Annex 2

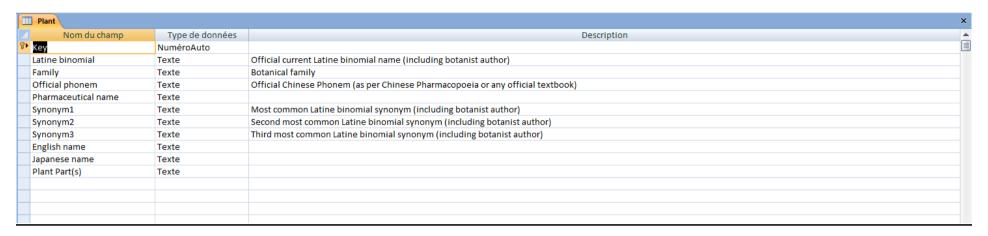## Proposed forms for entry of risk/benefit data

The following tables are proposed for entry of risk/benefit data. These are only suggestions, open to any comments / modifications. This document presents:

- For each table the actual structure of data (each line corresponds to a field of the database):
    - The first line is an auto-number required for the database.
    - The lines with data type "numérique"[1] refer to other tables (Tables of TCM, Plant and Bibliographic reference) ➜ avoid re-typing of data and allows standardisation; the system foresees either studies on a single plant or on a complex TCM.
    - The lines with data type "Text" are limited to maximum 256 characters; if this is judged insufficient for a given field, we can switch to type "Memo" with unlimited field size (but we then lose indexation capacities for this field).
- A few examples of possible data entry forms

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[1] Note : these screen captures are from the French version of Access; this automatically changes with the English version
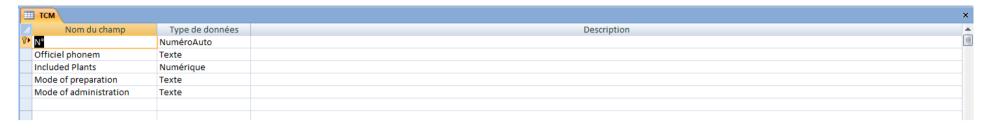
Table Plant

Nom du champ	Type de données	Description
Key	NuméroAuto	
Latine binomial	Texte	Official current Latine binomial name (including botanist author)
Family	Texte	Botanical family
Official phonem	Texte	Official Chinese Phonem (as per Chinese Pharmacopoeia or any official textbook)
Pharmaceutical name	Texte	
Synonym1	Texte	Most common Latine binomial synonym (including botanist author)
Synonym2	Texte	Second most common Latine binomial synonym (including botanist author)
Synonym3	Texte	Third most common Latine binomial synonym (including botanist author)
English name	Texte	
Japanese name	Texte	
Plant Part(s)	Texte	

Here is the beginning of the table we already compiled (missing at this stage: botanist name, name in Chinese, Japanese phonem, synonyms, adulterants, read-proofing)

Key	Latine binomial	Family	Official pho	Pharmaceutical name	Synonym1	Synonym2	Synonym3	English name	Japanese na	Plant Part(s)
5	Abrus cantoniensis	Fabaceae	Jigucao	Herba Abri				Canton Love-pea Vine		Dried herb
6	Abutilon theophrastii	Malvaceae	Qingmazi	Semen Abutili				Chingma Abutilon Seed		Dried ripe seed
7	Acacia catechu	Fabaceae	Ercha	Catechu				Cutch, Black Catechu		Dried concentrated decoction prepar
8	Acanthopanax gracilistylus	Araliaceae	Wujiapi	Cortex Acanthopanacis				Slenderstyle Acanthopan		Dried root bark
9	Acanthopanax senticosus	Araliaceae	Ciwujia	Radix seu Caulis Acanthopanaci				Manyprickle Acanthopan		Dried root and rhizome or stem
10	Achyrantes bidentata	Amaranthacea	Niuxi	Radix Achyranthis Bidentatae				Twotoothed Achyranthe:		Dried root
11	Aconitum carmichaeli	Ranunculaceae	Chuanwu	Radix Aconiti				Common Monkshood Mc		Dried parent root tuber (also process
12	Aconitum kusnezoffii	Ranunculaceae	Caowu	Radix Aconiti Kusnezoffii				Kusnezoff Monkshood Rc		Dried root tuber
13	Aconitum kusnezoffii	Ranunculaceae	Caowuye	Folium Aconiti Kusnezoffii				Kusnezoff Monkshood Le		Dried leaf
14	Acorus calamus	Araceae	Zangchangpu	Rhizoma Acori Calami				Tibet Sweetflag Rhizome		Dried rhizome
15	Acorus tatarinowii	Araceae	Shichangpu	Rhizoma Acori Tatarinowii				Grassleaf Sweetflag Rhiz		Dried rhizome
16	Adenophora tetraphylla	Campanulacea	Nanshashen	Radix Adenophorae*				Fourleaf Ladybell Root		Dried root
17	Adenophora stricta	Campanulacea	Nanshashen	Radix Adenophorae*				Fourleaf Ladybell Root		Dried root
18	Aesculus chinensis	Hippocastanac	Suoluozi	Semen Aesculi*				Buckeye Seed		Dried ripe seed
19	Aesculus chinensis var. chekia	Hippocastanac	Suoluozi	Semen Aesculi*				Buckeye Seed		Dried ripe seed
20	Agrimonia pilosa	Rosaceae	Xianhecao	Herba Agrimoniae				Hairyvein Agrimonia Her		Dried aerial part
21	Ailanthus altissima	Simaroubacea	Chunpi	Cortex Ailanthi				Tree-of-heaven Bark		Dried root bark or stem bark
22	Akebia quinata	Lardizabalacea	Yuzhizi	Fructus Akebiae*				Akebia Fruit		Dried nearly ripe fruit
23	Akebia trifoliata	Lardizabalacea	Yuzhizi	Fructus Akebiae*				Akebia Fruit		Dried nearly ripe fruit
24	Akebia trifoliata var. australis	Lardizabalacea	Yuzhizi	Fructus Akebiae*				Akebia Fruit		Dried nearly ripe fruit
25	Albizia julibrissin	Fabaceae	Hehuanhua	Flos Albiziae				Albizia Flower		Dried inflorescence
26	Albizia julibrissin	Fabaceae	Hehuanpi	Cortex Albiziae				Silktree Albizia Bark		Dried stem bark

Table TCM

Nom du champ	Type de données	Description
N°	NuméroAuto	
Officiel phonem	Texte	
Included Plants	Numérique	
Mode of preparation	Texte	
Mode of administration	Texte	

TCM

N°: 2

Officiel phonem: test

Included Plants: Aconitum kusnezoffii; Aesculus chinensis var. chekiangensis; Setaria italica; Sinocalamus beecheyanus

Mode of preparation:

Mode of administration:

N°	Officiel pho	Included Plants	Mode of preparation	Mode of administration
2	test	Aconitum kusnezoffii; Aesculus chinensis var. chekiangensis; Setaria italica; Sinocalamus beecheyanus var. pubescens		
* (Nouv.)				

Table Benefit Animal Study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese (C) or Japanese (J) phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Animal species	Texte	
Target organ(s)	Texte	
Administration	Texte	per os, i.p., i.v., percutaneous,...
Investigated pathology/model	Texte	
Inclusion criteria	Texte	
Number of animals	Texte	
End-point(s) of the study	Texte	
Quality of data	Texte	From (A) for "high quality"" to (E) "not assessable" with possible intermediate grading
Comments	Mémo	

Benefit : Animal study

N°: (Nouv.)

TCM:

Plant:

Bibliographic Reference of the paper:

Phonem as given in paper:

Eventual additional preparation/extraction:

Certainty of botanical identification:

Animal species:

Target organ(s):

Administration:

Investigated pathology/model:

Abrus cantoniensis	Jigucao	Dried herb
Abutilon theophrastii	Qingmazi	Dried ripe seed
Acacia catechu	Ercha	Dried concentra
Acanthopanax gracilistylus	Wujiapi	Dried root bark
Acanthopanax senticosus	Ciwujia	Dried root and r
Achyrantes bidentata	Niuxi	Dried root
Aconitum carmichaeli	Chuanwu	Dried parent ro
Aconitum kusnezoffii	Caowuye	Dried leaf
Aconitum kusnezoffii	Caowu	Dried root tube
Acorus calamus	Zangchangpu	Dried rhizome
Acorus tatarinowii	Shichangpu	Dried rhizome
Adenophora stricta	Nanshashen	Dried root
Adenophora tetraphylla	Nanshashen	Dried root
Aesculus chinensis	Suoluozi	Dried ripe seed
Aesculus chinensis var. chek	Suoluozi	Dried ripe seed
Agrimonia pilosa	Xianhecao	Dried aerial par

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Table Benefit Clinical Study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Target organ(s)	Texte	
Administration	Texte	per os, i.p., i.v., percutaneous,...
Investigated pathology/model	Texte	
Inclusion criteria	Texte	
Number of patients	Texte	
End-point(s) of the study	Texte	
Quality of clinical data	Texte	From (A) for "double-blind vs placebo" to (E) "unspecified" with possible intermediate grading
Comments	Mémo	

Table Benefit Epidemiological Study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Type of study	Texte	Prospective, retrospective, transversal
Target organ(s)	Texte	
Investigated pathology/model	Texte	
Inclusion criteria	Texte	
Number of patients	Texte	
End-point(s) of the study	Texte	
Quality of data	Texte	From (A) for "High quality" to (E) "Unassessable" with possible intermediate grading
Comments	Mémo	

Table Benefit in vitro Study

Benefit : in vitro study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese (C) or Japanese (J) phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Cell line	Texte	
Investigated model	Texte	
Measured parameter(s)	Texte	
Results	Texte	
Quality of data	Texte	From (A) for "high quality" to (E) "not assessable" with possible intermediate grading
Comments	Mémo	

Table Risk Adverse effects in Clinical study

Risk : Adverse effects in Clinical studies

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Target organ(s)	Texte	
Administration	Texte	per os, i.p., i.v., percutaneous,...
Investigated pathology/model	Texte	
Inclusion criteria	Texte	
Number of patients	Texte	
Acute toxicity : measured para	Texte	
Acute toxicity : results	Texte	
Chronic toxicity : measured pa	Texte	
Chronic toxicity : results	Texte	
Quality of clinical data	Texte	From (A) for "double-blind vs placebo" to (E) "unspecified" with possible intermediate grading
Comments	Mémo	

Table Risk Animal Study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese (C) or Japanese (J) phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Animal species	Texte	
Target organ(s)	Texte	
Administration	Texte	per os, i.p., i.v., percutaneous,...
Inclusion criteria	Texte	
Number of animals	Texte	
Acute toxicity : measured para	Texte	
Acute toxicity : results	Texte	
Chronic toxicity : measured pa	Texte	
Chronic toxicity : results	Texte	
Quality of data	Texte	From (A) for "high quality"" to (E) "not assessable" with possible intermediate grading
Comments	Mémo	

Table Risk Epidemiological / Pharmacovigilance study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Type of study	Texte	Prospective, retrospective, transversal, pharmacovigilance
Target organ(s)	Texte	
Investigated pathology/model	Texte	
Inclusion criteria	Texte	
Number of patients	Texte	
Acute toxicity : measured para	Texte	
Acute toxicity : results	Texte	
Chronic toxicity : measured pa	Texte	
Chronic toxicity : results	Texte	
Quality of data	Texte	From (A) for "High quality" to (E) "Unassessable" with possible intermediate grading
Comments	Mémo	

Table Risk in vitro Study

Nom du champ	Type de données	Description
N°	NuméroAuto	
TCM	Numérique	If study of a TCM
Plant	Numérique	If study of a single plant
Bibliographic Reference of the	Numérique	
Phonem as given in paper	Texte	Chinese (C) or Japanese (J) phonem described by the paper's author
Eventual additional preparatio	Texte	
Certainty of botanical identific	Texte	From (A) for "studies in which botanical specimens are collected and authenticated" to (C) "commercial samples" to (E) "unspecified source" with possible intermediate grading
Cell line	Texte	
Investigated model/toxicity	Texte	
Measured parameter(s)	Texte	
Results	Texte	
Quality of data	Texte	From (A) for "high quality" to (E) "not assessable" with possible intermediate grading
Comments	Mémo	