

ANNEX 1

**SURVEILLANCE STUDY OF PHOTOCONTACT DERMATITIS LEADING
TO HOSPITALIZATION IN EUROPE WITH A SPECIAL FOCUS ON
TOPICAL KETOPROFEN AND OTHER TOPICAL NSAIDs, INCLUDING
EVALUATION OF SEVERE PHOTOSENSITIVITY REACTIONS**

QUESTIONNAIRE

Case Control Questionnaire validation

Interviewer _____

Date of interview dd |__|__| mm |__|__| yyyy |__|__|__|__|

City of residence _____

GENERAL DATA

1. Gender Male
 Female

2. Date of birth dd |__|__| mm |__|__| yyyy |__|__|__|__|

3. Date of hospital admission dd |__|__| mm |__|__| yyyy |__|__|__|__|

4. Department of hospitalization

- Medicine
- Surgery
- Orthopaedics
- Intensive care
- ENT/Ophthalmology
- Dermatology
- Other _____

5. Primary diagnosis at admission _____ |__|__|__|. |__| (ICD-10)

6. Secondary diagnosis at admission _____ |__|__|__|. |__| (ICD-10)

DEMOGRAPHICS

1. Weight (Kg) |__|__|__|

2. Height (cm) |__|__|__|

ID (hospital code - subject n°) |__|__|__| - |__|__|__|

3. Ancestry

- White / Caucasian
- Mixed (unspecified)
 - White and black Caribbean*
 - White and black African*
 - White and Asian*
 - Other*
- Chinese
- Asian
- Black (unspecified)
 - Caribbean*
 - African*
 - Other*
- Other

4. Marital status

- Married / Common-law husband/wife
- Unmarried
- Divorced / Widowed
- Other

5. Occupational status

- Working
- Student
- Unemployed / Searching a job
- Retired
- Disability pension
- Housewife / Househusband
- Other

6. Present or last occupation

- Never worked
- Legislator, Senior Officials and Managers
- Professionals
- Technicians and Associate Professionals
- Clerks
- Service workers and Shop and Market sales workers
- Skill Agricultural and Fishery workers
- Craft and related workers
- Plant and Machine operators and Assemblers
- Elementary occupations
- Armed forces
- Other _____

7. Highest level of education

- Compulsory Education not completed
- Compulsory Education
- High school (unspecified)
 - Vocational training*
 - University training*
- First Level Degree (Bachelor degree, journalism, nurse training,...)
- Second Level Degree (Magister degree, Master, PhD,...)

8. Smoking habits

- Smoker
- Ex-smoker (at least one year abstinence)
- Non-smoker

9. Alcohol consumption

- Regular drinker
- Occasional drinker
- Ex-drinker (at least one year abstinence)
- Non-drinker

RECENT MEDICAL HISTORY

1. Onset of first symptoms leading to hospitalization (days before admissions) |_|_|_|

2. Brief description of symptoms before hospitalization

3. During the month before hospitalization did you undergo radiotherapy?

- Yes
- No
- Unknown

If Yes, specify:

the indication _____ |_|_|_|. |_| (ICD-10)
 the last date of treatment dd |_|_| mm |_|_| yyyy |_|_|_|_|

GENERAL MEDICAL HISTORY

1. During your lifetime have you ever had (MRQ): Age at first diagnosis (years)

Skin diseases

- Atopic Dermatitis |__|__|
- Psoriasis..... |__|__|
- Contact Dermatitis _____ |__|__| . |__| (ICD-10)... |__|__|
- Urticaria..... |__|__|
- Polymorphous light eruptions |__|__|
- Other photosensitivity reactions _____ |__|__| . |__| (ICD-10)... |__|__|
- Skin cancer _____ |__|__| . |__| (ICD-10)... |__|__|
- Rosacea..... |__|__|
- Herpes Simplex _____ |__|__| . |__| (ICD-10)... |__|__|
- Vitiligo..... |__|__|
- Any itchy skin rash _____ |__|__| . |__| (ICD-10)... |__|__|
- Other Skin disease (1) _____ |__|__| . |__| (ICD-10)... |__|__|
- (2) _____ |__|__| . |__| (ICD-10)... |__|__|

Diseases predisposing to photosensitivity

- Xeroderma pigmentosum |__|__|
- Porphyrias _____ |__|__| . |__| (ICD-10)... |__|__|
- Albinism |__|__|
- Systemic Lupus Erythematosus..... |__|__|
- Pellagra..... |__|__|
- Other Rheumatic disease _____ |__|__| . |__| (ICD-10)... |__|__|

Other diseases

- Cardiac disorders |__|__|
- Bronchial Asthma..... |__|__|
- Recurrent Urinary Tract Infections |__|__|
- Nephrolithiasis..... |__|__|
- Other Renal disease _____ |__|__| . |__| (ICD-10)... |__|__|
- Gastric/duodenal Ulcer..... |__|__|
- Cholelithiasis |__|__|
- Hepatitis B |__|__|
- HIV-positive..... |__|__|
- Chronic Liver disease _____ |__|__| . |__| (ICD-10)... |__|__|
- Epilepsy |__|__|
- Diabetes mellitus |__|__|
- Hyperuricaemia / Gout |__|__|
- Hyperlipemia |__|__|
- Hypertension |__|__|
- Thyroid disease _____ |__|__| . |__| (ICD-10)... |__|__|
- Neoplasm (1) _____ |__|__| . |__| (ICD-10)... |__|__|
- (2) _____ |__|__| . |__| (ICD-10)... |__|__|
- Joint diseases (1) _____ |__|__| . |__| (ICD-10)... |__|__|
- (2) _____ |__|__| . |__| (ICD-10)... |__|__|

- Neurologic diseases (1) _____ |__|__|__|. |__| (ICD-10)... |__|__|
 (2) _____ |__|__|__|. |__| (ICD-10)... |__|__|
- Other relevant disease _____ |__|__|__|. |__| (ICD-10)... |__|__|

During your lifetime have you ever experienced:

2. An allergic reaction to topical ketoprofen

- Yes
 No
 Unknown

If Yes, specify:

the drug name _____

Were you hospitalized?

- Yes
 No
 Unknown

3. An allergic reaction to other topical NSAIDs

- Yes
 No
 Unknown

If Yes, specify:

the drug name _____

Were you hospitalized?

- Yes
 No
 Unknown

4. Any adverse effect to other medications

- Yes
 No
 Unknown

If Yes, specify:

the drug name (1) _____

Were you hospitalized?

- Yes
 No
 Unknown

(2) _____

Were you hospitalized?

- Yes
 No
 Unknown

DRUG EXPOSURE

During the last month before hospitalization had you ever used:

1. Topical ketoprofen

- Yes
- No
- Unknown

If Yes, specify:

1.1.)				Weeks before hospitalization date												Prior use			
Drug Name	Body site(s)	Indication	Condition of use	Week 1							Week 2	Week 3		Week 4		Duration*	Usage	AEs	
_ _ _	_ _ _ _ _ _	_ _	<input type="checkbox"/> Free <input type="checkbox"/> Bandage <input type="checkbox"/> Occlusive <input type="checkbox"/> Other <input type="checkbox"/> Unknown	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _ _ M _ _ _ W _ _ _	<input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> U
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1.2.)				Weeks before hospitalization date												Prior use			
Drug Name	Body site(s)	Indication	Condition of use	Week 1							Week 2	Week 3		Week 4		Duration*	Usage	AEs	
_ _ _	_ _ _ _ _ _	_ _	<input type="checkbox"/> Free <input type="checkbox"/> Bandage <input type="checkbox"/> Occlusive <input type="checkbox"/> Other <input type="checkbox"/> Unknown	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _ _ M _ _ _ W _ _ _	<input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> U
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* Duration for continuation of a prior therapy

2. Other topical NSAIDs (ibuprofen, diclofenac, piroxicam...)

- Yes
- No
- Unknown

If Yes, specify:

2.1.)					Weeks before hospitalization date												Prior use			
Drug Name	Active ingredient	Body site(s)	Indication	Condition of use	Week 1							Week 2	Week 3		Week 4			Duration*	Usage	AEs
_ _ _	_ _	_ _ _ _ _ _	_ _	<input type="checkbox"/> Free <input type="checkbox"/> Bandage <input type="checkbox"/> Occlusive <input type="checkbox"/> Other <input type="checkbox"/> Unknown	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N	<input type="checkbox"/> N
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2.2.)					Weeks before hospitalization date												Prior use			
Drug Name	Active ingredient	Body site(s)	Indication	Condition of use	Week 1							Week 2	Week 3		Week 4			Duration*	Usage	AEs
_ _ _	_ _	_ _ _ _ _ _	_ _	<input type="checkbox"/> Free <input type="checkbox"/> Bandage <input type="checkbox"/> Occlusive <input type="checkbox"/> Other <input type="checkbox"/> Unknown	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N	<input type="checkbox"/> N
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													<input type="checkbox"/> U	<input type="checkbox"/> U	<input type="checkbox"/> U	<input type="checkbox"/> U				

* Duration for continuation of a prior therapy

3. Other topical medications

- Yes
- No
- Unknown

If Yes, specify:

3.1.)				Weeks before hospitalization date												Prior use		
Name	Body site(s)	Indication	Condition of use	Week 1							Week 2	Week 3	Week 4	Duration*	Usage	AEs		
	_ _ _ _ _ _	_ _	<input type="checkbox"/> Free <input type="checkbox"/> Bandage <input type="checkbox"/> Occlusive <input type="checkbox"/> Other <input type="checkbox"/> Unknown	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N <input type="checkbox"/> N
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												<input type="checkbox"/> U		<input type="checkbox"/> U		<input type="checkbox"/> U		

3.2.)				Weeks before hospitalization date												Prior use		
Name	Body site(s)	Indication	Condition of use	Week 1							Week 2	Week 3	Week 4	Duration*	Usage	AEs		
	_ _ _ _ _ _	_ _	<input type="checkbox"/> Free <input type="checkbox"/> Bandage <input type="checkbox"/> Occlusive <input type="checkbox"/> Other <input type="checkbox"/> Unknown	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N <input type="checkbox"/> N
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												<input type="checkbox"/> U		<input type="checkbox"/> U		<input type="checkbox"/> U		

* Duration for continuation of a prior therapy

4. Systemic NSAIDs (including ketoprofen)

- Yes
- No
- Unknown

If Yes, specify:

4.1.)				Weeks before hospitalization date												Prior use				
Drug Name	Active ingredient	Administration route	Indication	Week 1							Week 2	Week 3	Week 4	Duration*	Usage	AEs				
_ _ _	_ _	<input type="checkbox"/> Oral <input type="checkbox"/> Inhalational <input type="checkbox"/> Parenteral <input type="checkbox"/> Suppository <input type="checkbox"/> Unknown	_ _	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N	<input type="checkbox"/> N	
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4.2.)				Weeks before hospitalization date												Prior use				
Drug Name	Active ingredient	Administration route	Indication	Week 1							Week 2	Week 3	Week 4	Duration*	Usage	AEs				
_ _ _	_ _	<input type="checkbox"/> Oral <input type="checkbox"/> Inhalational <input type="checkbox"/> Parenteral <input type="checkbox"/> Suppository <input type="checkbox"/> Unknown	_ _	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N	<input type="checkbox"/> N	
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											<input type="checkbox"/> U		<input type="checkbox"/> U		<input type="checkbox"/> U					

* Duration for continuation of a prior therapy

5. Other systemic drugs taken according to indications (e.g. drugs for pain, antihypertensive, anticonvulsivants, lipid and cholesterol lowering drugs)

- Yes
- No
- Unknown

If Yes, specify:

5.1.)				Weeks before hospitalization date												Prior use		
Drug Name	Active ingredient(s)	Administration route	Indication	Week 1							Week 2	Week 3	Week 4	Duration*	Usage	AEs		
		<input type="checkbox"/> Oral <input type="checkbox"/> Inhalational <input type="checkbox"/> Parenteral <input type="checkbox"/> Suppository <input type="checkbox"/> Unknown	_ _	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N <input type="checkbox"/> N
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5.2.)				Weeks before hospitalization date												Prior use		
Drug Name	Active ingredient(s)	Administration route	Indication	Week 1							Week 2	Week 3	Week 4	Duration*	Usage	AEs		
		<input type="checkbox"/> Oral <input type="checkbox"/> Inhalational <input type="checkbox"/> Parenteral <input type="checkbox"/> Suppository <input type="checkbox"/> Unknown	_ _	1	2	3	4	5	6	7		Freq		Freq		Freq	Y _ _	<input type="checkbox"/> N <input type="checkbox"/> N
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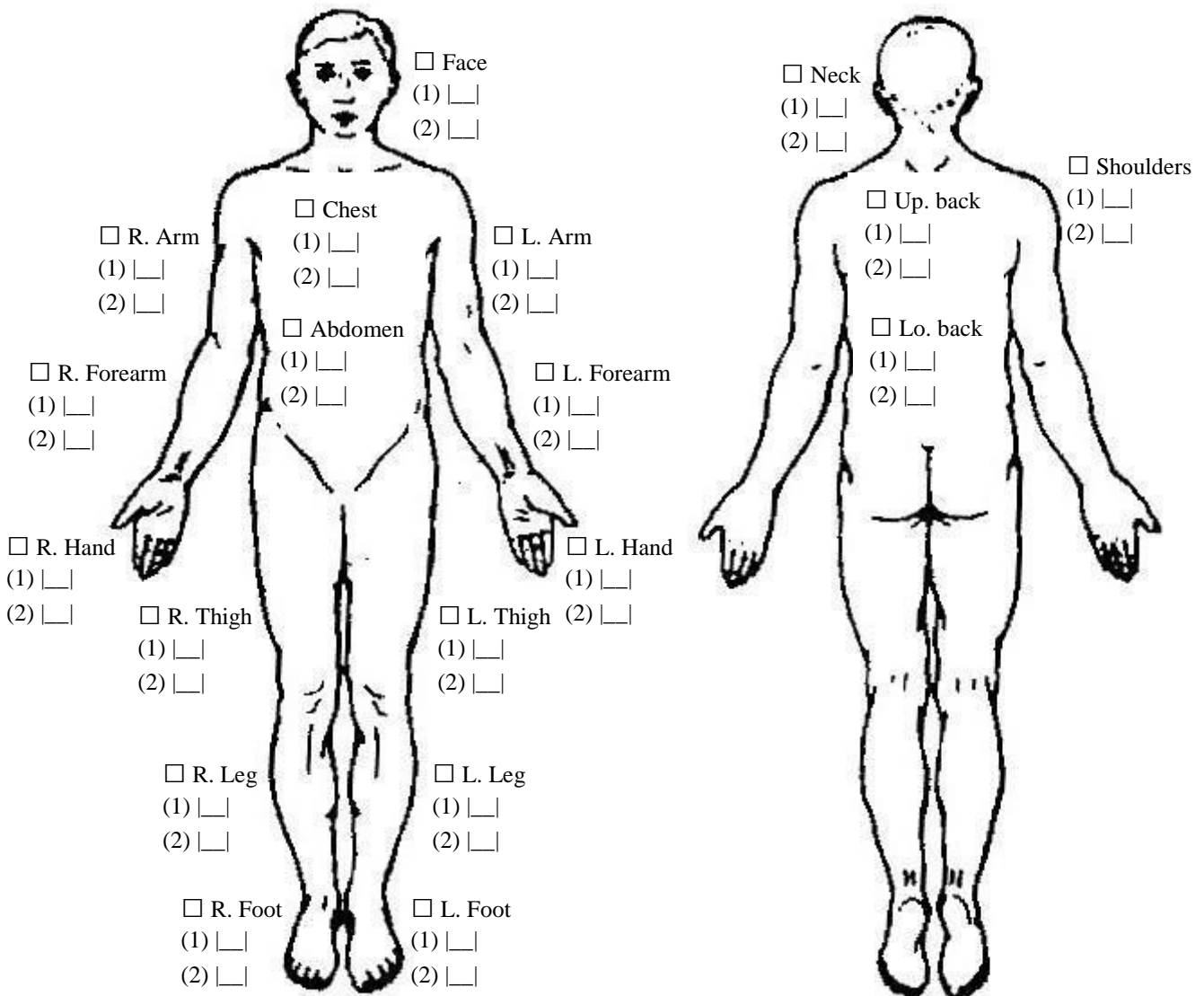
* Duration for continuation of a prior therapy

HISTORY OF SUN EXPOSURE

1. During the last month before hospitalization did you expose your skin to the sun?

- Yes
- No
- Unknown

If yes, which of these body sites did you expose to the sun (*MRQ*)?



1. Frequency of exposure during the last week before hospitalization
2. Average frequency of exposure during the last month before hospitalization, excluding the last week

2. During the last week before hospitalization had you ever been exposed to UVA or UVB light sources?

- Yes
 No
 Unknown

If Yes, which kind of UV source:

- UVA
 UVB
 Both
 Unknown

3. During the last month before hospitalization, excluding the last week, had you ever been exposed to UVA or UVB light sources?

- Yes
 No
 Unknown

If Yes, which kind of UV source:

- UVA
 UVB
 Both
 Unknown

4. During the last week before hospitalization had you ever used sunscreens?

- Yes
 No
 Unknown

If Yes, which kind of sun protection factor did you use?

- Low
 Medium
 High
 Unknown

5. During the last month before hospitalization, excluding the last week, had you ever used sunscreens?

- Yes
 No
 Unknown

If Yes, which kind of sun protection factor did you use?

- Low
- Medium
- High
- Unknown

PHENOTYPIC FEATURES

1. Colour of eyes

- Black
- Dark brown
- Light brown
- Green brown
- Green
- Gray-hazel
- Blue
- Other

2. Natural Colour of hair

- Black
- Dark brown
- Brown-Red
- Light brown
- Blond
- Red
- Other

3. Skin colour

- Pale white
- Fair white
- Darker white
- Light brown
- Brown
- Dark brown / Black

4. When you expose to the sun for one hour, after at least one month without exposure, your skin:

- Always burns, does not tan
- Burns easily, tans poorly
- Tans after initial burn
- Burns minimally, tans easily
- Rarely burns, tans darkly easily
- Never burns, always tans darkly

ENVIRONMENTAL EXPOSURE

1. During the last week before hospitalization had you ever come into contact with pesticides?

- Yes
 No
 Unknown

If Yes, which of these pesticides (*MRQ*):

- Insecticides
 Fungicides
 Herbicides
 Rodenticides
 Pediculicides
 Other not listed
 Unknown

2. During the last month before hospitalization, excluding the last week, had you ever come into contact with pesticides?

- Yes
 No
 Unknown

If Yes, which of these pesticides (*MRQ*):

- Insecticides
 Fungicides
 Herbicides
 Rodenticides
 Pediculicides
 Other not listed
 Unknown

3. During the last week before hospitalization had you ever come into contact or assumed (with food/drink) one of these herbs, seed, roots or essential oils (*MRQ*)?

- Bergamot lime
 Celery
 Citron
 Parsnip
 Parsley
 Fennel
 St. John's wort (Hypericum)
 Anise
 Angelica
 Arnica
 Other not listed
 Unknown

4. During the last month before hospitalization, excluding the last week, had you ever come into contact or assumed (with food/drink) one of these herbs, seed, roots or essential oils (*MRQ*)?
- Bergamot lime
 - Celery
 - Citron
 - Parsnip
 - Parsley
 - Fennel
 - St. John's wort (Hypericum)
 - Anise
 - Angelica
 - Arnica
 - Other not listed
 - Unknown

ADDITIONAL DATA FOR CASES

1. Which of these clinical signs and symptoms resulted in hospitalization (*MRQ*)?
- Bumps
 - Blisters, bullae
 - Skin rash
 - Hyperpigmentation (dark patches on skin)
 - Pain and swelling
 - Pruritus
 - Chills
 - Headache
 - Fever (>38,5 °C)
 - Nausea
 - Peeling
 - Oozing
 - Bleeding
 - Dryness
 - Crusting
 - Flaking
 - Cracking
 - Other _____

2. If you had bumps, blisters or skin rash, in which of these body sites did you have signs (MRQ)?

Face
 (1)
 (2)

R. Arm
 (1)
 (2)

Chest
 (1)
 (2)

L. Arm
 (1)
 (2)

R. Forearm
 (1)
 (2)

Abdomen
 (1)
 (2)

L. Forearm
 (1)
 (2)

R. Hand
 (1)
 (2)

L. Hand
 (1)
 (2)

R. Thigh
 (1)
 (2)

L. Thigh
 (1)
 (2)

R. Leg
 (1)
 (2)

L. Leg
 (1)
 (2)

R. Foot
 (1)
 (2)

L. Foot
 (1)
 (2)

Neck
 (1)
 (2)

Up. back
 (1)
 (2)

Lo. back
 (1)
 (2)

Shoulders
 (1)
 (2)