Braille on folding cartons

1 Preface

In 1825, Frenchman Louis Braille (1809-1852) invented a reading system for the blind through which the alphabet, numbers, and punctuation marks were represented in a tangible form via a series of raised dots. The Braille system established itself internationally, and is now in use in all languages. While A to Z is standardised, there are, of course, special characters, which are unique to local languages.

The requirement for Braille on pharmaceutical packaging stems from the European Directive 2004/27/EC – amending Directive 2001/83/EC (community code to medicinal products for human use). This Directive includes changes to the label and package leaflet requirements for pharmaceuticals, (which will not be discussed in this booklet), and it requires pharmaceutical cartons to show the name of the medicinal products, and if need be the strength, in Braille format. The Directive has to be transposed into national law by all Member States in the European Union by October 30, 2005. For concrete information on implementation, (e.g. transition arrangements), the national drug law of the respective EU member state should be consulted.

This code of practice for the standardised fabrication of Braille on folding cartons contains established rules which form an easily-comprehensible standard for the technical implementation of Braille on folding cartons, as well as offering guidelines for a sequence of steps from the creation of the artwork files to the delivery of the folding cartons to ensure the integrity and security of the Braille content. However, it is understood that deviations from this standard and guidelines may be valid and necessary in some cases – either for technical or organisational reasons - to meet the requirements of specific customer/folding carton manufacturer agreements.

Also included in this booklet is a reference list containing the Braille letters, numbers and internationally standardised special characters, as well as the relevant special Braille characters for six of the main languages in the EU, to be supplemented at a later stage in written form and/or via the ECMA website www.ECMA.org.

References

This document is published by the European Carton Manufacturers Association, ECMA, in co-operation with other industrial organisations and interested parties. Founded in 1960, ECMA today has become the established forum and umbrella organisation for the European folding carton industry, representing over 500 manufacturers in nearly all countries in the European Economic Area, and a current workforce of about 50,000 people. ECMA works to fulfil its mission for the benefit of member companies in a variety of functions, including the development and promotion of business tools and industry standards.

ECMA wishes to acknowledge its affiliated national folding carton associations (listed on the back of this publication), and especially FFI (Germany) and Aspack (Spain) for their documentation, manpower and expertise dedicated to this ECMA Standard.
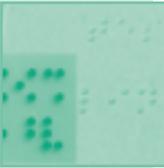
The Hague, September 2005

2 Basic grid and Braille characters

The basic grid of a Braille character consists of six dots, positioned like the figure "six" on a die, in two parallel vertical lines of three dots each. They are numbered as follows:

Top left dot 1	1 ● ● 4
Dots below 2 and 3	2 ● ● 5
Top right dot 4	3 ● ● 6
Dots below 5 and 6	

From the six dots that make up the basic grid, 64 different signs can be created.

Reading direction of Braille is the same as for regular type, and the rules for hyphenation that apply to regular typefaces also apply in Braille.

The European Commission's guidance on Braille requirements for labelling and packaging[1], and the European Blind Union's guidelines for European pharmaceutical companies and distributors/marketing agencies[2] both recommend that an un-contracted Braille system should be used. In un-contracted Braille, every individual letter of the alphabet, punctuation mark etc. is represented by its own Braille character(s).

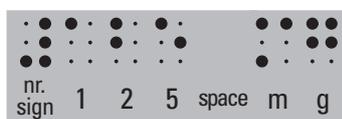## Letters - internationally standardised

a	b	c	d	e	f	g	h	i	j	k	l	m

n	o	p	q	r	s	t	u	v	w	x	y	z
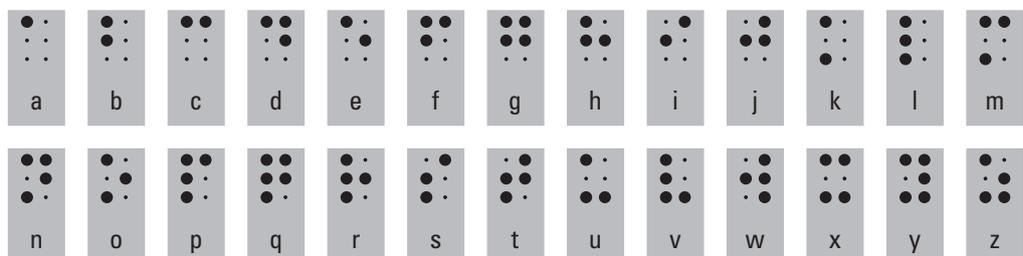
NB: There is no capitalisation in Braille text on folding cartons.

Numbers - internationally standardised

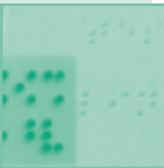	Number sign	1	2	3	4	5	6	7	8	9	0
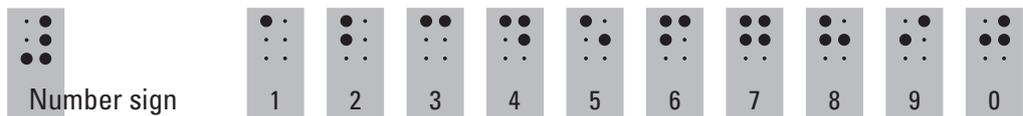
NB: When indicating numbers the number sign is followed by the letters A to J. The number is always terminated with a space. See example:

nr. sign	1	2	5	space	m	g

[1] See also www.tiresias.org/reports/braille_labelling_medicines.htm
[2] See also www.euroblind.org/fichiersGB/pharma.htm

Punctuation marks

Literary ,	;	:	!	Thousands Seperator	Decimal point	Full Stop

NB: in ink print, thousands separators and decimal points may be either "." or ","
depending on the country, but in Braille they are usually as shown above.

Examples of nationally different special characters used in six EU languages

English

/	%	‰

German

ä	ö	ü	ß	/	%	‰

French

à	â	ç	é	è	ê	ë	î	ï	ô	œ

û	ü	/	%	‰

Spanish

á	æ	é	ë	í	ñ	ó	ú	ü	/	%	‰

Italian

à	â	ç	é	è	ê	ë	ì	î	ï	ò

ô	ö	ù	û	ü	/	%	‰

Dutch

à	ä	ç	é	è	ê	ë	ï	ô

ö	û	y	'	-	/	%	‰

NOTE: While every care has been taken to check the accuracy of the symbols used in each
language, because there is no single European Braille authority, ECMA can not guarantee the
accuracy of this document. Additionally there have been recent changes to British and Dutch
Braille, and we are advised that there may also be changes in other languages in the near future.

3 Standardisation

To establish a common standard across the countries of the European Union, the European Carton Makers Association has specified "ECMA Euro Braille", which takes account of the major Braille fonts currently in use throughout Europe.

– The diameter at the base of the dot is 1.6 mm, this is also the diameter on the female matrix and the diameter of dots shown in the artwork file.
– The dot spacing is exactly 2.5 mm (from dot centre to dot centre).
– The character spacing amounts to 6.0 mm (from centre to centre).
– The line spacing is 10.0 mm with a tolerance of +0.0 mm/-0.1 mm.
– With regard to the height of the embossing on the surface of a folding carton, it is recommended that this is determined visually, since the deformed carton board is likely to recover slightly over time. The upper tolerance level is reached when the surface of the folding carton starts to burst.
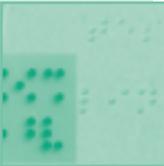
Dot matrix
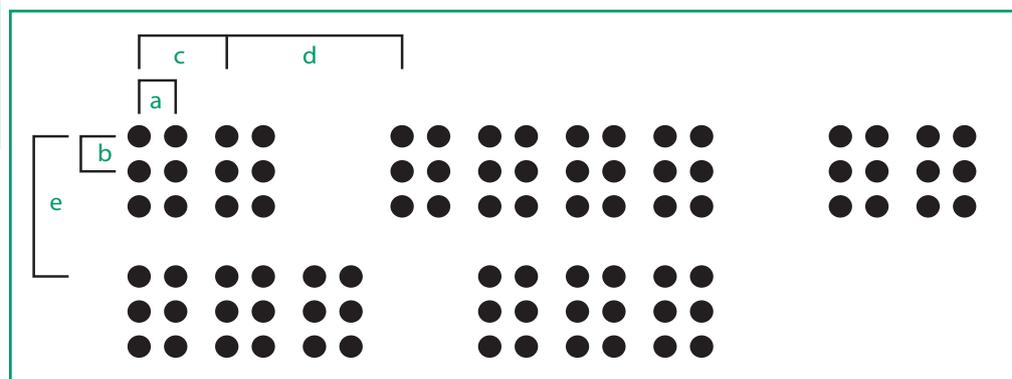
Dimensions:

a = 2.5 mm

b = 2.5 mm

c = 6.0 mm between two letters of one word

d = 12.0 mm hyphenation

e = 10.0 mm +0.0 mm /-0.1 mm line spacing

Positioning the Braille message (in alphanumeric characters)

The Braille text must also be set in regular type outside the die-line.
Reading direction and hyphenation rules for both Braille text and regular type must be the same.

4 Technical requirements

The dots of the Braille text must be clearly perceptible by human touch, but on folding cartons, the needs of both seeing and visually impaired people must both be met, though they are very different. While the visually-impaired require very strong Braille embossing to enable them to read the text, embossing can lead to breaks in the carton surface which could impair legibility and visual appearance for sighted people. The target must be to achieve a compromise so that both blind and sighted patients can easily identify their medicine.

Following the embossing process, the "perfect" dot is exposed in subsequent processes to mechanical and climatic influences, which could lead to a slight deterioration.

Material selection

In general, primary- and secondary-fibre carton board can be used. It must be remembered that with either board type it is not possible to prevent minimal variation in embossing heights on the same folding carton or in the same production batch.

5 Fabrication

These guidelines relate to the fabrication of Braille text according to the latest technical standards - i.e. cutting, creasing and embossing in one pass on a flatbed cutting and creasing machine. Braille text can generally be placed on any major surface of a folding carton (A1, B1, A2, B2); but for technical reasons it may not be possible to locate it on more than one panel of any carton.


Female part/matrix

Carton

Male part

Cutting and creasing plate
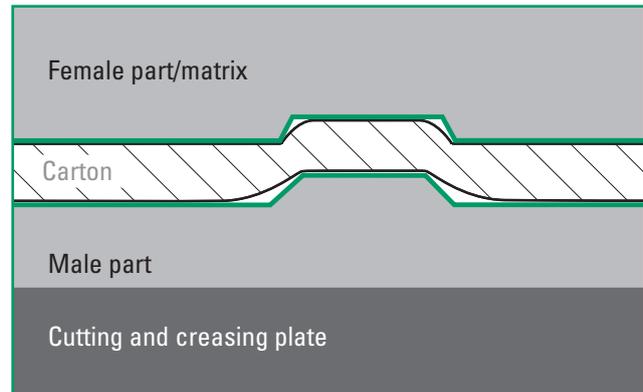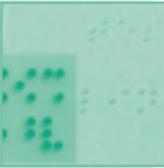
Braille embossing

The goal is to create a product-neutral cutting and creasing tool, i.e. only one 'master' cutting and creasing tool should be used for all folding cartons of the same size and profile. In order to achieve this, a universal female matrix is positioned in the biggest panel of the folding carton. The Braille text is embossed by the product-individual male embossing die. This facilitates the minimisation of adjustments to the individual carton and saves set-up time and costs. If an individual cutting and creasing tool is required for a particular pack, substantial additional costs will be incurred.
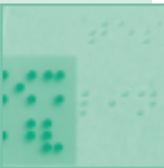
Positioning of Braille

The distance between the chosen Braille embossing location and the centre of the cutting and creasing lines must be 8 mm, (measured from the edge of the dot). The Position of the universal female matrix on the chosen panel of the carton – e.g. A1 – must be decided by the customer. Braille texts cannot be applied to locations on the carton where there are barcodes (EAN/PZN), or where labels/Bollini or perforations are applied. Maintaining these standards will ensure lowest tooling costs and set-up times.
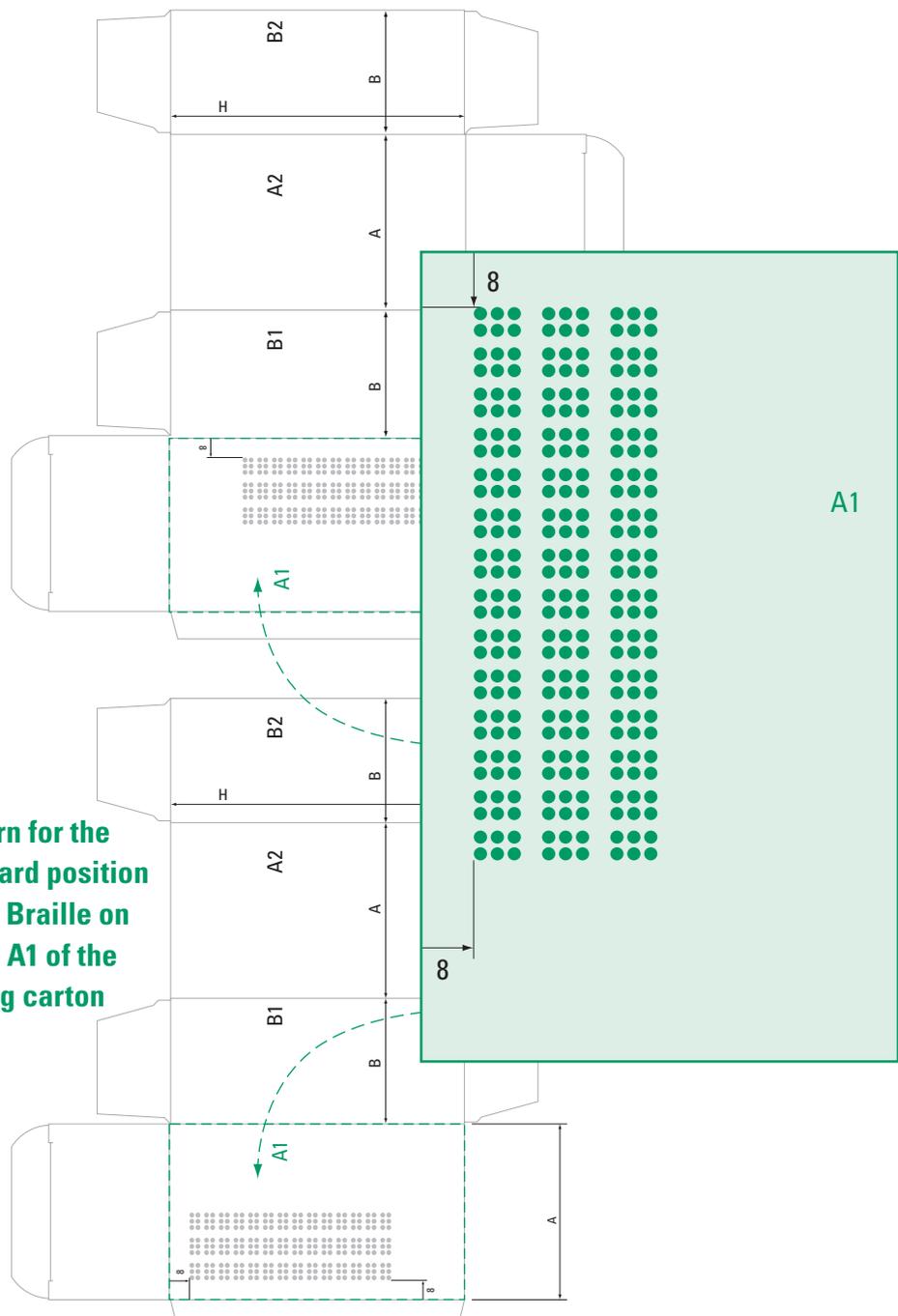
Pattern for the standard position of the Braille on Panel A1 of the folding carton

Amount of text

The number of available characters and lines for Braille text embossing are determined by the dimensions of the folding carton.

Number of Braille lines on a main side of the folding carton			
1	2	3	4
22.6	32.6	42.6	52.6
Dimension A/B (minimum) of the folding carton in mm			

Number of Braille characters per Braille line														
6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
50.1	56.1	62.1	68.1	74.1	80.1	86.1	92.1	98.1	104.1	110.1	116.1	122.1	128.1	134.1
Dimension H (minimum) of the folding carton in mm														
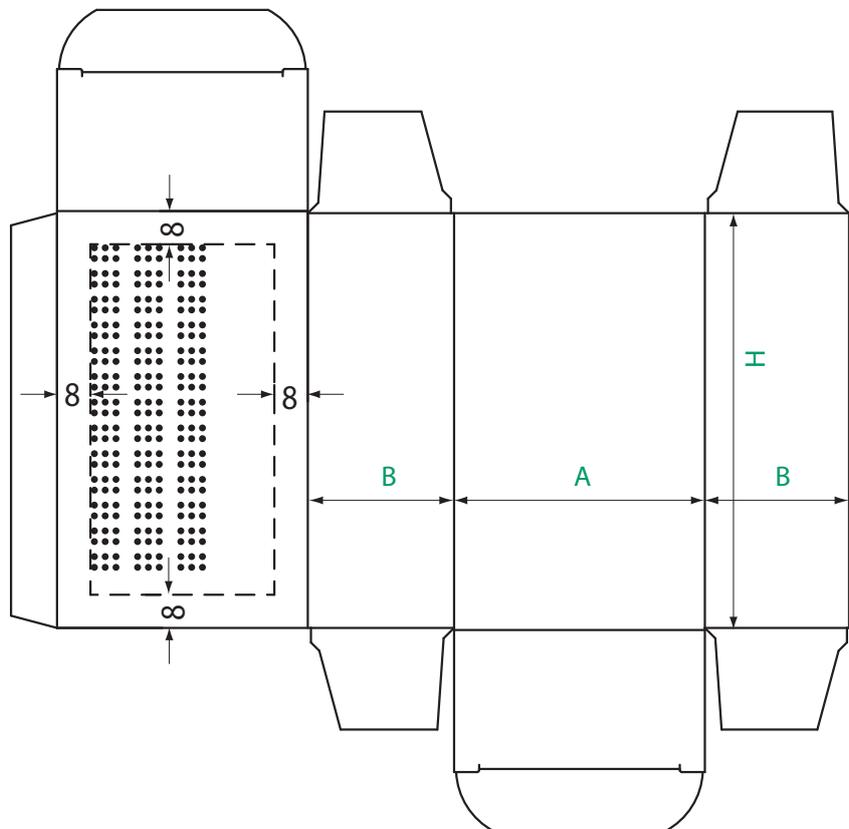
## Implementation of Braille in artwork files and print approvals
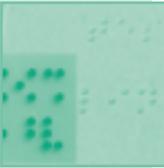
Braille text must be laid down as an additional layer in the artwork file. The colour used to represent the Braille text must not be used in any other place in the document. The Braille in the artwork file, in the print approval file, in the cutting and creasing tool, and in the finished folding carton must match exactly. The Braille message must also be reproduced in regular type outside the line of the embossing die. Braille text and dots must be clearly legible in documents supplied to the folding carton producer by the customer: Once artwork files have been supplied, the Braille dots in them are fixed and cannot be changed. The digital die-line, the embedded universal matrix and the printing files, must be approved by customer, artwork agency and folding carton producer. The universal matrix for the artwork creation has to be called-off from the folding carton producer.

In order to ensure that the Braille text can be checked at all stages of production, approved proofs for folding cartons carrying Braille must be set up as follows:

The first proof page must contain only the printed image, and should be used for approving regular print.
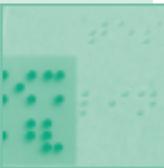
Print approval page 1
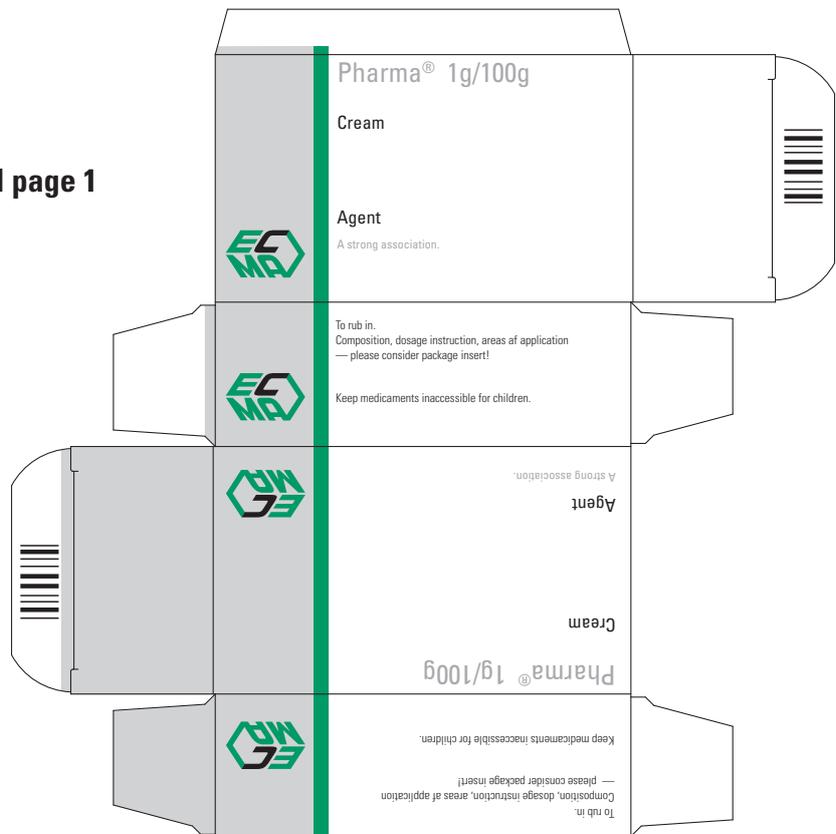
The second proof page must contain only the Braille dots together with the die-line and the Braille message in alphanumeric text, (outside the die-line).
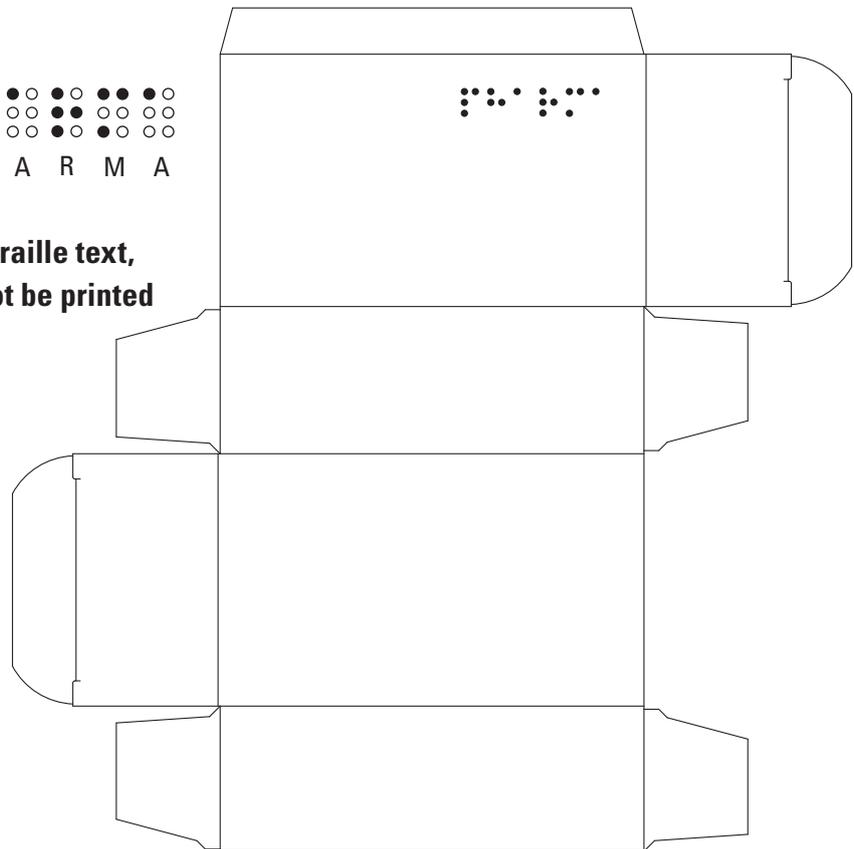
Braille approval page 2

P H A R M A

**Only Braille text,
will not be printed**

Quality assurance

– In all documents provided by the customer to the folding carton producer, the Braille content must be clearly legible.
– The artwork files as approved by the customer are the basis of the proofing process.
– All embossed Braille print must be verified continuously during production by using control films, or other agreed means.

A quality assurance agreement between customer and folding carton producer is necessary to ensure that the highest possible standards are guaranteed for the Braille reader.
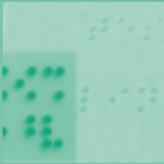
7 Conclusion

Standardisation reduces costs and brings security

Optimising the process requires the establishments of clear criteria and guidelines for:

– standardisation of fonts
– standardisation of positioning
– standardisation of folding carton formats
– agreed standards for the profile of the Braille dots
– integrated testing and control systems

When delivery schedules and cost aspects are taken into consideration, it is vitally important to have secure and efficient production processes.

Compliance with the Braille legislation and best practice can only be achieved economically and effectively by exchanging information.

Co-operation between all parties involved is crucial for success.

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National carton associations affiliated with ECMA:

Austria:	Verband der Faltschachtelindustrie (www.ppv.at)
Belgium:	ECMABEL (www.fetra.be)
Denmark :	Emballage Industrien (www.emballageindustrien.dk)
France:	Fédération Française du Cartonnage (www.federation-cartonnage.org)
Germany:	Fachverband Faltschachtel-Industrie (www.ffi.de)
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	Swisscarton (www.swisscarton.ch)
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