1. PURPOSE

It is the goal of UCB, Inc. (UCB) to ensure that its interactions with Healthcare Professionals (HCPs) comply with all applicable state and federal laws. In addition, UCB endeavors to comply with the Pharmaceutical Research and Manufacturers Association (PhRMA) Code, and the Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers.

2. SCOPE

This standard operating procedure (SOP) sets forth UCB’s procedures for Commercial Field Personnel’s submission of Unsolicited Requests for Medical Information received from HCPs, including procedures to ensure that all requests for information about Off-Label uses for UCB products are handled in an appropriate manner.

3. HEALTH, SAFETY AND ENVIRONMENTAL PROTECTION

There are no significant hazards or special instructions relating to the arrangements described that need to be detailed in this SOP.

4. RESPONSIBILITIES

Field Personnel are responsible for:

- Submitting only those Unsolicited Requests that satisfy the criteria of this SOP.
- Providing all information required by this SOP for submission of an Unsolicited Request.

Medical Information Department is responsible for:

- Receiving and fulfilling Unsolicited Requests for Medical Information in accordance with SOP U.S. Handling of Unsolicited Requests for Medical Information.
- Monitoring Unsolicited Requests and activity trends and notifying the Compliance Department if non-compliance is suspected.
- Providing periodic and ad hoc reports of request statistics when requested from Compliance for monitoring purposes.

Compliance is responsible for:

- Monitoring request statistics (and supporting individual requests) to identify non-compliance with this procedure.
- Investigating potential non-compliant activity identified through Medical Information and Compliance monitoring.
5. **PROCEDURE**

5.1 **Subject Matter of Unsolicited Requests**

When an HCP asks an unsolicited question about Off-Label information for a UCB product, Field Personnel are not permitted to answer. Instead, they must submit an Unsolicited Request to Medical Information.

An Unsolicited Request for Medical Information may be submitted only in response to a truly Unsolicited Request from a HCP. If any Field Personnel prompts the request for information, the request will not be considered unsolicited, and no information may be provided in response to the request that is beyond the scope of the approved prescribing information.

5.1.1 Questions that are appropriate to submit as Unsolicited Requests for Medical Information when asked by HCPs include (but are not limited to):

- Inquiries that are within labeling, but beyond the Field Personnel’s understanding.
- Inquiries that are beyond the scope of the full prescribing information, approved reprints, and other approved promotional materials.
- Requests for information about a UCB product in comparison to a competitor product.
- Routine requests for information by HCPs about dosage that is not within label, or Adverse Events (AE) not related to a specific patient or an emergency.
- Questions about AEs or overdosage.
- Requests for an MSL follow-up visit to discuss in person the question or specific interest in UCB product or disease state or clinical trials.

5.1.2 Questions NOT appropriate to submit as Unsolicited Requests for Medical Information when asked by HCPs include (but are not limited to):

- Questions dealing solely with a competitor product(s). These should be addressed by the competitor company rather than by the UCB Medical Information Department or the Field Personnel.
- Reports of a possible Product Quality Complaint (PQC) related to a UCB medicinal product. Product Complaints should be reported immediately to UCBCares by phone, 844-599-CARE (2273), by fax 770-970-8859, or via e-mail to UCBCares@ucb.com.
- Reports of a possible AE in a patient who took a UCB product should be reported within 24 hours of receipt by the UCB Field Representative. AEs should be reported immediately to UCBCares by phone at 844-599-CARE (2273) or via e-mail to UCBCares@ucb.com. If a Field Personnel is uncertain
whether an AE has occurred because of the way that an HCP phrases a question, s/he should obtain clarification from the HCP during the visit/call and an AE Report (AER) should be filed, if warranted. All Field Personnel should be trained on AE and PQC reporting by an appropriate subject matter expert.

The following, while not appropriate to submit as an Unsolicited Request for Medical Information, can be addressed by contacting the UCBCares Center at 844-599-CARE (2273) to be handled by the most appropriate personnel:

- Pricing or contracting inquiries.
- Requests by a HCP for legal advice concerning his or her obligations or requests to speak with UCB Legal Counsel.
- Requests to assist with patient’s insurance to cover a UCB product for reimbursement.
- Requests for information available through approved reprints and promotional pieces.
- Competitive feedback.
- Questions prompted by Field Personnel or phrased in the words of Field Personnel.

### 5.2 Information Necessary to Submit an Unsolicited Request

If Field Personnel receive an Unsolicited Request for Medical Information, s/he may respond only by forwarding the Unsolicited Request to the Medical Information Department for follow up. The Field Personnel must state in writing the specific request and obtain the requesting HCP’s signature, indicating that the HCP made the Unsolicited Request for the information. The Medical Information Department will follow up directly with the HCP for inquiries forwarded by Field Personnel. Forwarding the Unsolicited Request to Medical Information shall constitute Field Personnel’s only response to the Unsolicited Request.

#### 5.2.1 Contact and General Information

Field Personnel shall gather all required information before submitting the Unsolicited Request. Each Unsolicited Request must include:

1. Field Personnel information, including name, title, and position at UCB (including region, district, and/or territory as applicable).
2. The demographics of the HCP. The following information must be complete, accurate, and in the correct U.S. Postal format to ensure that the HCP receives a reply from the Medical Information Department:
   - HCP’s full name, degree (e.g., M.D., D.O., R.Ph., Pharm.D., N.P., R.N., P.A., etc.) and title
• HCP’s office address, including zip code
• HCP’s office phone number
• Fax number or email address (if required for fulfillment of request)

3. Date of Inquiry

4. Nature and Topic of request (including exact language of the Unsolicited Request if made in writing). Requests should be narrowly tailored to a specific topic (not a general request). Whether the information is being requested as a result of an AE experienced by a patient previously or currently on a UCB product.

5. A signature (which may be electronic) of the HCP indicating that the HCP has made an Unsolicited Request for the information.

6. The requested question(s) including the product name within the body of the question.

7. Several questions may be submitted from the same HCP in one request submitted to Medical Information either via the automated sales force system or, if the automated system is not available, via the Medical Information Request Form, as long as the questions all concern the same UCB product.

8. Field Personnel must submit separate Unsolicited Requests for:
   • Questions from different HCPs, and
   • Questions regarding different UCB products, asked by one HCP.

**Documenting the HCP Question**

Unsolicited Requests must be submitted in the words of the requesting HCP; the request should not be the Field Personnel’s interpretation of the HCP’s question. Field Personnel must ensure that the Unsolicited Request is accurate by allowing the HCP to fill out the request or by first writing down the HCP’s question and reading it back to the HCP for confirmation. For example:

1. If a HCP initially asks a general question, Field Personnel may inquire whether the HCP can be more specific, but Field Personnel may only make a non-specific inquiry, and may not suggest specific areas of potential interest. Unsolicited Requests submitted with a general question will not receive a response.

2. To help avoid ambiguity, appropriate medical terms should be used.

3. The UCB product name should always be included.

4. Documentation of whether the information is being requested as a result of an AE by a patient previously or currently on a UCB product.

5. Additional information provided by the HCP, such as published references, should be included with the question to enhance the Medical Information Department’s understanding of the question.

6. The HCP should sign the Unsolicited Request indicating that the HCP is making the Unsolicited Request for information.
5.3 Methods for Submitting Unsolicited Requests

- The preferred method for submitting an Unsolicited Request is the medical request tab in the sales force automation system. Refer to your sales force automation system training guide for submission instructions. Requests for MSL follow up visits received via the sales force automation system will be forwarded promptly to the MSL for that geographic region.

- If an Unsolicited Request is unable to be submitted through the medical request tab in the sales force automation system and the HCP does not need an immediate response, the following methods are appropriate.

- Where appropriate, Field Personnel may submit the Unsolicited Request electronically (using the Medical Information Request Form) through email or sent via fax. Email: UCBCares@ucb.com or Fax: 770-970-8859. This method is required when submitting an Unsolicited Request from an HCP who is not listed in your sales force automation system.
  - All information required for submission of an Unsolicited Request pursuant to the SOP must be included in the Medical Information Request Form.
  - If the HCP provides additional information such as published references that will clarify the question, this information should also be included in the question section of the form.
  - Each field on the form must be complete, accurate, up-to-date, and typed or printed for legibility.

5.4 Immediate Need for Information

5.4.1 Contacting the Medical Information and Communication Department

- When a HCP needs an immediate response to a question, the HCP should contact the Medical Information Department via UCBCares 844-599-CARE (2273), selecting the appropriate option. This number is staffed Monday though Friday from 8 a.m. until 5 p.m. ET. During after hours, holidays, and weekends, Medical Information personnel are on-call 24 hours a day to respond to emergency questions from HCPs regarding UCB products and will follow up on non-urgent Unsolicited Requests left on voicemail the next business day.

- An HCP may call the Medical Information Department directly at any time via UCBCares at 844-599-CARE (2273). Alternatively, Field Personnel may place the call to the Medical Information Department for the HCP. If the Field Personnel places the call, Field Personnel should identify himself/herself and the HCP to the Medical Information Department personnel. They will connect the HCP with a Medical Information Department team member, who will
respond directly to the HCP. The Field Personnel will exit the room at the
time the HCP is connected with the MI Department.

5.5 Compliance Monitoring of Unsolicited Requests

Compliance will request periodic trending and ad hoc reports of request statistics from Medical Information for monitoring purposes. As part of this monitoring review, Compliance will assess if there is potential evidence of non-compliance with UCB processes and instances that may be indicative of Off-Label promotion. As warranted, Compliance may request additional supporting data to verify concerns identified during routine monitoring. Monitoring results will be captured as part of UCB’s Compliance Monitoring Program in accordance with SOP U.S. Compliance Program Monitoring.

5.6 Quality Checks for US Handling of Unsolicited Requests to Medical Information

Individual Case Monitoring

In the routine course of business, Medical Information Personnel will monitor individual requests and will notify the Compliance Department if potential non-compliance is suspected, and document any required action or follow up accordingly within the case record in the Inquiries Database (e.g., IRMS).

5.7 Field Personnel Notification of UCB’s Response

Field Personnel will not receive an electronic or hard copy of the Medical Information Department’s response to the HCP’s Unsolicited Request. A report of medical activities made pursuant to submitted Unsolicited Requests will be issued once weekly. The report is for background information only, and is intended to solely to inform Field Personnel that the HCP received a response from Medical Information. This report does not serve as training information for Field Personnel.

5.8 Documentation, Record Maintenance and Retention

All records, information and deliverables related to this procedure will be retained for a period of six (6) years or longer if required by applicable law, contract or regulatory requirement. Records related to this procedure will be maintained by the activity owner unless otherwise specifically directed by the Legal Department. For GxP records retention refer to Corporate SOP Global Archive Procedure for Critical Records.
6. **ABBREVIATIONS AND DEFINITIONS**

Abbreviations and definitions used in this document are in accordance with the UCB Glossary. To the extent that these definitions differ from those contained in the UCB Glossary, these definitions will take precedence for the purpose of this policy / procedure

### 6.1 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>AE</td>
<td>Adverse Event</td>
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<tr>
<td>HCP</td>
<td>Healthcare Professional</td>
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<tr>
<td>MI</td>
<td>Medical Information</td>
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<tr>
<td>MSL</td>
<td>Medical Science Liaison</td>
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<tr>
<td>PQC</td>
<td>Product Quality Complaint</td>
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### 6.2 Definitions

<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Adverse Event</td>
<td>Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (ICH E6, E2D).</td>
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<tr>
<td>Field Personnel</td>
<td>Field based personnel that report into sales, marketing or managed care (e.g., sales representatives, account executives, area business specialists, etc.).</td>
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<td>Healthcare Professional</td>
<td>Any individual who may directly or indirectly purchase, recommend, use, prescribe, or arrange for the use of UCB products. This includes individuals such as physicians, nurses, nurse practitioners, physician assistants, pharmacists, other allied healthcare professionals, health plan administrators, Formulary/Pharmacy &amp; Therapeutics Committee members, scientists, researchers, research coordinators and technicians.</td>
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<tr>
<td>Medical Information Personnel</td>
<td>Employee within U.S. Medical Affairs responsible for handling medical and scientific information provided in response to Unsolicited Requests for Medical Information regarding UCB products and/or disease states.</td>
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</table>
Medical Science Liaison | An employee within the Medical Affairs Department with specialized scientific and medical knowledge who communicates primarily with KOLs, other academics and HCPs on a peer-to-peer basis regarding UCB products and related topics.

Off-Label | Any information or data that are not consistent with the Food and Drug Administration (FDA)-approved package insert for a UCB product. Inconsistencies may include, but are not limited to, differences in intended use, special patient populations, dosage and administration, age groups, and/or the safety and effectiveness profile.

Product Complaint | Any verbal, written, or electronic expression of dissatisfaction with a company product’s identity, quality, stability, reliability, safety, effectiveness, performance, or usage. The report could be made by a patient, HCP, or health authority. Product Quality Complaints include Adverse Events and Product Complaints.

Unsolicited Request for Medical Information (Unsolicited Request) | A request for medical and scientific information related to UCB Products or related disease states that is not prompted, facilitated, or encouraged by any UCB employee.

UCBCares | The U.S. single source customer solution center.

### 7. RELATED DOCUMENTS

#### 7.1 Associated Documents
- sop-af-004558, Medical Information Request Form
- sop-af-008747, Medical Information Quality Check Form - Medical Responses (Field and non-Field)

#### 7.2 References
- sop-009342, Global Archive Procedure for Critical Records
- sop-009832, U.S. Handling of Unsolicited Requests for Medical Information
- sop-009913, U.S. Affiliate Product Complaint Process and Reconciliation
- sop-010323, U.S. Compliance Program Monitoring

### 8. LIST OF APPENDICES
N/A
9. **SOP HISTORY**

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<td>SR SOP 211</td>
<td>Migration into MIKADO CD</td>
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<tr>
<td>sop-009894 v1.0</td>
<td>Updated due to changing business requirements</td>
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<tr>
<td>sop-009894 v2.0</td>
<td>Updated Sections 6.5 Compliance Monitoring and added Section 6.6 Medical Information Monitoring due to findings from IRO. Minor Changes to Section 6.7- Field Notification memo frequency from bi-monthly to weekly. Minor addition to Section 6.1.1.- added bullet of how to submit unsolicited MSL request for follow up. Added and Updated Associated Documents sop-af-008747 Medical Information Quality Check Form to be more specific and comprehensive relative to CIA requirements for documentation in inquiries database. Minor change on form sop-af-004558, Medical Information Request Form to include check boxes for specific Field Personnel Types (e.g., MSL, Account Executive, Sales Specialist, etc.).</td>
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<td>sop-009894 v3.0</td>
<td>v3.0 never made effective. When the document was at approved status it was changed back to draft in order to update the Scope to the correct option in the Properties.</td>
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<tr>
<td>sop-009894 v4.0</td>
<td>Updated to reflect changes in organizational structure around UCBCares. Section 5.6.2 was removed and will be captured in sop-009832.</td>
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## Document Approval Electronic Signatures

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