients, which can make them look different.

When a company makes a new medicine, they can patent it so that they’re the only ones who can make it. While a medicine is under patent, the pharmaceutical company can charge more for it. This covers the cost of developing, testing and marketing the new medicine. Once the patent expires, other companies can start making the same medicine, the “generic” version. It costs less for other companies to put the medicine on the market. They don’t have to: develop the medicine from scratch pay for research; market it; carry out the same clinical trials.

Competition between different companies also reduces the cost of generic medicines.

Drug can be manufactured as a generic drug when:

*Its patent has expired.

*The company that would manufacture the generic drug certifies that the patents held on the drug are either unenforceable, are invalid or would not be infringed upon.

*There has never been any patents on the drug before.

*In countries where the drug has no patent protection.

Once the generic drug is on the market, the monopoly of the patent holder is removed. This encourages competition and results in a significant drop in drug costs, which ensures that life-saving and important drugs reach the general population at comparative prices.

As we know, India is the biggest country that manufactures and sells patented drugs. Because India’s patent protection law is loose, India’s patent law only protects process patents, not pharmaceutical ingredient patents, that is, different production methods. In addition, the government of India may grant

compulsory licenses as required. Compulsory license is to authorize the imitation enterprise to copy and sell legally without the consent of the patentee and forcibly paying a small amount of patent transfer fee. China, because of its accession to the WTO, should strictly abide by the intellectual property protection law and will not approve generic drugs within the patent period. During the patent period, the original research price is expensive and the imitation is wrong. What can we do?

Solutions

1. Medical insurance negotiation

The National Medical Insurance Bureau will select a batch of drugs every year, including some new drugs that have just been approved for marketing for “bargaining negotiations”.

On the one hand, pharmaceutical enterprises have new drugs and want to enter the medical insurance as soon as possible to open sales; On the other hand, there is a large medical insurance market and patients in urgent need of drugs. Both sides have chips and concerns, so they need to find a price balance.

2. R & D of generic drugs

After the patent of patented drugs became invalid, domestic generic drugs quickly took over, and civilian price drugs began to appear. Although this is imitation, with the national implementation of the “consistency evaluation of generic drugs”, generic drugs need to reach the level of the original drug in terms of quality and efficacy before they can pass. Therefore, generic drugs are also serious and effective drugs.

3. R & D period

In order to shorten the time required for generic drugs to be developed and put on the market, generic drugs can be developed before the expiration of patented drugs. When the R & D is completed and the application for listing is submitted, it can not be approved until the patent of the patented drug expires.

proprietary	[prəˈpraɪətərɪ]	*adj*. 专利的
invalid	[ˈɪnvəlɪd]	*adj*. 无效的

certify [ˈsɜːtɪfaɪ] *v*. 证明；证实

patented drugs 专利药
original drugs 原研药
generic drugs 仿制药
R & D process 研发过程
intellectual property protection 知识产权保护

1. Finish the following sentences by using the words in the box.

takes	expiration	divided	apply for
approve	patent	account for	demand
in terms of	invalid		

1. Once a new drug is discovered, the company files a _____ to protect against other companies making copies and selling the drug.

2. These research and development costs, along with marketing costs, _____ most of the higher prices we pay for most brand name drugs.

3. The whole process normally _____ more than ten years.

4. China Food and Drug Administration will not _____ generic drugs within the patent period.

5. Generic drugs can be developed before the _____ of patented drugs.

6. From the perspective of R & D, drugs can be _____ into patented drugs, original drugs and generic drugs.

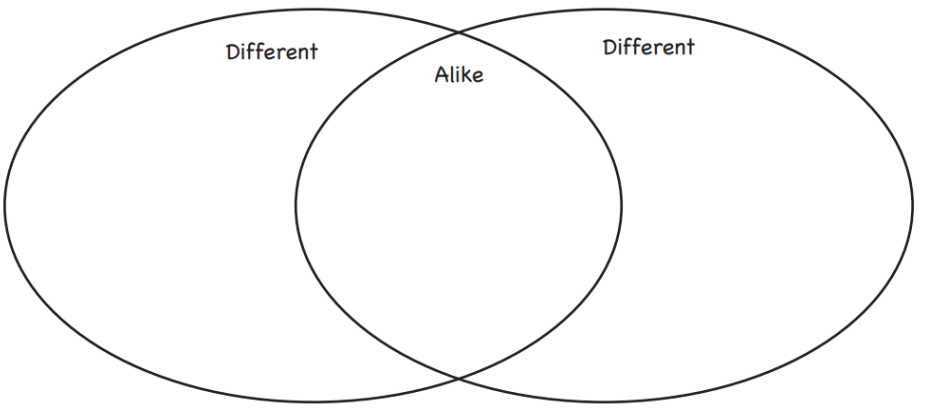
7. So enterprise must _____ patents long before marketing.

8. After the patent of patented drugs became _____, domestic generic drugs quickly took over.

9. Generic drugs need to reach the level of the original drug _____ quality and efficacy before they can pass.

10. There is a great _____ for generic drugs.

2. Find the difference and similarities between patented drug and generic drugs.



1. Read the story and help Joe clear his confusion with what you have learned from the text.

Joe has just been diagnosed with bipolar disorder. After talking to his doctor, he decides to see a therapist and go on medication. Joe's doctor gives him two weeks' worth of samples for patented drug called SteadyMood and asks him to come back to see him in two weeks. When he returns, Joe's feeling a little better and agrees to keep taking SteadyMood for another month. When he gets to the pharmacy, Joe learns that his insurance plan's co-pay for a month's supply of SteadyMood is $40. This seems a little expensive to him, so he asks the pharmacist about it. His pharmacist tells him that he's fortunate to have insurance coverage; without it, the patented would cost $100. Joe asks if there's another drug he could take that costs less. The pharmacist tells him that his medication comes in a generic form. His insurance co-pay would be $10 for a month's supply of the generic, but his doctor would have to approve it. The

pharmacist calls Joe's doctor and gets approval to fill his prescription with the generic. The next morning, Joe opens the bottle and sees 30 round, white pills. He's confused and believes there must be some kind of mistake since the SteadyMood samples his doctor gave him were pink ovals. Joe calls his pharmacist who tells him that the round, white pills are the generic form for SteadyMood and they should work just fine. After taking the generic for a month, Joe's feeling much better. He returns to the drugstore with another prescription from his doctor, and this time, it allows for generic substitution. Joe fills his prescription and leaves. The next morning, he opens the bottle to find a completely different-looking medicine – now, the pills are yellow and square. Joe's frustrated and even more confused. Is this a different drug altogether? Is it another type of generic drug? Should he simply stay with the brand name version that his doctor originally gave him?

2. Read the story and talk about how do you understand "People First, Life First".

中国故事——"灵魂砍价"

2022 年伊始，全国多个脊髓性肌萎缩症(SMA)患儿收到一份特殊的新年礼物：正式接受 SMA 靶向药注射。这得益于 2021 年 12 月 3 日火爆全网的"灵魂砍价"。国家医保局谈判代表与药企上演了 8 轮跌宕起伏的"剧情"，将原来近 70 万元每针的诺西那生钠注射液，"砍"至每针 3.3 万元，进入新版医保药品目录。国家医保局谈判代表们倾尽全力作为的表现，既体现出医保药品谈判的不易，也体现了国家推动解决老百姓用药难题的力度和决心，生动诠释了"人民至上、生命至上"的理念。医保药品谈判并非单纯杀价、挤压企业合理利润，而是通过以量换价挤掉药品中不合理的溢价和水分，企业合理利润并不受影响。医保局谈判追求的"不是最低价，而是合理价"，如果谈判"砍价"的幅度突破了企业可承受的范围，可能导致药品无法进入医保或影响到药品质量，最后伤害的还是患者利益。在 2022 年新年贺词中，习近平主席心系民生冷暖、情牵万家灯火，强调"民之所忧，我必念之;民之所盼，我必行之"。一轮又一轮的谈判拉锯战，就是为了利民惠民。一次又一次的"砍价"，是国家公职人员为民尽责的生动实践，标注着"人民至上、生命至上"

的高度与温度。

Lesson Four The Historical Development of TCM[①]

Humanity has created a colorful global civilization in the long course of its development, and the civilization of China is an important component of the world civilization harboring great diversity. As a representative feature of Chinese civilization, traditional Chinese medicine (TCM) is a medical science that was formed and developed in the daily life of the people and in the process of their fight against diseases over thousands of years. It has made a great contribution to the nation's procreation and the country's prosperity, in addition to producing a positive impact on the progress of human civilization.

TCM has created unique views on life, on fitness, on diseases and on the prevention and treatment of diseases during its long history of absorption and innovation. It represents a combination of natural sciences and humanities, embracing profound philosophical ideas of the Chinese nation. As ideas on fitness and medical models change and evolve, traditional Chinese medicine has come to underline a more and more profound value.

1. History of TCM

In remote antiquity, the ancestors of the Chinese nation chanced to find that some creatures and plants could serve as remedies for certain ailments and pains, and came to gradually master their application. As time went by, people began to actively seek out such remedies and methods for preventing and treating diseases. Sayings like "Shennong (Celestial Farmer) tasting a hundred herbs" and "food and medicine coming from the same source" are characteristic of those years.

The discovery of alcohol in the Xia Dynasty (2070 – 1600 BC) and the invention of herbal decoction in the Shang Dynasty (1600 – 1046 BC) rendered medicines more effective.

In the Western Zhou Dynasty (1046 – 771 BC), doctors began to be classified into four categories – dietitian, physician, doctor of decoctions and veterinarian.

During the Spring and Autumn and Warring States Period (770 – 221 BC),

① Excerpt from the white paper on the development of traditional Chinese medicine in China issued by The State Council Information Office.

Bian Que drew on the experience of his predecessors and put forward the four diagnostic methods — inspection, auscultation and olfaction, inquiry, and palpation, laying the foundation for TCM diagnosis and treatment.

The *Huang Di Nei Jing* (*Yellow Emperor's Inner Canon*) compiled during the Qin and Han times (221 BC – AD 220) offered systematic discourses on human physiology, on pathology, on the symptoms of illness, on preventive treatment, and on the principles and methods of treatment. This book defined the framework of TCM, thus serving as a landmark in TCM's development and symbolizing the transformation from the accumulation of clinical experience to the systematic summation of theories. A theoretical framework for TCM had been in place.

The *Shang Han Za Bing Lun* (*Treatise on Febrile Diseases and Miscellaneous Illnesses*) collated by Zhang Zhongjing in the Eastern Han Dynasty (25 – 220) advanced the principles and methods to treat febrile diseases due to exogenous factors (including pestilences). It expounds on the rules and principles of differentiating the patterns of miscellaneous illnesses caused by internal ailments, including their prevention, pathology, symptoms, therapies, and treatment. It establishes the theory and methodology for syndrome pattern diagnosis and treatment differentiation.

The *Shen Nong Ben Cao Jing* (*Shennong's Classic of Materia Medica*) – another masterpiece of medical literature appeared during this period – outlines the theory of the compatibility of medicinal ingredients. For example, it holds that a prescription should include at the same time the jun (or sovereign), chen (or minister), zuo (or assistant) and shi (or messenger) ingredient drugs, and should give expression to the harmony of the seven emotions as well as the properties of drugs known as "four natures" and "five flavors". All this provides guidance to the production of TCM prescriptions, safe application of TCM drugs and enhancement of the therapeutic effects, thus laying the foundation for the formation and development of TCM pharmaceutical theory. In the late years of the Eastern Han Dynasty, Hua Tuo (140 – 208) was recorded to be the first person to use anesthetic (mafeisan) during surgery.

The *Zhen Jiu Jia Yi Jing* (*AB Canon of Acupuncture and Moxibustion*) by Huangfu Mi during the Western Jin time (265 – 316) expounded on the concepts of zangfu (internal organs) and jingluo (meridians and collaterals). This was the

point when theory of jingluo and acupuncture and moxibustion began to take shape.

Sun Simiao, a great doctor of the Tang Dynasty (618 – 907), proposed that mastership of medicine lies in proficient medical skills and lofty medical ethics, which eventually became the embodiment of a moral value of the Chinese nation, a core value that has been conscientiously upheld by the TCM circles.

A herbology and nature masterpiece, the *Ben Cao Gang Mu* (*Compendium of Materia Medica*) compiled by Li Shizhen in the Ming Dynasty (1368 – 1644) was the first book in the world that scientifically categorized medicinal herbs. It was a pioneering work that advanced TCM pharmaceutical theory.

The *Wen Re Lun* (*A Treatise on Epidemic Febrile Diseases*) by Ye Tianshi during the Qing Dynasty (1644 – 1911) developed the principles and methods for prevention and treatment of pestilential febrile diseases. It represents the theory and results of the practice of TCM in preventing and treating such diseases.

Following the spread of Western medicine in China from the mid-Qing Dynasty, especially during the period of the Republic of China (1912 – 1949), some TCM experts began to explore ways to absorb the essence of Western medicine for a combination of TCM with Western medicine.

2. Characteristics of TCM

During its course of development spanning a couple of millennia, TCM has kept drawing and assimilating advanced elements of natural science and humanities. Through many innovations, its theoretical base covered more ground and its remedies against various diseases expanded, displaying unique characteristics.

First, setting great store by the holistic view. TCM deems that the relationship between humans and nature is an interactive and inseparable whole, as are the relationships between humans and the society, and between the internal organs of the human body, so it values the impacts of natural and social environment on health and illness. Moreover, it believes that the mind and body are closely connected, emphasizing the coordination of physical and mental factors and their interactions in the conditions of health and illness.

Second, setting great store by the principle of harmony. TCM lays particular stress on the importance of harmony on health, holding that a person’s physical

health depends on harmony in the functions of the various body organs, the moderate status of the emotional expression, and adaptation and compliance to different environments, of which the most vital is the dynamic balance between yin and yang. The fundamental reason for illness is that various internal and external factors disturb the dynamic balance. Therefore, maintaining health actually means conserving the dynamic balance of body functions, and curing diseases means restoring chaotic body functions to a state of coordination and harmony.

Third, emphasis on individuality. TCM treats a disease based on full consideration of the individual constitution, climatic and seasonal conditions, and environment. This is embodied in the term “giving treatment on the basis of syndrome differentiation”. Syndrome differentiation means diagnosing an illness as a certain syndrome on the basis of analyzing the specific symptoms and physical signs collected by way of inspection, auscultation & olfaction, inquiry, and palpation, while giving treatment means defining the treatment approach in line with the syndrome differentiated. TCM therapies focus on the person who is sick rather than the illness that the patient contracts, i.e., aiming to restore the harmonious state of body functions that is disrupted by pathogenic factors.

Fourth, emphasis on preventive treatment. Preventive treatment is a core belief of TCM, which lays great emphasis on prevention before a disease arises, guarding against pathological changes when falling sick, and protecting recovering patients from relapse. TCM believes that lifestyle is closely related to health, so it advocates health should be preserved in daily life. TCM thinks that a person’s health can be improved through emotional adjustment, balanced labor and rest, a sensible diet, and a regular life, or through appropriate intervention in the lifestyle based on people’s specific physical conditions. By these means, people can cultivate vital energy to protect themselves from harm and keep healthy.

Fifth, simplicity. TCM doctors diagnose patients through inspection, auscultation and olfaction, inquiry, and palpation. In addition to medication, TCM has many non-pharmacological alternative approaches such as acupuncture and moxibustion, tuina (massage), cupping and guasha (spooning). There is no need for complex equipment. TCM tools, for example, the small splints used in Chinese osteopathy, the spoons used in guasha, or the cups used in cupping

therapy, can draw from materials close at hand, so that such treatments can spread easily.

3. TCM's Contributions

TCM is an important component and a characteristic feature of traditional Chinese culture. Applying such principles as "man should observe the law of the nature and seek for the unity of the heaven and humanity", "yin and yang should be balanced to obtain the golden mean", and "practice of medicine should aim to help people", TCM embodies the core value of Chinese civilization. TCM also advocates "full consideration of the environment, individual constitution, and climatic and seasonal conditions when practicing syndrome differentiation and determining therapies", "reinforcing the fundamental and cultivating the vital energy, and strengthening tendons and bones", and "mastership of medicine lying in proficient medical skills and lofty medical ethics", all concepts that enrich Chinese culture and provide an enlightened base from which to study and transform the world.

TCM originated in the Chinese culture. It explains health and diseases from a macro, systemic and holistic perspective. It shows how China perceives nature. As a unique form of medicine, TCM exercises a profound influence on the life of the Chinese people. It is a major means to help the Chinese people maintain health, cure diseases, and live a long life. The Chinese nation has survived countless natural disasters, wars and pestilences, and continues to prosper. In this process, TCM has made a great contribution.

Born in China, TCM has also absorbed the essence of other civilizations, evolved, and gradually spread throughout the world. As early as the Qin and Han dynasties (221 BC – AD 220), TCM was popular in many neighboring countries and exerted a major impact on their traditional medicines. The TCM smallpox vaccination technique had already spread outside of China during the Ming and Qing dynasties (1368 – 1911).

The *Ben Cao Gang Mu* (*Compendium of Materia Medica*) was translated into various languages and widely read, and Charles Darwin, the British biologist, hailed the book as an "ancient Chinese encyclopedia". The remarkable effects of acupuncture and moxibustion have won it popularity throughout the world. The discovery of qinghaosu (artemisinin, an anti-malaria drug) has saved millions of

lives, especially in developing countries. Meanwhile, massive imports of medicinal substances such as frankincense and myrrh have enriched TCM therapies.

antiquity	[æn'tɪkwɪtɪ]	*n.* 古代
embodiment	[ɪm'bɒdɪmənt]	*n.* 典范
ancestors	['ænsestəz]	*n.* 祖先
herbology	[hɜ:'bɒlədʒɪ]	*n.* 草药学
remedy	['remədɪz]	*n.* 疗法
deem	[di:m]	*v.* 认为
ailments	['eɪlmənt]	*n.* 小病
innovation	[ˌɪnə'veɪʃən]	*n.* 革新
decoction	[dɪ'kɒkʃən]	*n.* 煎煮
harmony	['hɑ:mənɪ]	*n.* 和谐
veterinarian	[ˌvetrɪ'neərɪən]	*n.* 兽医
syndrome	['sɪnˌdrəʊm]	*n.* 综合征
auscultation	[ˌɔ:skəl'teɪʃən]	*n.* 听诊法
differentiation	[ˌdɪfərenʃɪ'eɪʃən]	*n.* 区分
olfaction	[ɒl'fækʃən]	*n.* 嗅；闻
advocates	['ædvəkeɪt]	*v.* 提倡
theoretical	[ˌθi:ə'retɪkl]	*adj.* 理论的
perspective	[pə'spektɪv]	*n.* 观点
treatise	['tri:tɪz]	*n.* 专著
febrile	['fi:braɪl]	*adj.* 狂热的
collate	[kə'leɪt]	*v.* 校对
exogenous	[ek'sɒdʒɪnəs]	*adj.* 外生的
expound	[ɪk'spaʊnd]	*vt.* 详细说明
acupuncture	['ækjʊˌpʌŋktʃə]	*n.* 针灸
compatibility	[kəmˌpætɪ'bɪlɪt	*n.* 相容性

ɪ]

moxibustion [ˌmɒksɪˈbʌstʃən] *n.* 灸术

]

&

laying the foundation for 为……奠定基础
drew on the experience of 借鉴……的经验
exert a major impact on 对……产生了重大影响

1. Read the text and fill the blanks.

Time	Contributors	Contributions
2070 – 1600 BC	unknown	The discovery of alcohol.
1600 – 1046 BC	unknown	The invention of herbal decoction.
1046 – 771 BC	unknown	Doctors began to be classified into four categories.
	unknown	*Yellow Emperor's Inner Canon*
	Zhang Zhongjing	
	unknown	*The Shen Nong Ben Cao Jing*
140 – 208	Hua Tuo	
265 – 316		
618 – 907		Proposed that mastership of medicine
		Ben Cao Gang Mu
1644 – 1911		
1912 – 49	Some TCM experts	A combination of TCM with Western medicine.

2. Read the text and fill in the blanks with the words in the text.

The history	
Huang Di Nei Jing	defined of TCM, thus serving as a _____ in TCM's development.
Shang Han Za Bing Lun	establishes the _____ for syndrome pattern diagnosis and treatment differentiation.
Shen Nong Ben Cao Jing	outlines the theory of the ___ of medicinal ingredients.
Zhen Jiu Jia Yi Jing	was the point when theory of jingluo and _____ began to take shape.
Ben Cao Gang Mu	was the first book in the world that scientifically categorized _____.
Wen Re Lun	represents the theory and results of the practice of TCM in _____ such diseases.
Characteristics	
First, setting great store by the holistic view;	
Second, setting great store by the principle of_____;	
Third, emphasis on_____.	
Fourth, emphasis on_____;	
Fifth, simplicity.	
Contributions	
TCM is an important component and a _____ of traditional Chinese culture.	
TCM embodies the _____ of Chinese civilization.	
TCM explains health and diseases from a macro, _____ and holistic perspective.	
TCM has absorbed the _____ of other civilizations, evolved, and gradually spread throughout the world.	

Role play the conversation with your partner. (P = patient D = doctor)

D: Hello, Mr. Smith. How are you felling today?

P: Much better, thank you! I can sit straight today. The acupuncture is really great.

D: Yes, Chinese Traditional Medicine (TCM) has a history of more than

5,000 years. It has a complete theory about the occurrence, development and treatment of diseases. Acupuncture is only one of the most effective ways to treat diseases such as your pleurapophysis.

P: All the same, many of my colleagues feel much puzzled about TCM.

D: Sure. According to TCM theory, the occurrence of diseases is the incoordination between Yin and Yang and the treatment of diseases is the reestablishment of the equilibrium between them.

P: Oh, what's Yin and Yang?

D: They are the two concepts from ancient Chinese philosophy and they represent the two contradictories in everything. In TCM theory, Yin and Yang are used to explain physiological and pathological phenomena of the body. They are also the principles of diagnosing and treating diseases.

P: Then how do you Chinese doctors treat your patients by using this theory?

D: Roughly speaking, there are two common ways of TCM curing diseases: drug therapy and non-drug therapy.

P: That's very interesting. What drugs do you often apply?

D: As for drug therapy, traditional medicines are used such as herbs, mineral, animals, etc.

P: And how about non-drug therapy?

D: As for non-drug therapy, there are acupuncture and moxibustion, massage, cupping.

P: I know a little about acupuncture and massage. What's cupping?

D: It is a congested treatment using a vacuum cup sucked firmly on the skin. Usually, the doctor fires an alcohol sponge and puts it inside the cup for a short while to make the cup a vacuum one, then he places the vacuum cup instantly over the selected spot of the skin.

P: Is it effective?

D: Just as effective as acupuncture which we are using to treat you. But cupping therapy is specially good for pains.

P: That's really fantastic.

D: To tell the truth, according to statistics, Traditional Chinese Medicine is better for the treatment of diseases of viral infections, immune system,

cardio-cerebrovascular system and nervous system without causing any side-effects compared with western medicine.

P: Thank you very much! Doctor. I've got a better understanding of TCM now.

Module Review

1. Make the best choice.

1. What is the first step in drug discovery?

A. Understand the disease. B. Find a target.

C. Target validate. D. Test in lab.

2. What is the goal of preclinical test?

A. Target validation.

B. Find a target.

C. Find a potential drug.

D. Determine if the drug is safe enough for clinical tests.

3. What is the researcher's job after understanding a disease?

A. Target validation. B. Target identification.

C. Drug discovery. D. Lead optimization.

4. A promising molecule that could act upon the target and become a drug is called _____.

A. potential drug B. drug candidate

C. both A and B

5. The step of altering the structure of lead candidates to improve properties of lead compounds is called _____.

A. lead optimization B. lead discovery

C. target identification D. choose a target

6. What is the subject of preclinical?

A. Human. B. Healthy people.

C. Patient. D. Animal.

7. In vivo, tests are experiments conducted in the _____.

A. living cells and animals B. beaker

C. tubes

8. When does a company seek permission to market a product in the US?

A. Following the completion of Phase 1.

B. Following the completion of Phase 2.

C. Following the completion of Phase 3.

D. Following the completion of Phase 4.

9. Which phase in clinical development is the largest investment of both time and money?

A. Phase 1. B. Phase 2.

C. Phase 3. D. Phase 4.

10. What is a synonym/description for the Phase 4 trials?

A. Post Marketing Surveillance.

B. Pre Marketing Surveillance.

C. Pre FDA Approval.

D. Post FDA Approval.

11. The approval of IND is to _____.

A. protect volunteers in clinical trial

B. ensure the safety and efficacy of drug

C. protect patients

12. When is the IND submitted to FDA?

A. After phase 3 in clinical trial.

B. Before preclinical trial.

C. Before clinical trial.

13. When is the NDA submitted to FDA?

A. Before clinical trial.

B. Before preclinical trial.

C. Before marketing.

14. The approval of NDA is to _____.

A. decide if the drug can be market

B. ensure the safety and efficacy of drug

C. both A and B

D. to test whether the proposed drug actually works

15. What is the purpose of Phase 2 clinical trials?

A. Evaluate effectiveness.

B. Examine the possible short-term side effects and risks.

C. Analyze optimal dose strength .

D. All of the above.

16. What is the purpose of Phase 3 clinical trials?

A. To show safety.

B. To show efficacy.

C. To show the overall benefit-risk relationship of a drug.

D. All of the above.

2. Match phrases with their meaning.

保健品	medical representative
医疗手册	counterfeit drug
正版药	medical manual
仿制药	anti-cancer drug
药厂	illicit medicine
抗癌药	ultra-high-priced drug
假药	genuine medicine
天价药	pharmaceutical factory
医药代表	health insurance
违禁药	health care products
医保	generic drug

3. Discussion.

1. Scientific medicine is one of the greatest triumphs of humankind. Do you agree with this saying? Why?

2. In your opinion, what are the elements that facilitate the development of TCM?

中国故事——守正创新发展中医药

屠呦呦及其团队以东晋时期葛洪《肘后备急方》“青蒿一握，以水二升渍，绞取汁，尽服之”之说为起点。经过 40 多年的艰辛求证、百余次实验，提纯萃取青蒿素造福人类，挽救了国内外数以亿计的苍生，2015 年荣获诺贝尔生理学或医学奖，进一步增强了国际社会对中医药的认可和对中华文化的认同。新冠肺炎疫情肆虐，中医药专家以《伤寒杂病论》等中医药典籍为基础创新研制“清肺排毒汤”，成为挽救生命、控制疫情的通治方剂，总有效率达 90% 以上，为构建人类卫生健康共同体注入了强大的中医药力量。