

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

**IN RE: XARELTO (RIVAROXABAN)
PRODUCTS LIABILITY LITIGATION**

* **MDL NO. 2592**

* **SECTION L**

* **JUDGE ELDON E. FALLON**

* **MAG. JUDGE NORTH**

THIS DOCUMENT RELATES TO ALL CASES

**PRE-TRIAL ORDER NO. 14
(Defendant Fact Sheets)**

In conjunction with Paragraph 4 of the Case Management Order No. 1 (“CMO No. 1”), this Order governs the form and schedule for service of Defendant Fact Sheets (“DFS”) to be completed by Defendants in all individual cases that were: (1) transferred to this Court by the Judicial Panel on Multidistrict Litigation, pursuant to its Order of December 12, 2015; (2) subsequently transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to Rule 7.4 of the Rules of Procedure of that Panel; and (3) originally filed in this Court or transferred or removed to this Court.

DEFENDANT FACT SHEETS:

1. Defendants shall complete a DFS for each received Plaintiff Fact Sheet (“PFS”) using the form set forth in DFS Attachment A.
2. As outlined in Paragraph 4(a) of the CMO No. 1, Defendants shall submit a DFS to the Plaintiff using MDL Centrality within sixty (60) days of the date the Defendants receive a completed and verified PFS from a Plaintiff. Defendants will not be required to serve a DFS in any case until Plaintiff supplies a substantially complete PFS, which must provide

all the Core Case Information requested in Section I of the PFS, including copies of prescription and/or pharmacy records demonstrating use of Xarelto as well as medical records demonstrating an alleged injury.

3. If Defendants fail to provide a complete and verified DFS within the time period set forth hereinabove, Defendants shall be given notice by e-mail from Plaintiffs' Liaison Counsel and shall be given twenty (20) additional days to cure such deficiency. Failure to timely comply may result in a dismissal of a defense.
4. Defendants' responses on a DFS shall be treated as answers to interrogatories under Fed. R. Civ. P. 33 and responses to requests for production of documents under Fed. R. Civ. P. 34 and shall be supplemented in accordance with Fed. R. Civ. P. 26.
5. Plaintiffs' use of the DFS shall be without prejudice to the right of the Plaintiffs in a specific case to serve additional discovery

New Orleans, Louisiana this 4th day of May, 2015.



Hon. Eldon E. Fallon
United States District Judge

Attachments

DFS ATTACHMENT A

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: XARELTO (RIVAROXABAN) * MDL NO. 2592
PRODUCTS LIABILITY LITIGATION * SECTION L
*
* **JUDGE ELDON E. FALLON**
*
* **MAG. JUDGE NORTH**
***** *

THIS DOCUMENT RELATES TO:

DEFENDANT FACT SHEET

For each case, Defendants Janssen Research & Development, LLC, Janssen Ortho, LLC, Janssen Pharmaceuticals, Inc. (collectively “Janssen”); Johnson & Johnson (“J&J”); Bayer Corporation, Bayer Healthcare, AG, Bayer Pharma, AG, Bayer, AG, Bayer Healthcare, LLC, and Bayer Healthcare Pharmaceuticals, Inc. (collectively “Bayer”); must complete this Defendant Fact Sheet (“DFS”) and identify or provide documents and/or data responsive to the questions set forth below to the best of their knowledge. In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates number.

Within 60 days of receiving a substantially completed and verified Plaintiff Fact Sheet (“PFS”), Defendants must complete and serve this DFS on each Plaintiff’s counsel identified in the PFS. Defendants will not be required to serve a DFS on each Plaintiff’s counsel until Plaintiff supplies a substantially complete PFS, which must provide all of the Core Case Information requested in Section I of the PFS, including copies of prescription and/or pharmacy records demonstrating use of Xarelto® as well as medical records demonstrating an alleged injury.

DEFINITIONS

As used herein, the terms "YOU," "YOUR," or "YOURS" means the responding Defendants.

As used herein, the term “XARELTO” includes Rivaroxaban.

As used herein, the phrase “PRESCRIBING HEALTHCARE PROVIDER” means any physician, medical provider, practice, clinic, person, or entity identified in Section III.A.1(a) of the PFS who prescribed and/or dispensed Xarelto® to the Plaintiff

As used herein, the phrase “PRIMARY TREATING PHYSICIAN” means that one physician, medical provider, practice, clinic, person, or entity identified in Section III.B.1 of the PFS who treated plaintiff for the injuries claimed in this case.

I. Case Information

This DFS pertains to the following case:

Case caption: _____

Court in which action was originally filed: _____

Date that this DFS was completed: _____

II. Contacts With Prescribing Healthcare Providers & Primary Treating Physician

For each Prescribing Healthcare Provider identified in Section III.A.1(a) of the PFS and Primary Treating Physician identified in Section III.B.1 of the PFS, please state the following:

A. Dear Doctor Letters:

1. Please identify any “Dear Doctor,” “Dear Health Care Provider,” “Dear Colleague,” or any other similar type of document or letter sent to the Plaintiff’s Prescribing Healthcare Provider(s) and Primary Treating Physician concerning Xarelto®.

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)	Bates Number

B. Physician’s Information Request Letters (“PIR”):

1. Please indicate if any of the Prescribing Healthcare Provider(s) identified in Section III.A.1(a) of the PFS and Primary Treating Physician identified in Section III.B.1 of the PFS has (have) ever initiated a PIR by identifying the

name and address of the sender of the PIR; the date it was sent; the name and address of the recipient; and whether or not a response to the PIR or similar document was sent.

Sender (Name and Address)	PIR Date	Recipient (Name and Address)	Response Sent? (Yes or No)

2. For each PIR in which a response was sent as indicated by a “Yes” above, please identify the format of the response; the date the response was sent; the name and address of the sender of the response; the name and address of the recipient of the response; and provide and identify by Bates number any and all documentation, including lists or database records, which demonstrates that the responsive documents were sent.

Original PIR or Request Document Date	Format of Response (Letter or Otherwise)	Date Response Sent	Response Sender (Name and Address)	Response Recipient (Name and Address)	Bates Number of Supporting Documentation

C. Other Contacts:

1. For each Prescribing Healthcare Provider identified in Section III.A.1(a) of the PFS and Primary Treating Physician identified in Section III.B.1 of the PFS, please identify by name any of the Defendants’ Detail Representatives and/or any other detail person (“Representative”) who called on the Prescribing Healthcare Provider and/or Primary Treating Physician and provide dates of each contact that related in any way to Xarelto®.

Prescribing Health Care Provider(s) and/or Primary Treating Physician	Name of Representative	Current or Former Employee	Date(s) of Each Contact with Prescribing Health Care Provider

2. Have Defendants or their representatives ever provided any Xarelto® samples to Plaintiff’s Prescribing Healthcare Provider(s) identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS? To be answered only if Plaintiff answers in the affirmative to Section III.A.4 of the PFS.

Yes _____ No _____ Not Applicable _____

A. If the answer is “Yes,” please state the Prescribing Healthcare Provider(s) identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS that received the samples; the dates in which such samples were provided; the amount, and dosage of such samples; and the name of the Representative(s) who provided the samples.

Prescribing Health Care Provider(s) and/or Primary Treating Physician	Date Shipped to and/or Provided	Amount and Dosage	Representative Who Provided

III. Consulting With Plaintiffs Prescribing Health Care Provider(s) and/or Primary Treating Physician

A. Consulting and Professional Relationships

1. If any of Plaintiff’s Prescribing Health Care Providers identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS have been retained and/or compensated by Defendants as a “key opinion leader,” “thought leader,” member of a speaker’s bureau, or clinical investigator, consultant, relating to the subject of anticoagulants (including Xarelto®) stroke prevention, and/or the treatment/prevention of Atrial Fibrillation, PE, DVT, or strokes, please identify date(s) that each Prescribing Health Care Provider and/or Primary Treating Physician was retained or compensated; the nature of the affiliation; and the amount of any compensation and/or reimbursement for expenses.

Prescribing Health Care Provider(s) and/or Primary Treating Physician	Date(s) that Prescribing Health Care Provider Retained or Compensated	Nature of Affiliation	Compensation and/or Reimbursement

IV. Plaintiff’s Prescribing Healthcare Providers’ and Primary Treating Physician’s Practices

For each Prescribing Healthcare Provider identified in Section III.A.1(a) of the PFS and Primary Treating Physician identified in Section III.B.1 of the PFS, please state and produce the following:

- A. Do you have or have you had access to any databases, documents, or other information that track or purport to track the prescribing or treating practices of Plaintiff’s Prescribing Healthcare Provider(s) identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS, with respect to Xarelto®.

Yes _____ No _____

V. Plaintiff's Medical Condition

- A. Have you been contacted by Plaintiff, or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) concerning Plaintiff?

Yes _____ No _____

- B. If you have been contacted by any person or entity concerning the Plaintiff (other than Plaintiff's counsel) for a reason other than reporting an adverse event, please state the name of the person(s) who contacted you and the name and address of the person(s) who responded to the contact on your behalf.

- C. Please identify and produce all documents created before the filings of this lawsuit which reflect any communication between any person and you concerning Plaintiff.

- D. Please produce a copy of any MedWatch form, other than documents initiated in the course of litigation, which refers or relates to Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

VII Documents

- A. To the extent you have not already done so, please produce a copy of all documents and things that fall into the categories listed below. These include documents in the possession of any of your present and former employees, including information provided to your attorneys:

1. Any document created before the filing of this lawsuit which relates to or refers to Plaintiff other than documents received or produced in discovery in this matter.

2. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, any document sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS.
3. "Dear Doctor," "Dear Health Care Provider," "Dear Colleague" letters, or PIRs sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS.
4. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, any and all documents reflecting any contacts or communications between you and any of Plaintiff's Prescribing Health Care Providers identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS regarding Xarelto®.
5. Any and all documents which purport to describe, analyze, investigate, track, and/or report the prescribing practices of any of Plaintiff's Prescribing Healthcare Providers identified in Section III.A.1(a) of the PFS and/or Primary Treating Physician identified in Section III.B.1 of the PFS relating to Xarelto®, subject to the approval and/or agreement of the owner of the prescribing data (IMS Health) to release the data, which approval and/or agreement Defendant will request.

CERTIFICATION

I am employed by _____, one of the Defendants in this litigation. I am authorized by _____ [names of other Defendants] to execute this certification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for Defendants, upon whose advice and information I relied. I declare under penalty of perjury that all of the information as to the foregoing Defendants provided in this Defendant Fact Sheet is true and correct to the best of my knowledge upon information and belief.

Signature

Print Name

Date