Contents

1. Purpose 目的 2
2. Scope 范围 2
3. General Requirements 一般要求 3
4. Procedures 流程 5
4.1 Initiation of the Request 发出请求 5
4.2 Review and Approval of Medical Books 医学书籍审批 6
4.3 Purchase of Medical Books 采购医学书籍 7
4.4 Delivery and Tracking of Medical Books 医学书籍的交付与跟进 7
5. Roles and Responsibilities 角色与职责 8
6. Definitions 定义 9
7. Appendices 附录 9
8. Forms and Template 9
9. References 10
10. Contact Information 联系信息 10
11. Document History 文件历史 11

1. Purpose 目的

This SOP describes the rules and accountability that apply to the provision of Medical Books which are not provided in the context of a grant or charitable donation and include:

本 SOP 中介绍了适用于医学书籍的规定及责任，此类医学书籍的包括以下种类，不在资助或慈善捐赠范畴内提供：

- Medical and scientific texts, textbooks

  医学及科学文本、教材

- Subscriptions to medical and scientific publications

  订阅医学、科学出版物

Medical Books are produced by third parties, with no involvement of Ipsen, and are provided only to Healthcare Professionals (HCPs) or Healthcare Organizations (HCOs) with the objective of providing unbiased, balanced and scientifically rigorous information for medical education purposes.

医学书籍由第三方负责制作，益普生公司不参与其中，这些医学书籍仅可以被提供给医疗卫生专业人士（HCP）或医疗卫生专业组织（HCO），目的是为其提供无偏见、均衡及科学严谨的用于医学教育目的的资料。

2. Scope 范围

This SOP is applicable to all Ipsen China employees and third-party contractors.

本 SOP 适用于所有益普生中国的员工及第三方派遣员工。

NOTE: The following are outside the scope of this document:

注：下列内容不在本规程的范围之内：

- Ipsen Non-Promotional materials, including but not limited to, educational materials supplied in large quantity during a congress or symposium to several HCPs.

  益普生公司非推广材料，包括但不限于在大会或论坛期间为若干医疗卫生专业人士提供的、大量提供的教育材料。

- Ipsen Promotional materials.

  益普生公司推广材料。

- Other similar low-value items as defined by applicable local laws, regulations, and codes or Ipsen procedural documents.

  适用的当地法律、法规及规范或者益普生公司程序文件所允许的品牌提示物、推广辅助用品或其他类似低价物品。

- Materials provided by Medical Information.

  由医学信息部门所提供的材料。

NOTE: All Medical Books are subject to this SOP whether they are paired with other materials. If, however, they are physically paired with or used in conjunction with promotional or non-promotional materials, they are additionally subject to the same review and approval requirements that apply to the accompanying materials.

注：所有医学书籍均以本 SOP 为准，不管其是否与其他材料配合使用。然而如果其与推广或非推广材料配合或同时使用，则还应同时符合该类材料所适用的审批要求。

3. General Requirements 一般要求

3.1 Medical Books provided by Ipsen are non-promotional in nature and are produced by third parties with no involvement of any kind from Ipsen. All other materials are to be considered Ipsen materials and therefore must be approved per applicable promotional/non-promotional procedural documents, as appropriate.

由益普生公司所提供的医学书籍在性质上属于非推广材料，由第三方负责制作。益普生公司不以任何形式参与其制作，否则该材料将被视作益普生公司的材料，在适当的情况下必须依据适用的推广/非推广材料程序文件予以批准。

3.2 The provision of Medical Books is strictly for scientific/educational purposes and must not be based upon the number of prescriptions written or as an incentive or perceived incentive to prescribe, supply, recommend, buy, or sell any Ipsen products. Thus, no financial return on investment analysis in terms of product sales or prescriptions is permitted in relation to the provision of Medical Books.

应严格基于科学/教育目的而提供医学书籍，不得以所开具处方数量为基础或者将其作为开具处方、供应、推荐、购买或销售任何益普生公司产品的激励手段或者使人理解其为激励手段。因此，不得基于医学书籍的提供进行相关的产品销售或处方方面的投资回报分析。

3.3 Medical Books Owner is responsible of the process for reviewing, approving, purchasing/funding, providing, and tracking Medical Books, and it is responsible for ensuring completion of the Medical Books activities in compliance with this procedural document.

医学书籍负责人负责医学书籍的审查、批准、采购/提供资金工作与医学书籍的提供、跟进工作，并且负责遵守本程序文件的要求确保完成相关的工作流程。

3.4 Medical Affairs department is responsible for reviewing the request for Medical Books on its scientific nature.

由医学事务部负责对医学书籍的科学性质是否符合要求进行审查。

3.5 Medical Books may contain advertisements from pharmaceutical companies (e.g., journals) if other companies can purchase advertising space in the 医学书籍. However, where Ipsen is the sole entity to have advertising in the material, it cannot be considered a Medical Book, and cannot be distributed under this SOP.

医学书籍中可包含来自于制药公司的广告（例如期刊），如其他公司可购买其中的广告位。然而，当益普生公司是在材料中发布广告的唯一企业时，则不能将其视为医学书籍，因而不能依据本规程要求进行分发。

3.6 Medical Books must be:

医学书籍必须：

- Of scientific value

  具有科学价值

- Related to the practice of medicine and/or pharmacy

  与医学和/或药学实践相关

- Designed to enhance patient care and/or the quality use of medicines; and

  意于加强患者关怀和/或用药质量；以及

- Of a nature that will increase the knowledge of the HCPs or HCOs

  可以提高医疗卫生专业人士或医疗卫生专业机构的知识

3.7 The unit price for Medical Books (i.e., one book or subscription of one journal) must not exceed 500RMB and the provision of such items to HCPs must not exceed once per year per HCP.

医学书籍的单价（即，一本书籍，或者订阅一套期刊）不得超过 500 元人民币，向某个医疗卫生专业人士提供该类物品不得超过每年一次的频率。

3.8 Medical Books must be provided only after receipt of a request from the HCP/HCO.

医学书籍只得在接收到医疗卫生专业人士/医疗卫生专业机构的请求后予以提供。

3.9 Ipsen employees (including Field Force) can receive a request for medical books. This request should be redirected to the responsible Medical Books Owner. The request should contain the name or the recipient including any contact details of the HCP/HCO, and Name/Content of the Medical Books.

益普生公司雇员（包括外勤人员）均可接收关于医学书籍的请求。应将这一请求递交给医学书籍负责人。请求中应包含姓名或接收者，包括医疗卫生专业人士/医疗卫生专业机构的联系信息以及医学书籍的名称/内容。

4. Procedures 流程

4.1 Initiation of the Request 发出请求

Task 1 **工作 1**	**Initiation of the Request** **发出请求**
Ipsen Employee (including Field Force) 益普生公司雇员（包括外勤人员）	1.1 Receive request for a Medical Book and forward to the Medical Books Owner. 接收关于医学书籍的请求并提交给对应的医学书籍负责人。
Medical Books Owner 医学书籍负责人	1.2 Review of Applicable Rules to ensure the request is in alignment with Ipsen procedural documents. 对适用规定进行审核以确保该请求符合益普生公司程序文件要求。
	1.3 Initiate the review and approval of the Medical Book using Medical Books Review and Approval Form (Form 01). 使用《医学书籍审批表》（表01）启动对医学书籍进行审查及批准。
	1.4 Review the Medical Book request to: 对医学书籍的请求进行审查以： • Ensure that the yearly threshold for the requestor has not been reached 确保请求者未达到每年一次的限 • Ensure that the value of the Medical Book does not exceed the limits established 确保医学书籍的价值不超过规定的限额 • Determine if the Medical Book has already been approved 确定医学书籍是否已经获得批准
	1.5 Send the Medical Book using Medical Books Review and Approval Form to the appropriate Medical Reviewer for review and approval. 将《医学书籍审批表》发送至适当的医学部审核人员处以进行审核批准。

4.2 Review and Approval of Medical Books 医学书籍审批

Task 2 **工作 2**	**Review and Approval of Medical Books** **医学书籍审批**
Medical Reviewer 医学部审核人员	1.6 Review the Medical Book using Medical Books Review and Approval Form as well as the Medical Books to ensure that the materials meet the requirements set forth in the General Requirements section of this SOP that relates to the requirements of the responsibilities of the Medical Reviewer. 对《医学书籍审批表》及医学书籍进行审查以确保材料符合本规程的"一般要求"章节中所给出与医学部审核人员责任相关的要求。 Where applicable, reviewers may request advice from other functions (e.g., Legal, Business Ethics, etc.) to ensure that the materials meet the requirements set forth in the General Requirements section of this SOP. 在适当情况下，医学部审核人员可从其他职能部门（例如法务、商业道德等）征求意见以确保材料符合本规程的"一般要求"章节中所给出的要求。
	1.7 Provide the requested advice on the Medical Book using Medical Books Review and Approval Form, Sign and date the Form. 向《医学书籍审批表》提供意见并签署姓名和日期。
	1.8 Indicate decision on the Medical Book using Medical Books Review and Approval Form either: 在医学书籍审批表中注明所作的决定： • Approved or 批准或者 • Not approved and reasons 不批准，提供原因。
Functional Approver (Business Unit Head/Department Head) 部门审批人(业务单元负责人/部门负责人)	1.9 Review Medical Books Review and Approval Form once it has been approved by Medical Reviewer and indicate decision on the Medical Book using Medical Books Review and Approval Form either: 在《医学书籍审批表》经过医学部审核人员批准后，在表中注明所作的决定： • Approved or 批准或者 • Not approved and reasons 不批准，提供原因。

4.3 Purchase of Medical Books 采购医学书籍

Task 3 **工作 3**	**Purchase of Medical Books** **采购医学书籍**
Purchasing 采购部	1.10 Following Ipsen Purchasing process, contact third parties to purchase the adequate quantity of Medical Books at the best price within the validated budget. 依据经批准的《医学书籍审批表》，根据益普生公司采购流程联系第三方以便在有效预算范围内以最佳价格采购足量的医学书籍。

4.4 Delivery and Tracking of Medical Books 医学书籍的交付与跟进

Task 4 **工作 4**	**Delivery and Tracking of Medical Books** **医学书籍的交付与跟进**
Medical Books Administrator 医学书籍管理员 (Nominated by each function) 由各部门自行提名	1.11 Prepare the following documents: 准备下列文件： Cover letter or Complimentary Slip stating that the Medical Book has been provided by Ipsen (e.g., "This educational material has been provided with the support of Ipsen"). These written documents must not contain any element of the product branding scheme; however, the corporate logo is permitted. 说明信或赠礼便条，用于表明该医学书籍是由益普生公司提供的（例如："此教育材料在益普生公司支持下予以提供"）。这些书面文件中不得含有任何产品品牌内容；然而允许含有企业标志。 1.12 Ensure that Medical Books contain a Complimentary Slip. 确保医学书籍中包含有赠礼便条。
	1.13 Update Medical Books Tracking Record (Form 02) in a clear, accurate and transparent manner for Medical Books purchased and provided. 在《医学书籍统计表》（表02）中清楚、准确及透明地记录医学书籍采购及供应跟进详情。
	1.14 Deliver to related Ipsen staff the Medical Books purchased and maintain the delivery record. 向相关益普生人员寄送医学书籍，并保留相关单据。
	1.15 Maintain a repository of the following documents: 对下列文件的进行保存和维护： • Medical Books Review and Approval Form with approval signatures for those Medical Books reviewed and supplied 经审批的《医学书籍审批表》Copy of the requests for the Medical Books (where applicable)

	对医学书籍的需求副本（如适用） • Copy of the Medical Books supplied (where applicable) 所供应医学书籍的副本（如适用） • Signature of the recipient (where applicable) 接收人签名（如适用） • Other related documents 其他相关文件

5. Roles and Responsibilities 角色与职责

Role **角色**	**Responsibilities** **职责**
Ipsen Employee 益普生员工	• Receive requests for Medical Books and forward to the Medical Books Owner. 接收关于的医学书籍的请求并提交给医学书籍负责人。 • Comply with this SOP and report violations to management 依照本规程进行工作并将违反情况报告给管理人员。
Medical Books Owner 医学书籍负责人	• Central Marketing; Medical Affairs; Market Access; R&D. 中央市场部；医学事务；市场准入；研发部。 • Complete the Medical Book using Medical Books Review and Approval Form. 填写《医学书籍审批表》。 • Route Medical Book for approval. 递交《医学书籍审批表》以用于批准。 • Ensure compliance with all appropriate regulations. 确保符合所有适用法规的要求。 • Coordinate with Purchasing team to purchase Medical Books. 与采购团队协作以采购医学书籍。
Medical Books Administrator 医学书籍管理员	• Prepare the cover letter of complimentary slip stating the Medical Book has been provided by Ipsen. 准备说明信或赠礼便条，用于表明医学书籍由益普生公司提供。 • Maintain Medical Books Tracking Record. 对《医学书籍统计表》跟进记录进行维护。 • Maintain a repository of applicable documents. 对适用文件的储存库进行维护。
Medical Reviewer 医学部审核人员	• May be conducted by a Medical Affairs Manager (for requests initiated by the business functions) or Medical Department Head (for requests initiated by Medical or R&D). 可以由医学事务部经理（针对医学部以外的部门所发出的请求）或医学部负责人（针对医学部所发出的请求）担任。 • Review Medical Books to ensure they meet the requirements in terms of the scientific nature. 对医学书籍进行审查以确保其科学性质符合要求。
Functional Head 部门负责人	• Provide final opinion on Medical Books Review and Approval Form. 对《医学书籍审批表》提供最终审批。

Role 角色	Responsibilities 职责
	• If the request is initiated by Medical, then the Medical Reviewer is the final approver. 如果需求由医学部提出，则此种情形下的医学部审核人员即为最终审批人。

6. Definitions 定义

Term 术语	Definition 定义
Healthcare professionals (HCP) 医疗卫生专业人士	Healthcare professional means any member of the medical, dental, pharmacy or nursing professions or any other person who during his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product. 医疗卫生专业人士是指所有医疗、牙科、药剂或护理专业人员，或者所有其他在其职业活动过程中可能开出处方、推荐、采购、供应或管理某一药品的人员。
Healthcare Organizations (HCO) 医疗卫生专业机构	HCO means any legal entity that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university, or other teaching institution or learning society. 医疗卫生专业机构是指所有医疗保健、医学或科学协会或组织等法人实体（无论其法律或组织形式），例如医院、诊所、基金会、大学或其他教育机构或学习社团。
Complimentary Slip 赠礼便条	Notation on the Medical Books or accompanying the Medical Books that indicates that the material is provided at no cost with the support of Ipsen ("complimentary"). 医学书籍上的说明或者医学书籍随附的说明，表明材料是由益普生公司免费提供的（"赠送"）。
Medical Books 医学书籍	Non-promotional educational items to include medical and scientific textbooks, subscriptions to medical and scientific publications and any other education materials in any format which are produced by third parties and provided to HCPs/HCOs by Ipsen) but not in the context of a grant or donation. Their provision is strictly related to scientific educational purposes. 非推广性教育用品，包括医学及科学教材、订阅的医学及科学出版物、由第三方制作并由益普生公司提供给医疗卫生专业人士/医疗卫生专业机构的任何形式的其他教育材料，不属于补助或捐赠范畴。提供此类物品时严格局限于科学教育目的。
Subscription 订阅	A purchase made by signed order, for a medical periodical or medical journal for a specified period. 按签约订单采购一定时期的医学期刊或医学杂志。

7. Appendices 附录

Not Applicable

不适用

8. Forms and Template

表格与模板

The below forms and templates may be changed independently of this SOP without requiring review and approval of the entire SOP but only of the updated form.

以下表格可在本 SOP 之外单独予以修订，修订后的表格仅需就其修订内容获得审查与批准，无需再对本 SOP 全文进行审查与批准。

Form Identification Number **表格识别编号**	**Form name** **表格名称**
FORM 01 表格 01	Medical Books Review and Approval Form 《医学书籍审批表》
FORM 02 表格 02	Medical Books Tracking Record 《医学书籍跟进记录》

9. References

参考文献

External 外部:

EU Directive 2001/83/EC 欧盟指南 2001/83/EC

IFPMA Code, International Federation of Pharmaceutical Manufacturers and Associations 国际药品制造商协会联合会

EFPIA Code, European Federation of Pharmaceutical Industries and Associations 欧洲制药工业协会联合会规范

The RDPAC Code 外商投资企业协会药品研制和开发行业委员会规范

Other applicable laws, regulations, rules, polices, industrial codes and standards 其他适用法律、法规、规章、政策、行业规范及标准

Internal 内部:

Ipsen Code of Conduct 益普生道德行为准则

GLB-POL-002 Global Policy on Interactions with External Stakeholders 与外部利益相关者的互动交流

Global Anticorruption Policy 全球反腐政策

GLB-DIR-002 Interaction with HCPs and HCOs 全球指南：与医疗卫生专业人士/医疗卫生专业机构的互动交流

10. Contact Information 联系信息

Direct questions about this document to the authors (see Document History).

直接向作者询问关于此文件的问题（参见文件历史）。

11. Document History 文件历史

Effective Date **生效日期**	**Version Number** **版本号**	**Authors (name, title)** **作者（姓名，职务）**	**Description** **说明**
1st July 2017 2017 年 7 月 1 日	1st Version 第 1 版	Gisele Lu Senior Ethics & Compliance Officer, Ipsen China 陆昕然 益普生中国公司高级道德与合规官	N/A
1 Jan 2022 2022 年 1 月 1 日	2nd Version 第 2 版	Gisele Lu Business Ethics Senior Director 陆昕然 益普生中国商业道德高级总监	Updated details regarding brand reminders 更新了关于品牌提示物的细节规定

Form 01 Medical Books Review and Approval Form 表格01《医学书籍审批表》

<table>
<tr><th colspan="3">MEDICAL Books – REVIEW and APPROVAL FORM
医学书籍审批表</th></tr>
<tr><th colspan="3">Part 1/2: General Information
第 1/2 部分：一般信息</th></tr>
<tr><td>Date:
日期：

Name of MEDICAL BOOK:
医学书籍名称
Description of MEDICAL BOOK:
医学书籍简介：

Therapy Area of MEDICAL BOOK:
医学书籍所涉及的治疗领域：

Market Value of MEDICAL BOOK:
医学书籍的市场价格：

Photocopy of Cover of the MEDICAL BOOK:
医学书籍的封面复印件：</td><td colspan="2"></td></tr>
<tr><td>Recipient information filled by MEDICAL BOOK Owner
医学书籍负责人填写接收人信息
(Please complete one form per *recipient)
（*每名接收人各填写一份表格）</td><td>( ) HCP 医疗卫生专业人士

Name
姓名

Hospital/Department:
医院/科室：

Address:
地址：</td><td>( ) HCO 医疗卫生专业机构

Name
名称

Address:
地址：

Contact Person:
联系人：

Department:
部门：</td></tr>
</table>

Have any of the recipients been provided with Medical books that relate to the therapy area in this calendar year? **在此日历年内，是否有任何接收人被提供了与治疗领域相关的医学书籍？**	**( )** No 否 **( )** Yes 是 If yes, please specify for each recipient either below or on the attachment to this form (number of MEDICAL BOOKs, date provided and value): 如果是，请在下面或此表格附件中详细说明每一接收人的情况（M 医学书籍数量、提供日期及价值）：
Total value of MEDICAL BOOKs for the therapy area **治疗领域 MEDICAL BOOK 的总价值** **- this calendar year:** **此日历年** **- to date:** **至今**	

MEDICAL BOOKS – REVIEW and APPROVAL FORM **医学书籍审批表**		
Part 2/2: Approval **第 2/2 部分：批准**		
MEDICAL BOOKs Owner: **医学书籍负责人：** Name: 姓名： ..... Position: 职务：	Signature: 签名： …… Date: 日期： ……..	**Comments** 备注 ....
Medical Reviewer: As noted by my signature above, I confirm that these materials are non-promotional in nature and are produced by third parties with no involvement from Ipsen. 医学审查员：通过上述本人签名，本人确认这些材料在性质上不属于推广材料，是由第三方所制作的，益普生公司未参与制作。		
Medical Reviewer: **医学审查员：** Name: 姓名： ..... Position: 职务：	Signature: 签名： …… Date: 日期： ……	**Decision & Comments** 决定及备注 ....
Approver: **批准人：** **Name:** 姓名：	Signature: 签名： …….. Date: 日期： ……	**Decision & Comments** 决定及备注 ....

Form 02 Medical Books Tracking Record 表格02《医学书籍跟进记录》

No. 序号	Medical Books Owner 医学书籍负责人	Initiating Function 发起部门	Title of the Medical Book 医学书籍名称	Price 价格	Name of the Requesting HCP/HCO 需求方名称	Other information of the requesting HCP/HCO 其他需求方信息*	Date of request 需求日期	Cost Center 成本中心	Medical Book RAF archived? 医学书籍审批表已存档?	Notes 备注

***Please fill in "Other information of the requesting HCP/HCO" the following information more additional information as deemed necessary:**

***在"其他需求方信息"部分，请填写以下内容，以及其他必要信息：**

- Name of the organization 工作单位名称
- Address地址
- Department科室
- Name 姓名
- Contact Info 联系信息
- Name and function of the Medical Book Administrator 医学书籍管理员姓名及部门