Breast Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

_

Reporter information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Adverse event details			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died

1.Please describe the malignancy:

- Anatomical location:_____

- Histological type:_____

- TNM classification:_____

- Grade:_____

- Hormone receptor status- Estrogen:_____
  -Progesterone:_____
  -Her2/neu:_____

- Second/Secondary:_____

Breast Cancer Questionnaire
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Case ID #:_____

Manufacturer Date of Receipt: _____

2. Was the event a new diagnosis (acute event) or a relapse/disease progression of a preexisting condition?
☐ New diagnosis ☐Relapse/Disease progression.
What was the prior disease?_____
What was the prior onset date?_____

3. Was there a precipitating factor for exacerbation?
☐ No ☐ UNK ☐ Yes, Please specify:_____

4. Please provide prior screening test results with dates if appropriate (e.g. mammogram):

5. Please provide the method of diagnosis and test result(s). Choose all that apply.
☐ CT/MRI/Ultrasound. Result of:_____
☐ Histopathology. Result of:_____
☐ Cytology. Result of:_____
☐ Genetic testing. Result of:_____
☐ CD marker evaluation. Result of:_____
☐ Other, specify:_____

Dapagliflozin therapy

Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:

Was dapagliflozin stopped due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A

Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A

Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)?
☐ Yes ☐ No Please explain:

Concomitant medications
Exclude drugs to treat the event(s)

Drug Name	**Indication**	**Daily Dosage**	**Route**	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Was this also a suspect medication?**
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

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Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Relevant medical history/concurrent diseases and risk factors, Please provide details if available	
- Alcohol>2drinks/day: ☐Yes ☐No ☐UNK - Overweight/Obese: ☐Yes ☐No ☐UNK - Medication-induced (e.g. hormone replacement therapy (HRT), diethylstilbestrol (DES): ☐Yes ☐No ☐UNK - Radiation exposure: ☐Yes ☐No ☐UNK - Early menarche<12 yrs: ☐Yes ☐No ☐UNK - Late menopause >55 yrs: ☐Yes ☐No ☐UNK - Nulliparous/1st child>30 yrs: ☐Yes ☐No ☐UNK - Past personal history of breast cancer/benign breast disease (e.g fibroadenoma) or ovarian cancer: ☐Yes ☐No ☐UNK	- Family history of breast cancer (1st degree relative w/BC): ☐Yes ☐No ☐UNK - BRCA-1 or BRCA-2 mutation: ☐Yes ☐No ☐UNK - Lobular carcinoma in situ: ☐Yes ☐No ☐UNK - Increased breast density (mammogram): ☐Yes ☐No ☐UNK - Lack of physical activity: ☐Yes ☐No ☐UNK - High fat diet: ☐Yes ☐No ☐UNK - Other gene changes (ATM, p53, CHEK2, PTEN, CDH1): ☐Yes ☐No ☐UNK Other; please specify:_____

Please provide corrective treatment with dates of administration of treatment:
☐ No corrective treatment administered
☐ Surgery: Specify type of surgery: _____ Date of surgery _____/_____/_____ (DDMMYY)
☐ Medical treatment: Specify type of medical treatment: _____Date of treatment_____/_____/_____ (DDMMYY)
☐ Radiotherapy: Date of radiotherapy _____/_____/_____ (DDMMYY)

Date and Signature
Date: _____
Signature (Reporting Physician): _____

Contact information
Please return completed form to:
Fax:
E-mail:
Mail:

Thank you for completing this form.

Bladder Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Reporter information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Adverse event details			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died

1.Please describe the malignancy:

- Anatomical location on bladder (e.g. neck, fundus, body):_____

- Growth pattern (e.g. papillary, non-papillary, metastatic, isolated):_____

- Histological type (e.g. transitional, squamous, adeno):_____

- TNM classification (e.g. pT1, pN2, M0):_____

- Grade/Stages (e.g. high-grade, low-grade or other):_____

Bladder Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

2. Was the event a new diagnosis (acute event) or a relapse/disease progression of a preexisting condition?

☐ New diagnosis ☐ Relapse/Disease progression. What was the prior disease?_____

What was the prior onset date?_____

3. Does the subject have a history of hematuria (micro and/or macro)?

☐ No ☐ UNK ☐ Yes, (If Yes, please complete information below)

Start date: _____/_____/_____ (DDMMYY)

Other occasion dates:_____

Known cause of the hematuria:_____

4. Does the subject have urinary symptoms (or other symptoms)?

☐ No ☐ UNK ☐ Yes, dysuria, start date of _____/_____/_____ (DDMMYY)

☐ Yes, urgency, start date of _____/_____/_____ (DDMMYY)

☐ Yes, polyuria, start date of _____/_____/_____ (DDMMYY)

☐ Yes, increased frequency, start date of _____/_____/_____ (DDMMYY)

☐ Yes, other:

Specify: _____, start date of _____/_____/_____ (DDMMYY)

5. What prompted the investigations that led to diagnosis?

☐ Urinary or other symptoms, please specify: _____

☐ Hematuria, please specify if gross or microscopic hematuria: _____

☐ Other, please specify: _____

6. Please provide the method of diagnosis and test result(s). Choose all that apply. You may provide copies of any test results.

☐ Cystoscopy. Result of: _____

☐ Histopathology. Result of: _____

☐ Cytology. Results of: _____

☐ Imaging (e.g. CT scan, MRI, ultrasound) Result of: _____

☐ Other, specify: _____

Dapagliflozin therapy

Bladder Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:
Was dapagliflozin stopped due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A			
Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A			
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)? ☐ Yes ☐ No Please explain:			

Concomitant medications
Exclude drugs to treat the event(s)

Drug Name	**Indication**	**Daily Dosage**	**Route**	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Was this also a suspect medication?**
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Relevant medical history/concurrent diseases and risk factors

a. Does the patient smoke?

☐ No ☐ UNK ☐Yes (If Yes, please complete information below)

Number of packs/day: _____

Number of years been smoking: _____

b. Has the patient ever smoked previously?

☐ No ☐ UNK ☐Yes (If Yes, please complete information below)

Number of packs/day: _____

Number of years been smoking: _____ Stopped smoking: _____ (Year)

c. Does the subject have any of the following risk factors? Check all that apply

i. Exposure to arsenic, aromatic amines (e.g. aniline), phenacetin, Chinese herbs (e.g. aristolochic acid) and chemicals used in the manufacture of dyes, rubber, leather, textiles and paint products, cyclophosphamide

☐ No ☐ UNK ☐ Yes (If Yes, please complete information below)

Compound: _____ Exposure (dose and time): _____

ii. Has the subject ever used products or combination products containing pioglitazone?

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Case ID #:_____

Manufacturer Date of Receipt: _____

☐ No ☐ UNK ☐ Yes

If Yes, specify dates: _____

iii. Chronic cystitis

☐ No ☐ UNK ☐ Yes

iv. Indwelling urinary catheter

☐ No ☐ UNK ☐ Yes

v. Radiation exposure

☐ No ☐ UNK ☐ Yes

vi. Past personal history of bladder cancer or benign bladder neoplasms

☐ No ☐ UNK ☐ Yes

vii. Family history of bladder cancer

☐ No ☐ UNK ☐ Yes

viii. Family history of hereditary nonpolyposis colorectal cancer (HNPCC) or Lynch syndrome

☐ No ☐ UNK ☐ Yes

ix. ☐ Other, specify:_____

Please provide corrective treatment with dates of administration of treatment:

☐ No corrective treatment administered
☐ Surgery: Specify type of surgery: _____ Date of surgery _____/_____/_____ (DDMMYY)
☐ Medical treatment: Specify type of medical treatment:_____
Date of treatment_____/_____/_____ (DDMMYY)
☐ Radiotherapy: Date of radiotherapy _____/_____/_____ (DDMMYY)

Date and Signature

Bladder Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Date: _____

Signature (Reporting Physician): _____

Contact information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.

Prostate Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Reporter information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Adverse event details			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died

1.Please describe the malignancy:

- Histological type:_____

-TNM classification (e.g. pT1, pN2, M0):_____

- Grade (Gleason score if available, or other system) :_____
(Please indicate type of grading system)

- Stage:_____

2. ☐ **Has the cancer metastasized (specify secondary location(s))?** _____

☐ Still confined to the prostate

3. Is this a:

☐ New diagnosis (acute event) or

☐Relapse/Disease progression. What was the prior disease?_____

What was the prior onset date?

4. Did the subject have prior elevation of PSA? ☐_____

Highest value of PSA on study drug: _____ on: _____/_____/_____ (DDMMYY)

PSA value prior to beginning of study drug: _____ on: _____/_____/_____ (DDMMYY)

Prostate Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

5. Please provide prior screening results with dates of tests (e.g. Digital Rectal Exam):_____
_____
_____

6. What prompted the investigations that led to diagnosis?

☐ Routine screening

☐ High PSA values

☐ Other, please specify: _____

7. Specify any history of symptoms preceding the diagnosis and dates (if known)

☐ Hematuria (micro and/or macro) : _____ on: _____/_____/_____ (DDMMYY)

☐ Hematospermia: _____ _____ on: _____/_____/_____ (DDMMYY)

☐ Other urinary symptoms (e.g. dysuria, urgency, polyuria, pollakiuria: _____
_____ on: _____/_____/_____ (DDMMYY)

☐ Persistent pain in the back, hips or pelvis:_____ on: _____/_____/_____ (DDMMYY)

☐ Painful ejaculation: _____ _____ on: _____/_____/_____ (DDMMYY)

8. Please provide the method of diagnosis and test result(s). Choose all that apply. You may provide copies of any test results.

☐ Histopathology. Result of: _____

☐ Cytology. Results of: _____

☐ Imaging (e.g. CT scan, MRI, ultrasound) Result of: _____

☐ Other, specify: _____

Dapagliflozin therapy			
Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:
Was dapagliflozin stopped due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A			
Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A			
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)? ☐ Yes ☐ No Please explain:			

Prostate Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Concomitant medications
Exclude drugs to treat the event(s)

Drug Name	Indication	Daily Dosage	Route	Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	Was this also a suspect medication?
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Relevant medical history/concurrent diseases and risk factors

a. Does the patient smoke?

☐ No ☐ UNK ☐ Yes (If Yes, please complete information below)

Number of packs/day: _____

Number of years been smoking: _____

b. Has the patient ever smoked previously?

☐ No ☐ UNK ☐ Yes (If Yes, please complete information below)

Number of packs/day: _____

Number of years been smoking: _____ Stopped smoking: _____ (Year)

c. Does the subject have any of the following risk factors? Check all that apply

i. Exposure to heavy metals (e.g. cadmium)

☐ No ☐ UNK ☐ Yes (If Yes, please complete information below)

Compound: _____ Exposure (dose and time): _____

ii. Exposure to agent orange or chlorderone?

☐ No ☐ UNK ☐ Yes

If Yes, specify dates: _____

iii. Prior androgen use?

☐ No ☐ UNK ☐ Yes

iv. High dietary fat intake?

☐ No ☐ UNK ☐ Yes

v. Lack of physical activity / inactivity?

☐ No ☐ UNK ☐ Yes

vi. Past personal history of prostate cancer or benign prostate neoplasms?

Prostate Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

☐ No ☐ UNK ☐ Yes

vii. Past personal history of prostitis or trichomonas?

☐ No ☐ UNK ☐ Yes

viii. Family history of prostate cancer?

☐ No ☐ UNK ☐ Yes (specify father, brother, son etc):_____

ix. Vasectomy?

☐ No ☐ UNK ☐ Yes

x. BRCA 1 and / or 2 mutation?

☐ No ☐ UNK ☐ Yes

xi. Heavy alcohol use (ethanol >50g per day, > ~5 alcoholic drinks per day)?

☐ No ☐ UNK ☐ Yes

xii. ☐ Other, specify:_____

10. Please provide corrective treatment with dates of administration of treatment:

☐ Surgery :_____ _____ on: _____/_____/_____ (DDMMYY)

☐ Medical treatment :_____ _____ on: _____/_____/_____ (DDMMYY)

☐ Radiotherapy :_____ _____ on: _____/_____/_____ (DDMMYY)

☐ Active monitoring :_____ _____ on: _____/_____/_____ (DDMMYY)

11. Please provide outcome/current status of the disease:

☐Complete response to treatment (no cancer present)

☐Stable disease (no change to report)

☐ Progressive disease (cancer has progressed since initial reporting)

☐ Death, specify date of death : _____/_____/_____ (DDMMYY)

Prostate Cancer Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Please provide corrective treatment with dates of administration of treatment:

☐ No corrective treatment administered
☐ Surgery: Specify type of surgery: _____ Date of surgery _____/_____/_____ (DDMMYY)
☐ Medical treatment: Specify type of medical treatment:
_____ Date of treatment_____/_____/_____ (DDMMYY)
☐ Radiotherapy: Date of radiotherapy _____/_____/_____ (DDMMYY)

Date and Signature

Date: _____

Signature (Investigator or Reporting Physician): _____

Contact information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.

Request for Additional Information in response to event or symptoms of diabetic ketoacidosis

Case ID #_____
Manufacturer Date of Receipt _____

Reporter Information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax#:** **Email:**

Please note that information already provided in the original event report does not need to be repeated in this form!

Patient Details							
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:**	☐ lb	☐ kg	**Height:**	☐ in	☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**			**Race:**		

Type of diabetes					
Not applicable ☐ (non-diabetic)	T1DM ☐	T2DM ☐	LADA ☐	Ketosis prone ☐	Other:

Duration of diabetes				
< 1 Year ☐	1-3 Year ☐	3-5 Year ☐	5-10 Year ☐	>10 Year ☐

Adverse Event Details				
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Outcome**	
			☐ Recovered ☐ Event ongoing	☐ Recovered with sequelae ☐ Patient died
			☐ Recovered ☐ Event ongoing	☐ Recovered with sequelae ☐ Patient died
Diagnostic criteria and clinical diagnosis of the event(s):				
Was the patient hospitalized for the event(s)? ☐ Yes ☐ No **Was treatment provided?** ☐ Yes ☐ No			*If 'Yes' to any of the questions to the left, please provide a brief statement of clinical course, relevant treatment and any complications from the event(s):*	

Dapagliflozin therapy			
Indication:	**Daily dosage:**	**Start Date** *(DD/MM/YY):*	**Stop Date** *(DD/MM/YY):*
Was dapagliflozin stopped due to the event(s)?		☐ Yes, permanently ☐ Yes, temporarily	☐ No ☐ N/A

If yes, did the event(s) improve after stopping dapagliflozin?	☐ Yes, permanently ☐ Yes, temporarily	☐ No	☐ N/A
Was dapagliflozin re-introduced?	☐ Yes, permanently ☐ Yes, temporarily	☐ No	☐ N/A
If yes, did the event(s) recur after reintroduction?	☐ Yes, permanently ☐ Yes, temporarily	☐ No	☐ N/A
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)?		☐ Yes	☐ No
Please explain:			

Antidiabetic medications (include treatments up to 3 months in advance of the reported event)

Drug Name	Indication	Daily Dosage	Route	Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	Was this a suspect medication?
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Please comment on any known missed or changed doses in addition to what is listed above:

Other relevant concomitant medications
Exclude drugs used to treat the event

Drug Name	Indication	Daily Dosage	Route	Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	Was this a suspect medication?
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Relevant medical history, concurrent diseases or other contributing factors		Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	If yes, please provide details
Previous episodes of ketoacidosis	☐ Yes ☐ No			
Carbohydrate reduced diet/Reduced caloric intake	☐ Yes ☐ No			
Surgery	☐ Yes ☐ No			
Infection	☐ Yes ☐ No			
Alcohol intake	☐ Yes ☐ No			
Recent Cardiovascular Episode	☐ Yes ☐ No			
Missed insulin dose	☐ Yes ☐ No			
Insulin pump failure	☐ Yes ☐ No			
Pancreatic disorder	☐ Yes ☐ No			

Relevant medical history, concurrent diseases or other contributing factors		Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	If yes, please provide details
Dehydration	☐ Yes ☐ No			
Increased exercise	☐ Yes ☐ No			
Other, please specify:	☐ Yes ☐ No			
	☐ Yes ☐ No			
	☐ Yes ☐ No			

Laboratory Test	Peak Value	Unit	Sample date *(DD/MM/YY)*	Reference Values (…….to ……)	Follow-up value If available	Follow-up Date *(DD/MM/YY)*
Blood/Plasma Glucose						
Blood pH						
PCO_2						
Serum Bicarbonate						
Serum Potassium (K)						
Serum Sodium (Na)						
Blood/Serum Ketones						
Urine Ketones						
c-Peptide						
Lactate						
Betahydroxybutyrate						
eGFR						
Creatinine						
Other, please specify :						

Date and Signature

Date: _____

Signature (Reporting Physician): _____

Contact Information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.

Potential Liver Injury Questionnaire Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Reporter information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Adverse event details			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died

Diagnostic criteria and clinical diagnosis of the event(s) (brief description, including (a) symptoms, abdominal pain, jaundice, mental status changes etc, (b) Findings from physical examination and (c) clinical diagnosis of the liver adverse event). If a GI consult was obtained please specify the findings or provide the consultation report:

Was the patient hospitalized for the event(s)?
☐ Yes ☐ No ☐ UNK

Was treatment provided? if yes, please describe ☐ Yes ☐ No ☐ Unknown

Were there any complications caused by the event(s)?
if yes, please describe ☐ Yes ☐ No ☐ Unknown

Potential Liver Injury Questionnaire Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Dapagliflozin therapy			
Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:
Was dapagliflozin stopped or the dosage altered due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A			
If yes, did the event(s) improve after stopping/altering dapagliflozin? ☐ Yes, date stopped or dose changed: _____ ☐ No ☐ N/A			
Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A			
If yes, did the event(s) recur after reintroduction? ☐ Yes, date recurred: _____ ☐ No ☐ N/A			
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)? ☐ Yes ☐ No Please explain:			

Concomitant medications
Exclude drugs to treat the event(s)

Drug Name	**Indication**	**Daily Dosage**	**Route**	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Was this a suspect medication?**
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Relevant medical history/concurrent diseases
Please provide details: approximate dates of diagnosis and resolution if applicable

- Hepato-biliary disease (if yes, specify): ☐Yes ☐No ☐UNK
- Hyperlipidemia: ☐Yes ☐No ☐UNK
- Bleeding disorders (if yes, specify): ☐ Yes ☐No ☐UNK
- Ischemic hepatitis (eg: hypotension or CHF): ☐Yes ☐No ☐UNK
- Viral hepatitis A, B, C or E (specify): ☐Yes ☐No ☐UNK
- Cardiovascular disease (if yes, specify): ☐Yes ☐No ☐UNK
- Autoimmune disease/ immune-compromised status (if yes, specify): ☐Yes ☐No ☐ UNK
- Obesity: ☐Yes ☐No ☐UNK
- Alcohol and/or drug abuse (if yes, specify): ☐Yes ☐No ☐UNK
- Recent vaccinations or travels (if yes, specify): ☐Yes ☐No ☐UNK
- Occupational toxic agent/environmental exposure (if yes, specify): ☐Yes ☐No ☐UNK
- Relevant family history (if yes, specify): ☐Yes ☐No ☐UNK
- Neoplasm (if yes, specify): ☐Yes ☐No ☐UNK

Other (specify):_____

Potential Liver Injury Questionnaire Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Laboratory Results- Before/During/After Treatment: or provide a copy of the results with special importance to liver function tests (AST, ALT, Total Bilirubin Alk-phosphatase), albumin, PT, INR, bicarbonate, eosinophils, imaging studies, serology for viral hepatitis (antigen/antibody/DNA), histopathology/biopsy, immune-histochemistry (antinuclear antibody, antismooth muscle antibody etc) or any other testing done at. a) baseline, b) at time of the event, c) after interrupting/discontinuing suspect medication, d) after restarting suspect medication, e) if the suspect medication was continued, uninterrupted, subsequent test results

Test	**Reference Values** (please provide units) (……..to …….)	**Baseline Value** (pre-treatment) Date *(DD/MM/YY)*/ Result	**Event Onset Value** Date *(DD/MM/YY)*/ Result	**Peak Value** Date *(DD/MM/YY)*/ Result	**Post-withdrawal Test Value** Date *(DD/MM/YY)*/ Result	**Return to Normal** Date *(DD/MM/YY)* Result
ALT						
AST						
Bilirubin						
ALP						
Other, please specify :						

Relevant imaging studies (e.g., abdominal ultrasound, CT scan, MRI) and other investigations (e.g., drug screening, biopsy, autopsy):

Name of Test	**Test Date**	**Results (describe abnormality)**
		☐ Normal ☐ Abnormal Describe:
		☐ Normal ☐ Abnormal Describe:

Date and Signature

Date: _____

Signature (Reporting Physician): _____

Contact information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.

Potential Renal Impairment/Failure Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Reporter information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Adverse event details (for renal failure be specific about chronicity: acute, chronic or acute on chronic)			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died
			☐ Event ongoing ☐ Recovered ☐ Recovered wth sequele ☐ Patient Died
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died

Diagnostic criteria and clinical diagnosis of the event(s) (brief description, including (a) symptoms, abdominal pain, mental status changes etc, (b) Findings from physical examination and (c) clinical diagnosis of the renal adverse event).
If a nephrologist consult was obtained please specify the findings or provide the consultation report:

Type of renal failure
☐ pre-renal ☐ renal (intrinsic) ☐ post-renal ☐ Other(e.g. acute glomerulonephritis, interstitial nephritis, tubular necrosis)

Was the patient hospitalized for the event(s)?
☐ Yes ☐ No ☐ Unknown

Was treatment provided? if yes, please describe
☐ Yes ☐ No ☐ Unknown

Were there any complications caused by the event(s)? if yes, please describe
☐ Yes ☐ No ☐ Unknown

Dapagliflozin therapy			
Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:
Was dapagliflozin stopped or the dosage altered due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A			
If yes, did the event(s) improve after stopping/altering dapagliflozin? ☐ Yes, date stopped or dose changed: _____ ☐ No ☐ N/A			

Potential Renal Impairment/Failure Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A
If yes, did the event(s) recur after reintroduction? ☐ Yes, date recurred: _____ ☐ No ☐ N/A
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)? ☐ Yes ☐ No Please explain:

Concomitant medications
Exclude drugs to treat the event(s)

Drug Name	Indication	Daily Dosage	Route	Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	Was this also a suspect medication?
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Relevant medical history/concurrent diseases
Please provide details: approximate dates of diagnosis and resolution if applicable

Hypertension: ☐Yes ☐No ☐UNK

Diabetes mellitus: ☐Yes ☐No ☐UNK

Heart failure: ☐Yes ☐No ☐UNK

Drug abuse: ☐Yes ☐No ☐UNK

Exposure to contrast media: ☐Yes ☐No ☐UNK

Obstruction of urinary tract: ☐Yes ☐No ☐UNK

HIV/AIDS: ☐Yes ☐No ☐UNK

Organ transplantation: ☐Yes ☐No ☐UNK

Hematological disorder, if yes, specify: ☐Yes ☐No ☐UNK

SLE: ☐Yes ☐No ☐UNK

Rhabdomyolysis: ☐Yes ☐No ☐UNK

Sepsis/shock: ☐Yes ☐No ☐UNK

Thrombosis: ☐Yes ☐No ☐UNK

Tumor lysis syndrome: ☐Yes ☐No ☐UNK

Malignant disease, if yes, specify: ☐Yes ☐No ☐UNK

Trauma: ☐Yes ☐No ☐UNK

Liver disease, if yes, specify: ☐Yes ☐No ☐UNK

Other, specify:_____

Potential Renal Impairment/Failure Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Laboratory Results- Before/During/After Treatment: or provide a copy of the results with special importance to renal function tests (serum and urine creatinine, BUN, urea, GFR, cystatin C, glucose/creatinine ratio, urianalysis, urine volume, proteinuria, etc) or any other testing done at. a) baseline, b) at time of the event, c) after interrupting/discontinuing suspect medication, d) after restarting suspect medication, e) if the suspect medication was continued, uninterrupted, subsequent test results

Test	**Reference Values** (please provide units) (…….to …….)	**Baseline Value** (pre-treatment) Date *(DD/MM/YY)/* Result	**Event Onset Value** Date *(DD/MM/YY)/* Result	**Peak Value** Date *(DD/MM/YY)/* Result	**Post-withdrawal Test Value** Date *(DD/MM/YY)/* Result	**Return to Normal** Date *(DD/MM/YY)/* Result
Serum creatinine						
BUN/Urea						
GFR						
Proteinuria						
Other, please specify :						

Relevant imaging studies (e.g., abdominal ultrasound, CT scan, MRI) and other investigations (e.g., drug screening, biopsy, autopsy):

Name of Test	**Test Date**	**Results (describe abnormality)**
		☐ Normal ☐ Abnormal, Describe:
		☐ Normal ☐ Abnormal, Describe:
		☐ Normal ☐ Abnormal, Describe:

Date and Signature

Date: _____

Signature (Reporting Physician): _____

Contact information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.

Hypersensitivity Reaction, including Severe Cutaneous Adverse Reaction, Questionnaire Request for Additional Information

Case ID #_____

Manufacturer Date of Receipt _____

Reporter Information		
Reporter Name:	**Reporter address:**	**Telephone #** **Fax#**

Patient Details							
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:**	☐ lb	☐ kg	**Height:**	☐ in	☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**			**Race:**		

Adverse Event Details				
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Outcome**	
			☐ Recovered ☐ Event ongoing	☐ Recovered with sequlae ☐ Patient died
			☐ Recovered ☐ Event ongoing	☐ Recovered with sequlae ☐ Patient died
			☐ Recovered ☐ Event ongoing	☐ Recovered with sequlae ☐ Patient died
Diagnostic criteria and clinical diagnosis of the event(s):				
Was the patient hospitalized for the ev ent(s)? ☐ Yes ☐ No **Was treatment provided?** ☐ Yes ☐ No **Was treatment provided?** ☐ Yes ☐ No			*If 'Yes' to any of the questions to the left, please provide a brief statement of clinical course, relevant treatment and any complications from the event(s):*	

Did the patient experience any of the following:		**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Comments**
Anaphylactoid reaction, anaphylactic reaction/shock	☐ Yes ☐ No			
Angioedema	☐ Yes ☐ No			
Respiratory reaction, including dyspnea, wheezing, bronchospasm, tongue swelling and/or throat swelling/obstruction	☐ Yes ☐ No			
Rash,urticaria with/without pruritis	☐ Yes ☐ No			
Rash with eosinophilia and systemic symptoms	☐ Yes ☐ No			
Serious skin reaction, such as erythema multiforme, SJS, TEN, or exfoliative dermatitis (please specify)	☐ Yes ☐ No			
Other, please specify:	☐ Yes ☐ No			

Dapagliflozin therapy					
Indication:	**Daily dosage:**	**Start Date** *(DD/MM/YY):*		**Stop Date** *(DD/MM/YY):*	
Was dapagliflozin stopped due to the event(s)?		☐ Yes, permanently ☐ Yes, temporarily		☐ No	☐ N/A
If yes, did the event(s) improve after stopping dapagliflozin?		☐ Yes, permanently ☐ Yes, temporarily		☐ No	☐ N/A
Was dapagliflozin re-introduced?		☐ Yes, permanently ☐ Yes, temporarily		☐ No	☐ N/A
If yes, did the event(s) recur after reintroduction?		☐ Yes, permanently ☐ Yes, temporarily		☐ No	☐ N/A
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)?			☐ Yes	☐ No Please explain:	

Concomitant medications Exclude drugs used to treat the event						
Drug Name	**Indication**	**Daily Dosage**	**Route**	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Was this a suspect medication?**
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Does the patient possess any of the following disorders or risk factors?		**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**If yes, please provide details**
History of allergies	☐ Yes ☐ No			
Family history of allergies	☐ Yes ☐ No			
Previous drug reactions	☐ Yes ☐ No			
Asthma or COPD	☐ Yes ☐ No			
Significant cardiac disorders	☐ Yes ☐ No			
Autoimmune disease	☐ Yes ☐ No			
Immunocompromised status	☐ Yes ☐ No			
Recent vaccination	☐ Yes ☐ No			
Infection	☐ Yes ☐ No			
Other, please specify:	☐ Yes ☐ No			
	☐ Yes ☐ No			

Diagnostic Investigations (drug screening, biopsy, lab tests, autopsy):			
Name of Test	**Was the test performed?**	**Test Date** *(DD/MM/YY)*	**Results (specify abnormality)**
Skin test or biopsy	☐ No ☐ Yes		☐ Normal ☐ Abnormal
Drug provocation test	☐ No ☐ Yes		☐ Normal ☐ Abnormal
Immunoglobulin tests (please specify):	☐ No ☐ Yes		☐ Normal ☐ Abnormal
Other, please specify:	☐ No ☐ Yes		☐ Normal ☐ Abnormal

Specialist consultation

Has a specialist been consulted? ☐ No ☐ Yes (If yes, please summarize or send a copy of the consultation report)

Please provide any further relevant information about the Adverse Event

Include any other treatments received that have not been previously stated.

Date and Signature

Date: _____

Signature (Reporting Physician): _____

Contact Information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.

dapagliflozin questionnaire
Request for Additional Information Amputation and Adverse Events that may precede Amputation

Case ID #:_____

Manufacturer Date of Receipt: _____

In diabetic patients, events such as gangrene, irreversibile infection, ulceration and peripheral vascular disease may lead to amputation. This is a request for information if the patient have had an amputation performed after initiation of dapagliflozin or dapagliflozin-metformin.

Reporter information	
Reporter Name:	
Reporter address:	
Telephone #:	**Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Amputation			
Did the patient have an amputation?		☐ Yes ☐ No ☐ Unknown	
If yes, type of event: Trauma by accident ☐ Surgical amputation ☐ Spontaneous/Non-Surgical ☐ **Location of amputation:**			
Left	☐	Right	☐
Below knee	☐	Below elbow	☐
Above knee	☐	Above elbow	☐
Foot	☐	Hand	☐
Big toe	☐	Thumb	☐
Index toe	☐	Index finger	☐
Middle toe	☐	Middle finger	☐
Fourth toe	☐	Ring finger	☐
Little toe	☐	Little finger	☐

dapagliflozin questionnaire
Request for Additional Information Amputation and Adverse Events that may precede Amputation

Case ID #:_____

Manufacturer Date of Receipt: _____

Amputation	
Trans metatarsal	☐
Other	☐
specify:_____	

Adverse event contributing to/leading up to the amputation			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Specify_____ ☐ Patient Died
			Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Specify_____ ☐ Patient Died
			Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Specify_____ ☐ Patient Died

Diagnostic criteria and clinical diagnosis of the event(s) (brief description, including (a) symptoms, (b) Findings from physical examination and (c) clinical diagnosis of the event(s) leading up to the amputation

Was the patient hospitalized for the event(s)?
☐ Yes ☐ No ☐ Unknown

Was treatment provided?
☐ Yes ☐ No ☐ Unknown

If yes, please describe: _____

Were there any complications caused by the event(s)?
☐ Yes ☐ No ☐ Unknown

If yes, please describe: _____

Dapagliflozin therapy			
Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:
Was dapagliflozin stopped or the dosage altered due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A			
If yes, did the event(s) improve after stopping/altering dapagliflozin? ☐ Yes, date stopped or dose changed: _____ ☐ No ☐ N/A			
Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A			

dapagliflozin questionnaire
Request for Additional Information Amputation and Adverse Events that may precede Amputation

Case ID #:_____

Manufacturer Date of Receipt: _____

Dapagliflozin therapy
If yes, did the event(s) recur after reintroduction? ☐ Yes, date recurred: _____ ☐ No ☐ N/A
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)? ☐ Yes ☐ No Please explain:

Concomitant medications, including antidiabetic and diuretic medications (Exclude drugs to treat the event(s))

Drug Name	Indication	Daily Dosage	Route	Start Date *(DD/MM/YY)*	Stop Date *(DD/MM/YY)*	Was this a suspect medication?
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Relevant medical history/ risk factors/concurrent diseases
Please provide details: approximate dates of diagnosis and resolution if applicable

Diabetes:	☐Yes ☐No ☐UNK
Diabetes Type:	☐Type I ☐Type II
Date of Diabetes diagnosis:	Day:_____ Month:_____Year_____
Ankle-brachial pressure index measured	☐Yes ☐No ☐UNK
If yes, Date of measurement	Day:_____ Month:_____Year_____
Results:_____	
est. Glomerular Filtration Rate (eGFR) prior to treatment	☐Yes ☐No ☐UNK
If yes, Date of measurement:	Day:_____ Month:_____Year_____
Result:_____	
Diabetic neuropathy	☐Yes ☐No ☐UNK
Renal disease	☐Yes ☐No ☐UNK

dapagliflozin questionnaire
Request for Additional Information Amputation and Adverse Events that may precede Amputation

Case ID #:_____

Manufacturer Date of Receipt: _____

Relevant medical history/ risk factors/concurrent diseases Please provide details: approximate dates of diagnosis and resolution if applicable	
Dehydration	☐Yes ☐No ☐UNK
Infection (of limb):	
Wet gangrene	☐Yes ☐No ☐UNK
Non-healing infectious ulcer	☐Yes ☐No ☐UNK
Osteomyelitis	☐Yes ☐No ☐UNK
Other Infection	☐Yes ☐No ☐UNK
If yes, please specify:	

Tobacco use		
Never smoked ☐	Current smoker ☐	Former smoker ☐
Tobacco stop date:	Day:_____ Month:_____Year_____	
If current or former smoker		
Amount of smokes/day:_____		
Number of years smoking:_____		
Tobacco type:_____		

Date and Signature

Date: _____

Signature (Reporting Physician): _____

Contact information

Please return completed form to:
Mail:

Fax: E-mail:

Thank you for completing this form.

Urinary Tract Infection Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Reporter information		
Reporter Name:	**Reporter address:**	**Telephone #:** **Fax #:**

Patient details			
Initials:	**Sex:** ☐ Male ☐ Female	**Weight:** ☐ lb ☐ kg	**Height:** ☐ in ☐ cm
Date of Birth *(DD/MM/YY)* **or Age:**		**Ethnic Origin:**	**Race:**

Adverse event details (for renal failure be specific about chronicity: acute, chronic or acute on chronic)			
Adverse Event(s)	**Start Date** *(DD/MM/YY)*	**End Date** *(DD/MM/YY)*	**Outcome**
			☐ Event ongoing ☐ Recovered ☐ Recovered with /sequele ☐ Patient Died
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died
			☐ Event ongoing ☐ Recovered ☐ Recovered with sequele ☐ Patient Died

Diagnostic criteria and clinical diagnosis of the event(s) (brief description), please specify how the diagnosis was performed:

Please also specify signs and symptoms associated with the event(s), i.e pain or burning or uncomfortable pressure in the lower abdomen/pelvic area while passing urine, blood in the urine, and symptoms of urinary urgency (a strong and uncontrolled urge to pass urine). Other suggestive signs or symptoms such as dysuria, urgency or frequency of urination, suprapubic or perineal discomfort, flank, back or abdominal pain, costovertebral angle tenderness, nausea, vomiting, chills or sepsis:

Fever? If yes, please add degree
☐ Yes ☐ No ☐ Unknown

Was the patient hospitalized for the event(s)?
☐ Yes ☐ No ☐ Unknown

Was treatment provided? if yes, please describe
☐ Yes ☐ No ☐ Unknown

Urinary Tract Infection Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

First event of urinary infection while on treatment with DAPA? if no, please specify episode and date
☐ Yes ☐ No ☐ Unknown

Were there any complications caused by the event(s)? if yes, please describe
☐ Yes ☐ No ☐ Unknown

Did the patient receive antimicrobial medication? if yes, please describe
☐ Yes ☐ No ☐ Unknown

Dapagliflozin therapy			
Indication:	**Daily dosage:**	**Start date** *(DD/MM/YY)*:	**Stop date** *(DD/MM/YY)*:
Was dapagliflozin stopped due to the event(s)? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ N/A			
If yes, did the event(s) improve after stopping/altering dapagliflozin? ☐ Yes, date stopped or dose changed: _____ ☐ No ☐ N/A			
Was dapagliflozin re-introduced? ☐ Yes, date re-introduced: _____ ☐ No ☐ N/A			
If yes, did the event(s) recur after reintroduction? ☐ Yes, date recurred: _____ ☐ No ☐ N/A			
Does the reporter consider there to be a causal relationship between dapagliflozin and the adverse event(s)? ☐ Yes ☐ No Please explain:			

Concomitant medications
Exclude drugs used to treat the event(s)

Drug Name	**Indication**	**Daily Dosage**	**Route**	**Start Date** *(DD/MM/YY)*	**Stop Date** *(DD/MM/YY)*	**Was this also a suspect medication?**
						☐ Yes ☐ No
						☐ Yes ☐ No
						☐ Yes ☐ No

Urinary Tract Infection Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Relevant medical history/concurrent diseases Please provide details: approximate dates of diagnosis and resolution if applicable	
- Catheter or urinary tract instrumentation/surgery: ☐Yes ☐No ☐UNK - Bladder pathology: ☐Yes ☐No ☐UNK - Chronic prostatitis: ☐Yes ☐No ☐UNK - Chronic pyelonephritis: ☐Yes ☐No ☐UNK - Estrogen deficiency: ☐Yes ☐No ☐UNK - Urine incontinence: ☐Yes ☐No ☐UNK - Vesicoureteral reflux: ☐Yes ☐No ☐UNK - Urethral obstruction: ☐Yes ☐No ☐UNK - Recurrent UTI: ☐Yes ☐No ☐UNK	- Smoking: ☐Yes ☐No ☐UNK - Alcoholism: ☐Yes ☐No ☐UNK - Glucocorticoid treatment: ☐Yes ☐No ☐UNK - Recent or ongoing treatment with antibiotics: ☐Yes ☐No ☐UNK - Birth control pills: ☐Yes ☐No ☐UNK Other, please specify:_____

Was any diagnostic test performed? (e.g. CRP, leucocyte count)
☐ Yes ☐ No ☐ Uknown; if yes, please describe below

Name of test	Test date	Results (describe abnormality)
		☐ Normal ☐ Abnormal, Describe:
		☐ Normal ☐ Abnormal, Describe:
		☐ Normal ☐ Abnormal, Describe:

Urinary culture performed? ☐ Yes ☐ No ☐ Unknown; if yes, tick below question
Results indicative of UTI? ☐ Yes ☐ No ☐ Unknown; if yes, please describe below

Organism	Test date	Quantification

Did this event require more than one course of antimicrobial treatment?
☐ Yes ☐ No ☐ Unknown, if yes, please describe below

Urinary Tract Infection Questionnaire
Request for Additional Information

Case ID #:_____

Manufacturer Date of Receipt: _____

Date and Signature

Date: _____

Signature (Reporting Physician): _____

Contact information

Please return completed form to:

Fax:

E-mail:

Mail:

Thank you for completing this form.