Global Drug Facility Packaging Guidelines

Packing, identification and markings of anti-TB medicines and kits

Stop TB Partnership
GLOBAL DRUG FACILITY

1 Introduction

These guidelines have been drawn-up for the purpose of clarifying a corporate identity for Global Drug Facility (GDF) packaging. The purpose of this document is to provide a consistent identification for all the products managed by the programme of the GDF. It is important to follow these guidelines for overall uniformity and for ease of management through the standardization of the product catalogue.

Note:
The packaging texts are provided for information purposes only and are not legally binding.

2 The key elements

The logo and its red line

The logo of the GDF is inseparable from its red line.
No modification of proportions can be made.
No modification of design and the associated legal text can be made.
The red line has no horizontal limit. It only follows the alignment designed by the organization of the zones.
See page 5 to discover how to position the logo and the line in the layout.

The organization of the information by zones

See page 5 to discover the guidelines for organizing the zones and the space on the main face of a packaging.

The organization of the 4 languages

Each packaging needs to be developed in 4 languages.
See the following examples to discover how to position the languages in the layout. It is the responsibility of the Manufacturer to provide the relevant information and correct translation in 4 required languages.

The name of the product

The names of all the products follow very clear rules and guidelines.
See page 5 and examples to discover how to manage the names for each face of the packaging. See page 4 for the font.

Stop TB Kit
Kanamycin

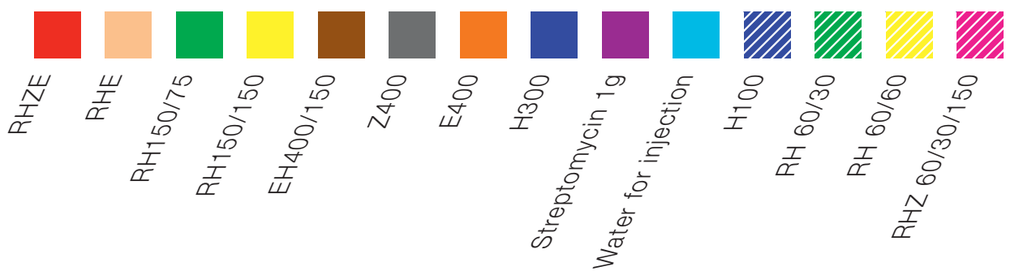
Linezolid 600 mg
Ethambutol 400 mg

The icons

To animate the layout and help to understand the information, the packaging uses a range of icons according to the dosage form.
See page 5 and examples to discover how to manage these icons for each face of the packaging.

The GDF colour code

The Global Drug Facility programme has decided to allow colours for all first line products. To keep a simple “look and feel” and not overcrowd the layout, it was decided not to capitalize (upper case) these colours.
See page 8 and examples to discover how to use the colours in the context of the kits’ packagings.



3 Typography

- The font used for all the GDF packaging is the the Helvetica family.

Helvetica Neue

Black
ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
0123456789

Bold
ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
0123456789

Roman
ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
0123456789

Light
ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
0123456789

Helvetica Cyrillic

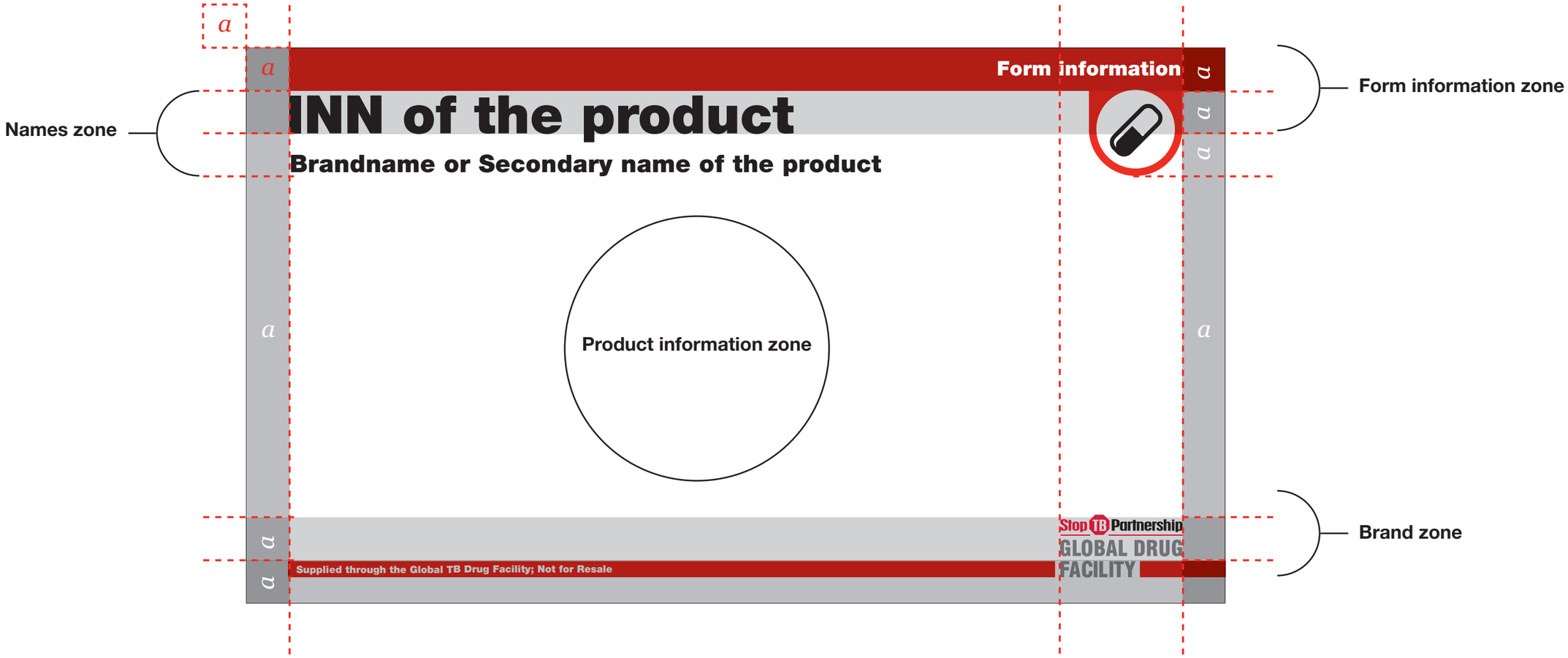
Bold
А Б В Г Д Е Ё Ж З И Й К Л М Н О П
Р С Т У Ф Х Ц Ч Ш Щ Ъ Ы Ь Э Ю Я
а б в г д е ё ж з и й к л м н о п р
с т у ф х ц ч ш щ ъ ы ь э ю я
0123456789

Plain
А Б В Г Д Е Ё Ж З И Й К Л М Н О П Р С Т
У Ф Х Ц Ч Ш Щ Ъ Ы Ь Э Ю Я
а б в г д е ё ж з и й к л м н о п р с т у ф х
ц ч ш щ ъ ы ь э ю я
0123456789

4 The organization of the information by zones

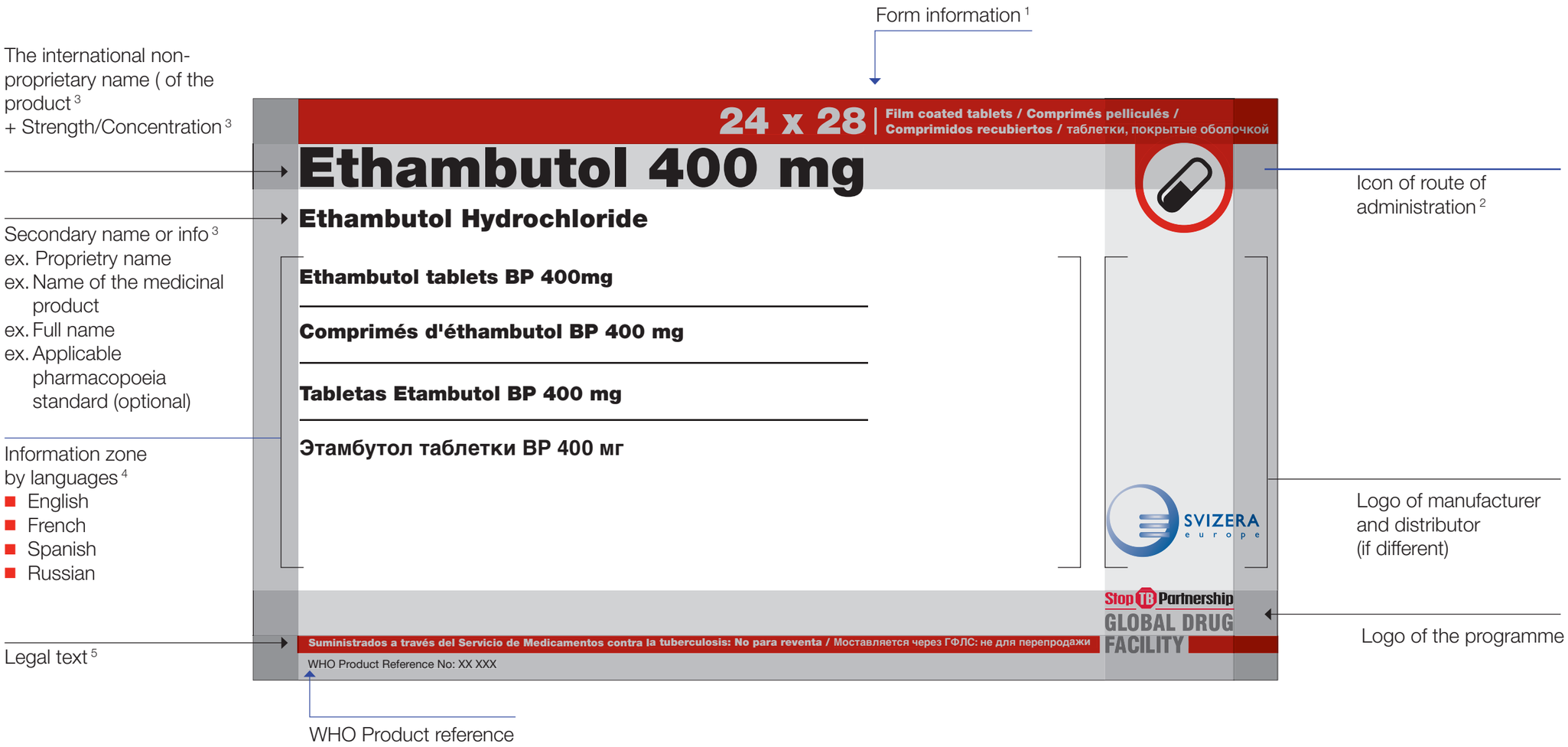
- The face of the packaging is built according to predetermined zones. The definition of a value (a) is the unit of measurement for a grid to fit the different zones and provide «breathing space».

  Each packaging has different sizes and each face has a role and contains some information. This item [a] might be to define the place to be dedicated to each element. Each element (Name, form info, product info, secondary info, manufacturing, branding, coloured band) are positioned in a zone. These zones are standardized in the layout. Define [a] with an appropriate unit of measurement relative to the size of the face or the size of the name's font, the height of the upper red band and the size of the GDF logo.



4 The organization of the information by zones

The position of the elements on a front face



1. Quantity per packaging - The dosage strength for a medicine should be expressed in an appropriate metric system unit.
2. Possibility to have 2 icons for the routes of administration (see page 10)
3. The font is standardized (see page 4)
4. According to the quantity of information, several implementations are possible (see examples)
5. This text is standardized in 4 languages and needs to be applied to the 4 faces of a box or on 1 face if the space is insufficient (see examples).

4 The organization of the information by zones

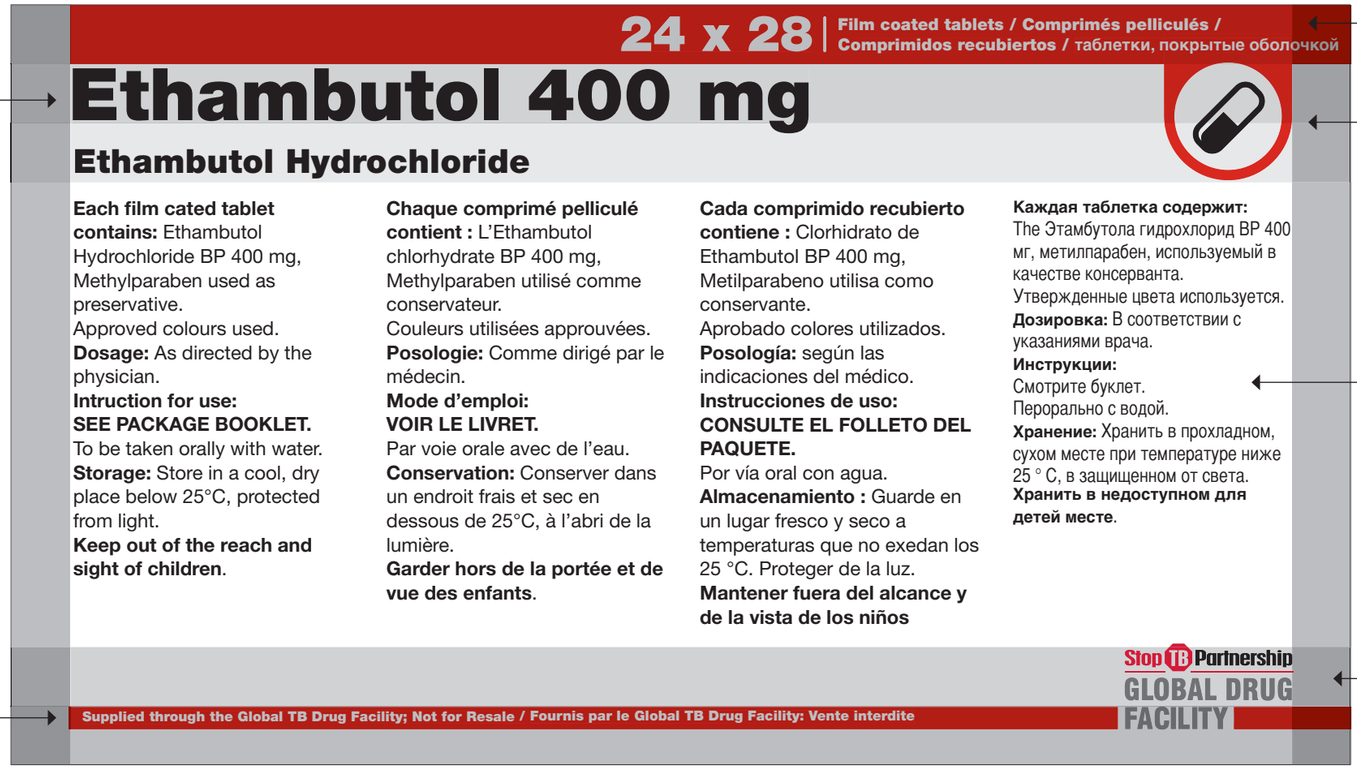
The position of the elements on a secondary face

Some elements: names, form info, icon and logo need to be positioned on each face of the packaging.
The layout needs to be adapted to the size of the face or the available space.

Duplication of the form info and the icon of dosage form

If possible in the 4 languages.

Duplication of the names



Adaptation in 4 columns of the contents in 4 languages

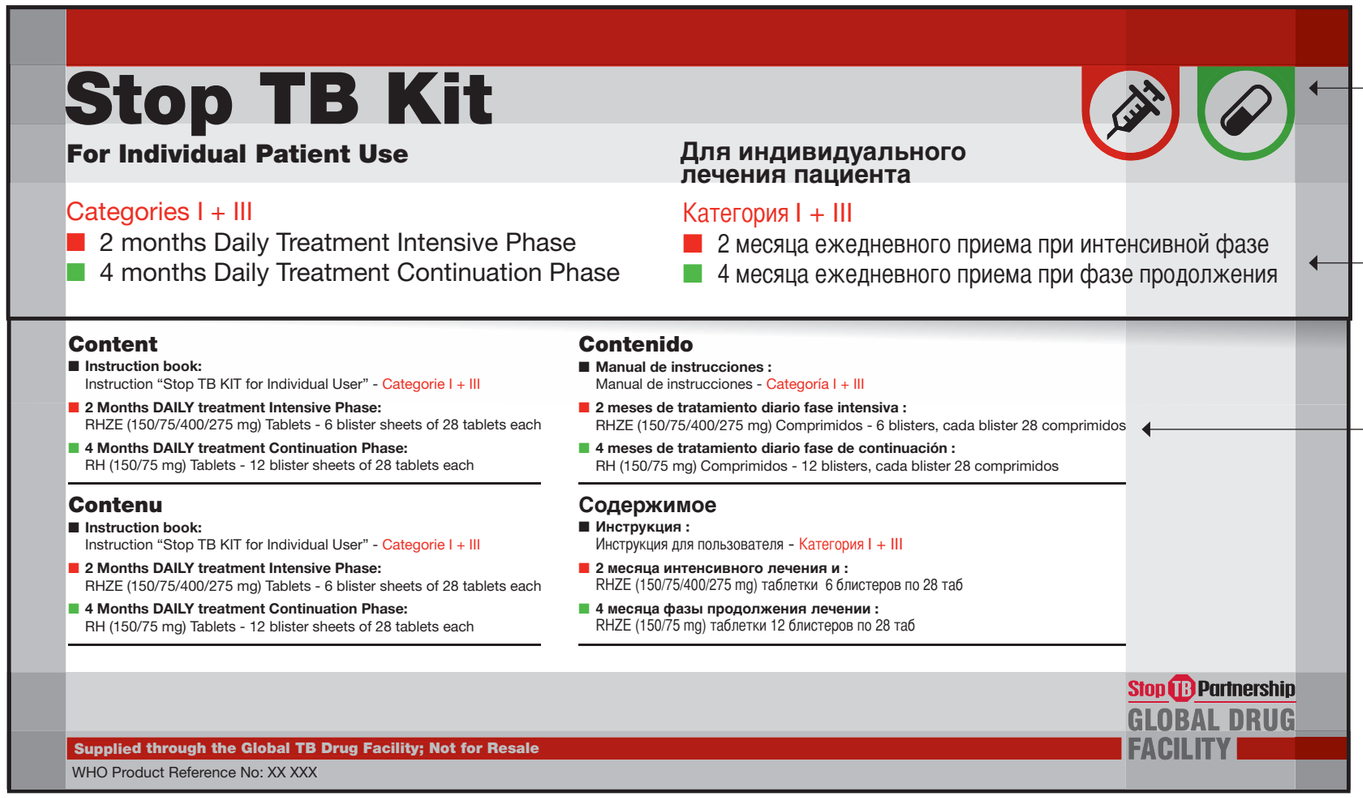
Adaptation of the legal text

Logo of the programme

4 The organization of the information by zones

The position of the elements on a Stop TB Kit enclosing 2 products

This type of big box has a cover. The information on each face should be adapted according to the 4 languages.
Each face of the box needs to present specific translated information. The layout needs to be adapted to the available space (see examples).



2 icons are required according to the appropriate GDF colour code

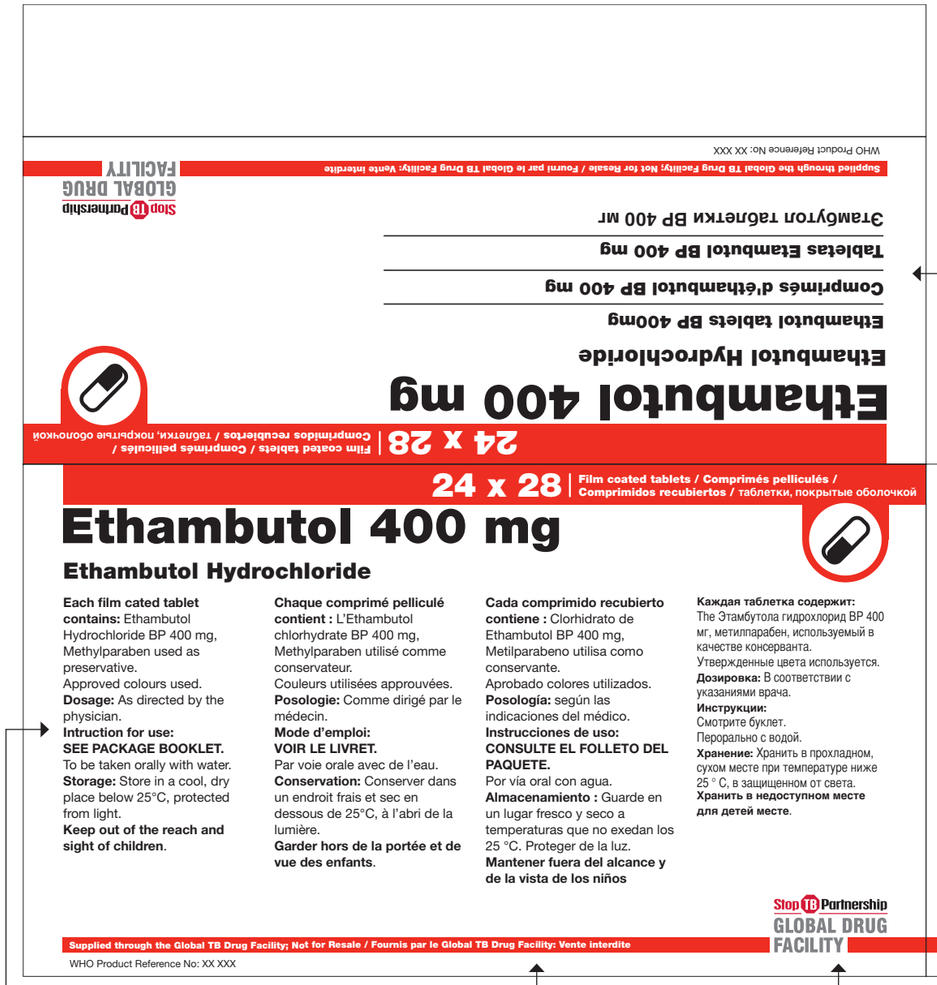
Only for kits, the GDF colour code can be used for bullets to distinguish the products' information. See the table below.

Adaptation in 2 columns/ 2 rows of the contents in 4 languages

GDF colour code

Product	Colour	Pantone	C	M	J	N
RHZE	red	185 C	0	95	100	0
RHE	peach	148 C	0	28	47	0
RH150/75	green	802 C	94	0	100	0
RH150/150	yellow	394 C	0	0	90	0
EH400/150	brown	140 C	10	63	97	40
Z400	grey	Cool Gray 9C	46	38	37	31
E400	orange	716 C	0	67	100	0
H300	blue	2736 C	90	81	0	0
Streptomycin 1g	Violet	253 C	45	97	0	0
Water for injection	Light blue	2985C	77	0	7	0
H100	diagonally striped blue & white	2736 C	90	81	0	0
RH 60/30	diagonally striped green & white	802 C	94	0	100	0
RH 60/60	diagonally striped yellow & white	394C	0	0	90	0
RHZ 60/30/150	diagonally striped purple & white	Rhodamine Red C	0	95	3	0

5 Example: product anti-TB medicine



The top face like the main face (if different) must to repeat the main information and branding elements.

One face is reserved for the Manufacturer and distribution information.

Reserved zone for batch number and date of product manufacturing and expiry. This zone must not be vernished.

Logo and information about the manufacturer and distributor (if different)

Complementary information zone by languages
- English
- French
- Spanish
- Russian

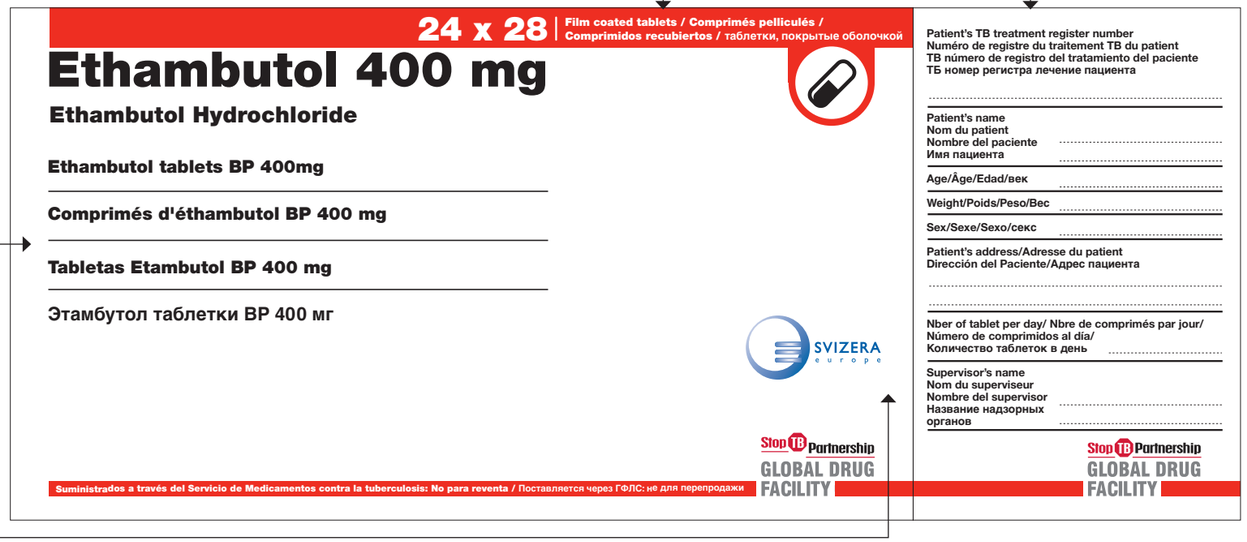
(per column or rows according to the content).

Translation of the Legal text on 2 faces.

The place and the organization of the logo block must follow the guidelines defined on page 5.

The main information in the 4 languages must to be present on the main face.

Logo of the manufacturer and distributor (if different)



Form information in the main language: English

It is recommended to reserve one face for the patient's card.

- All boxes contain the same elements helpful for the information of the users. According to the size of these boxes and the space available, the layout needs to be adapted without modifying the guidelines defined on page 5.

Each face of a box can be used to deliver specific information: Manufacturing, Patient's card, details of the dosage and administration instructions and the special warnings.

The front face of the box must to contain the main information in the 4 languages.

The main information must to be put int he same field of vision on a least three non-opposite faces: names, form info – in the 4 languages – and the icon.

All the texts need to be oriented in the same direction to help the user to discover the different contents present on each package faces.

5 Example: Stop TB kits

Stop TB Kit

Pour patient individuel

Catégories I + III
- 2 mois de traitement quotidien en phase intensive
- 4 mois de traitement quotidien en phase de prolongation

Patient's TB treatment register number
Numéro de registre du traitement TB du patient
TB número de registro del tratamiento del paciente
ТБ НОМЕР РЕГИСТРА ЛЕЧЕНИЕ ПАЦИЕНТА

Patient's name
Nom du patient
Nombre del paciente
ИМЯ ПАЦИЕНТА

Supervisor's name
Nom du superviseur
Nombre del supervisor
НАЗВАНИЕ НАДЗОРНЫХ ОРГАНОВ

Patient's address
Adresse du patient
Dirección del Paciente
АДРЕС ПАЦИЕНТА

Age/Âge/Edad/ВОЗРАСТ

Sex/Sexe/Sexo/СЕКС

Stop TB Partnership GLOBAL DRUG FACILITY

Поставляется через ГФЛС: не для перепродажи

Stop TB Kit

For Individual Patient Use

Для индивидуального лечения пациента

Categories I + III
- 2 months Daily Treatment Intensive Phase
- 4 months Daily Treatment Continuation Phase

Категория I + III
- 2 месяца ежедневного приема при интенсивной фазе
- 4 месяца ежедневного приема при фазе продолжения

Content
- **Instruction book:** Instruction "Stop TB KIT for Individual User" - Categorie I + III
- **2 Months DAILY treatment Intensive Phase:** RHZE (150/75/400/275 mg) Tablets - 6 blister sheets of 28 tablets each
- **4 Months DAILY treatment Continuation Phase:** RH (150/75 mg) Tablets - 12 blister sheets of 28 tablets each

Contenu
- **Instruction book:** Instruction "Stop TB KIT for Individual User" - Categorie I + III
- **2 Months DAILY treatment Intensive Phase:** RHZE (150/75/400/275 mg) Tablets - 6 blister sheets of 28 tablets each
- **4 Months DAILY treatment Continuation Phase:** RH (150/75 mg) Tablets - 12 blister sheets of 28 tablets each

Contenido
- **Manual de instrucciones :** Manual de instrucciones - Categoría I + III
- **2 meses de tratamiento diario fase intensiva :** RHZE (150/75/400/275 mg) Comprimidos - 6 blisters, cada blister 28 comprimidos
- **4 meses de tratamiento diario fase de continuación :** RH (150/75 mg) Comprimidos - 12 blisters, cada blister 28 comprimidos

Содержимое
- **Инструкция :** Инструкция для пользователя - Категория I + III
- **2 месяца интенсивного лечения и :** RHZE (150/75/400/275 mg) таблетки 6 блистеров по 28 таб
- **4 месяца фазы продолжения лечении :** RHZE (150/75 mg) таблетки 12 блистеров по 28 таб

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Supplied through the Global TB Drug Facility; Not for Resale

WHO Product Reference No: XX XXX

- The Stop TB kits sometimes contain 2 treatments with 2 routes of administration. 2 icons are required with the appropriate GDF colour code – see page 8. These icon are standardized.

Only for these kits, can the GDF colour code be used for bullets to distinguish the products' information.

The back face is reserved for the patient's control card and other complementary information.

It is recommended to reserve one face for the patient's card. This face is sometimes the only visible one when several boxes are stored in a cupboard.

Stop TB Kit

Para uso individual del paciente

Categorías I + III
- 2 meses de tratamiento diario fase intensiva
- 4 meses de tratamiento diario fase de continuación

Mfg. Ltc. No. 489

Logo Manufacturer

Name
Address
of the Manufacturer

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Fourni par le Global TB Drug Facility: Vente interdite

Do not worry about blank space. These zones can be used by the health workers or to write-in special information.

One face is reserved for the Manufacturer and distribution information.

Stop TB Kit - Control Card / Carte de contrôle / Tarjeta de Control / ПЛАТА УПРАВЛЕНИЯ

Patient's name / Nom du patient / Nombre del paciente / ИМЯ ПАЦИЕНТА

Patient's weight / Poids du patient / Peso del paciente / ВЕС ПАЦИЕНТА

- **Please note:** This card does not replace the patient treatment card in use in your program, but can be used to monitor the drug consumption from the kit. From the enclosed insert determine how many tablets you should give the patient for each dose based on patient's weight. Record patient's weight above and number of tablets in the tables.
- **À noter:** Cette carte ne remplace pas la carte de traitement du patient utilisée dans votre programme, mais peut être utilisé pour surveiller la consommation de drogue dans le kit. Le tableau ci-joint détermine combien de comprimés vous devez donner au patient pour chaque dose en fonction du poids du patient. Noter le poids du patient ci-dessus et le nombre de comprimés dans les tables.
- **Nota:** Esta tarjeta no reemplaza la tarjeta de tratamiento de los pacientes en uso en su programa, pero se puede utilizar para controlar el consumo del medicamento en el kit. De la nota incluida se puede determinar la cantidad de tabletas que debe dar al paciente para cada dosis según el peso del paciente. Anotar cada vez el peso del paciente y el número de tabletas en la tabla.
- **ПОЖАЛУЙСТА, ОБРАТИТЕ ВНИМАНИЕ:** эта карта не заменяет амбулаторную карту лечения используемая вашей программой, но она может быть использована для мониторинга потребления лекарств из комплекта. По вложенному вкладышу можно определить, сколько таблеток нужно давать больному для каждой дозы в зависимости от веса пациента. Занесите вес и количество таблеток для одной дозы в таблице выше.

- **Tick (✓) the appropriate box after the drugs have been administred beginning with dose 1 on the 1st day of treatment.**
- **Cochez (✓) la case appropriée après que le traitement soit administré en commençant avec la dose 1 au premier jour de traitement.**
- **Marque (✓) la casilla apropiada después de que los medicamentos se han administrado comenzando con dosis 1 en el primer día de tratamiento.**
- **Отметьте (✓) соответствующее поле после приема лекарств, начиная с 1 дозы на 1-й день лечения.**

■ Intensive phase (RHZE - 56 doses - red colour)
Phase intensive (RHZE - 56 doses - couleur rouge)
Fase intensiva (RHZE - 56 dosis - de color rojo)
Интенсивная фаза (RHZE - 56 доз - красный цвет)

Number of tablets to give to patient for each dose _ _ _ _ _ _ _ _ _ _
Nombre de comprimés à donner au patient pour chaque dose
Número de comprimidos para dar al paciente para cada dosis
Количество таблеток, чтобы дать пациенту для каждой дозы

Starting date / Date de début / Fecha de inicio / дата начала
_ _ / _ _ / _ _

Dose / Dose / Dosis / ДОЗА

1		2		3		4		5		6		7	
8		9		10		11		12		13		14	
15		16		17		18		19		20		21	
22		23		24		25		26		27		28	
29		30		31		32		33		34		35	
36		37		38		39		40		41		42	
43		44		45		46		47		48		49	
50		51		52		53		54		55		56	

Completion date / Date de fin /
Fecha de finalización /
срок сдачи в эксплуатацию
_ _ / _ _ / _ _

■ Continuation phase (RH - 112 doses - Green colour)
Phase de continuation (RH - 112 doses - couleur verte)
Fase de continuación (RH - 112 dosis - de color Verde)
Фаза продолжения (RH - 112 доз - зеленый цвет)

Number of tablets to give to patient for each dose _ _ _ _ _ _ _ _ _ _
Nombre de comprimés à donner au patient pour chaque dose
Número de comprimidos para dar al paciente para cada dosis
Количество таблеток, чтобы дать пациенту для каждой дозы

Starting date / Date de début / Fecha de inicio / дата начала
_ _ / _ _ / _ _

Dose / Dose / Dosis / ДОЗА

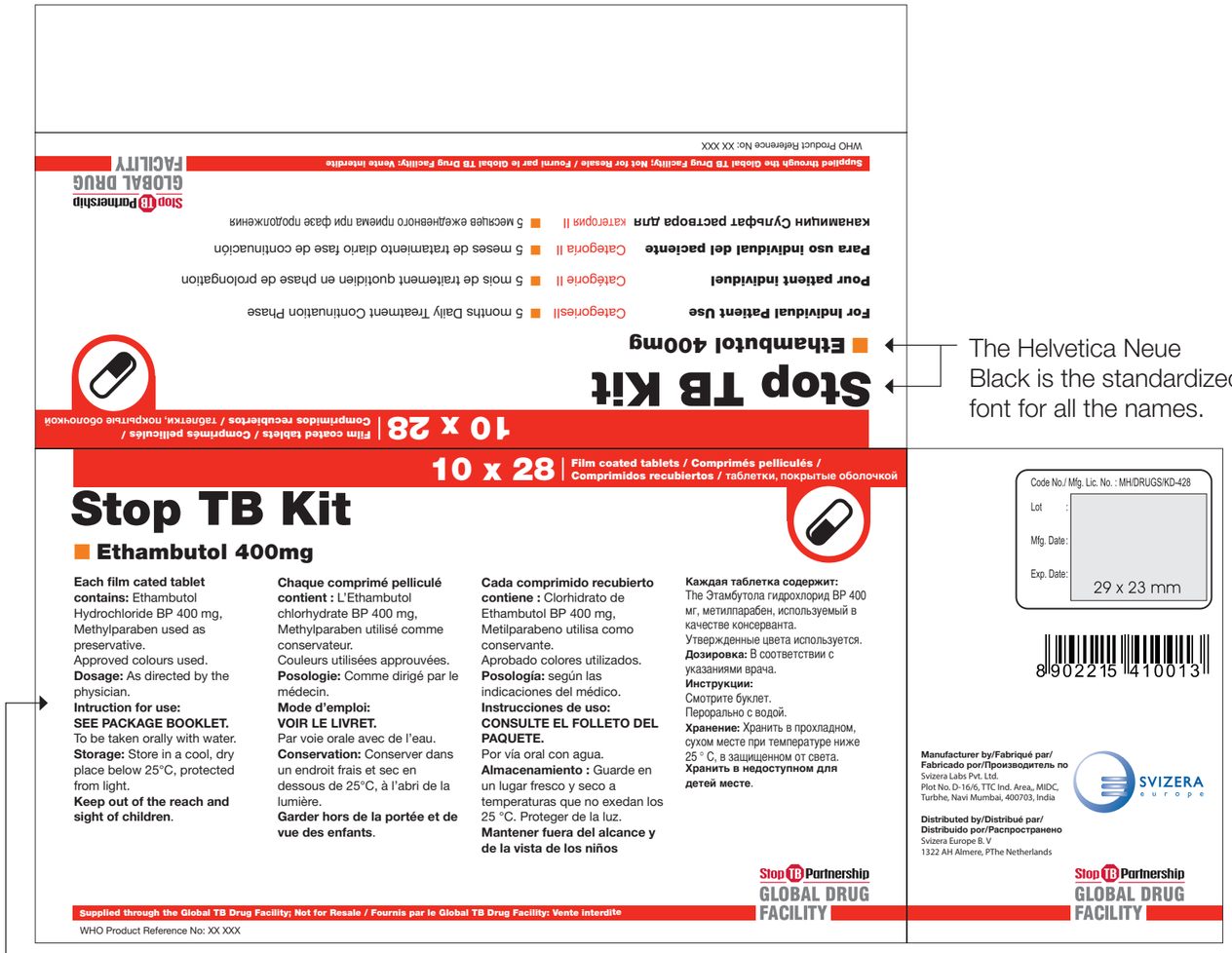
1		2		3		4		5		6		7	
8		9		10		11		12		13		14	
15		16		17		18		19		20		21	
22		23		24		25		26		27		28	
29		30		31		32		33		34		35	
36		37		38		39		40		41		42	
43		44		45		46		47		48		49	
50		51		52		53		54		55		56	
57		58		59		60		61		62		63	
64		65		66		67		68		69		70	
71		72		73		74		75		76		77	
78		79		80		81		82		83		84	
85		86		87		88		89		90		91	
92		93		94		95		96		97		98	
99		100		101		102		103		104		105	
106		107		108		109		110		11		112	

Completion date / Date de fin /
Fecha de finalización /
срок сдачи в эксплуатацию
_ _ / _ _ / _ _

Stop TB Partnership GLOBAL DRUG FACILITY

Suministrados a través del Servicio de Medicamentos contra la tuberculosis: No para reventa.

5 Example: product used for kits



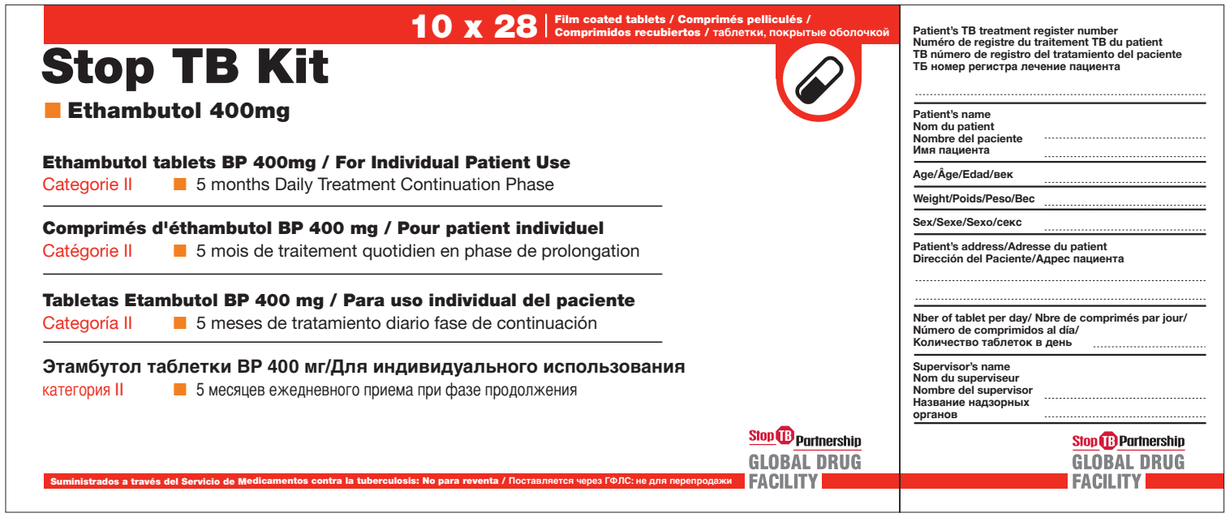
The Helvetica Neue Black is the standardized font for all the names.

- This kind of kit follows the same guidelines as for other packaging. Only the order of the names is different.

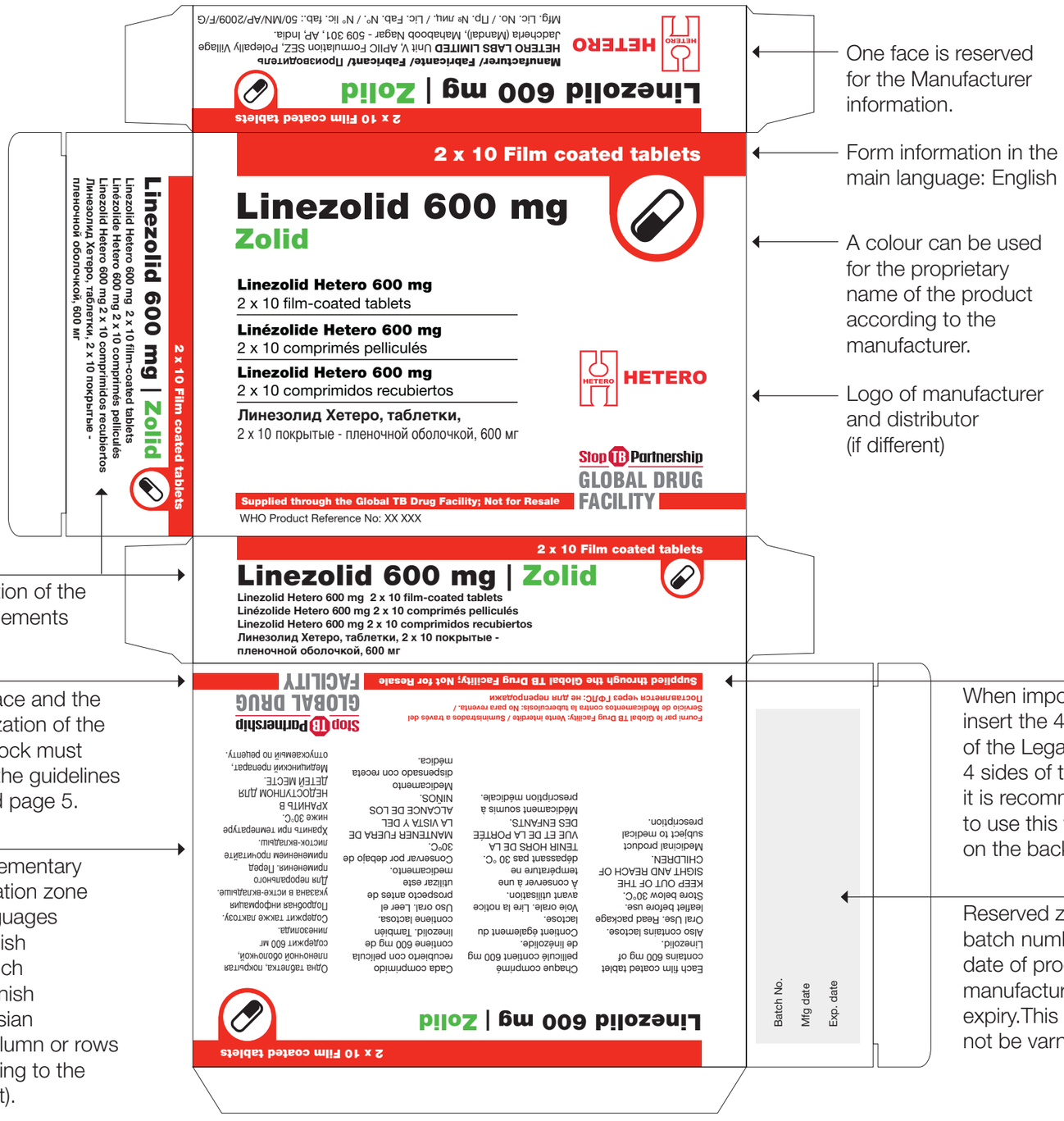
  To better distinguish this is a kit, this information is larger than the name of the product; but is highlighted by the addition of a coloured bullet in line with the GDF colour code – see page 8.

Complementary information:

- Statement of the active substance
- List of excipients known to be a safety concern for some patients
- Medical product subject to medical prescription
- Cautionary statement (Children) and any other additional cautionary statement
- Storing conditions and special instructions for storage if applicable
- Special warnings



5 Example: small packaging



One face is reserved for the Manufacturer information.

Form information in the main language: English

A colour can be used for the proprietary name of the product according to the manufacturer.

Logo of manufacturer and distributor (if different)

Repetition of the main elements

The place and the organization of the logo block must follow the guidelines defined page 5.

Complementary information zone by languages
- English
- French
- Spanish
- Russian

(per column or rows according to the content).

When impossible to insert the 4 languages of the Legal text on 4 sides of the box, it is recommended to use this version on the back face.

Reserved zone for batch number and date of product manufacturing and expiry.This zone must not be varnished.

- Some boxes contain a small quantity of medicine. The layout and the place of various elements must be adapted but always following the guidelines defined on page 5.

  The front face of the box must contain the main information in the 4 languages.

  It is also important to repeat on 5 faces of the packaging the following: names, form info – in the 4 languages – and the icon.

5 Example: Kanamycin primary packing

6 Contact information

This document was designed by **Stop TB Partnership - Global Drug Facility**
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