Results of the CMDh Survey on the PI translation

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Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	x	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	x	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	x	☐	☐	☐ optional
2. Consultancy for a company	x	☐	☐	☐ optional
3. Strategic advisory role for a company	x	☐	☐	☐ optional
4. Financial interests	x	☐	☐	☐ optional
5. Ownership of a patent	x	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	x	☐	☐	☐ optional
7. Investigator	x	☐	☐	☐ optional
8. Grant or other funding	x	☐	☐	☐ optional
9. Family members interests		x	☐	☐ optional

*Laura Galatti, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.
N.B. < I am not receiving any compensation>

Results of the CMDh Survey on the PI translation

Introduction

In Italy we have a huge workload related to the review of the PI national translations and we are trying to find ways to sort it out. Thus, the CMDh Members were kindly asked to provide with answers on the following questions:

1. Has your Agency adopted any specific ICT solutions (e.g. specific software/dual monitors to facilitate assessors work, etc) to support the assessors in the review of PI translations? If this is the case, what kind of ICT solutions are in place?
2. According to the EMA Reflection Paper, AI applications can be taken into consideration also in the review process of medicinal product information documents, provided that a close human supervision is needed. Do you have any experience?
3. Has your Agency adopted any other additional measure to streamline the translations review (e.g. requiring a certified translation in order to reduce the review burden)?
4. Has your Agency adopted any specific waivers to the PI national translation requirements (e.g. in case the product is not marketed)?

Results of the CMDh Survey on the PI translation

Results

Answers have been received from 19 Member States:
AT, BE, CZ, DE, DK, ES, FI, FR, HR, IS, IT, LV, NL, NO, PT, RO, SE, SI, SK.

Every single answer has provided a very useful contribution to have a clear picture of the situation in EU, aimed to try to simplify the workload on the check of national Product Information (PI) translation.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.1 about ICT/dual monitor:

Many MSs have no ICT solutions in place.

- In ES a dedicated group of assessors exclusively dedicated to this task on checking translations has been set up. Recently it has been set in Italy too.
- FI takes an advantage by using ‘compare’ function in word for example in cases they need to check if the texts are identical or to ease finding where the differences are in case the texts are quite similar (for example due to different indications, formulations, etc.).
- Also the NO assessors use the "compare" function in word in particular for generics.
- NL uses a software program that can measure the language level of texts to enhance patient friendly writing in the Dutch language.
- SE has an in-house developed ICT solution where they perform their assessment, communication and archiving. In this system, all co-workers can get access to all procedures and therefore the manager aid in prioritising which procedures/translations to focus on. i.e. the tasks the assessor get is prepared for both in regard of work load and time line of the procedure. Then they have practical issues such as multiple external screens and they use many of the standard office-tools in Word to facilitate the work.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.1 about ICT/dual monitor:
Except for DE, ES, IT and NO (where a large monitor is available) , the other MSs (15 MS) have dual monitor.

Answers on question 2 about any experience with AI:
16 MSs have no experience with AI (DE, IT and RO are planning/available to test its use).

- In ES AI tools have been tried, but results are not as expected for the time being.
- NO had a small project with regards to translation of EN PI to NO PI. However, this is on hold. There are several reasons, one of them is that they see and know that several MAH have already implemented their own AI translations tool. Some MAH have very good tools already. Or NCA initiative was also not quite in scope, which is to ensure that the quality is sufficient. Currently it is unclear if they will go on with this project.
- SE has no AI solution at present for the translational work, but it is working on developing technical solutions to aid in the assessment of mock up/artwork similarities. SE is also working on developing a tool that will aid in the assessment of product name. The intention is that both these solutions will be used as an aid for the manual assessment.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.3 about any other measure including certified translations:

- If the translation has very poor quality, many MSs send it back and ask the company for a new translation (AT, CZ, DE, DK, FI, IS, IT, LV, SE, SK).
- In case of huge workload to check translation, some MSs use external experts (HR, IT, RO, SI).
- Belgium does not check the entire translated PI documents. The MAH is requested to submit a signed "Declaration of conformity of translations for MRP and DCP", where it is certified that the translations into Dutch and French of the Summary of Product Characteristics (SPC), and the translations into Dutch, French and German, of the package leaflet and the labels are an accurate rendering of the original content of the approved English documents. The correct translation is thus the responsibility of the undersigned. Nevertheless, Belgium performs the review of the following in the translated PI documents: Name of the medicinal product, SPC – Section 1-3 and from Section 6 onwards + translations of the titles of other Sections, PL – headings, titles of the sections, storage conditions and Labelling – the whole document.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.3 about any other measure including certified translations:

- DE has no digital measure to streamline the translations but in BfArM a specific template is requested. The national texts are to be inserted into the “Bescheidmaske”, which is made available on the BfArM homepage. Submissions without a “Bescheidmaske” will be rejected unprocessed. For each strength, a separate “Bescheidmaske” must be submitted in which the first pages (up to the signature) are completely filled in. The „Bescheidmaske“ ensures that the national product information is available in a structured form. https://www.bfarm.de/SharedDocs/Downloads/EN/Drugs/licensing/zulassungsverfahren/mrp_dcp/Bescheidmaske_docx_EN.docx?__blob=publicationFile. Internal general agreements on how the linguistic review is to be conducted exist. In case translations are of poor quality they can be rejected.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.3 about any other measure including certified translations:

- In FI all the translations are reviewed by the assessors. Concerning clinical sections of the texts, all new MAs (all texts) of the NAS products are reviewed by their senior medical officers (clinical assessors), as well as SmPC sections 4.1-4.3 in case of extensions of indications. Other texts are reviewed by their clinical research coordinator team. Correspondingly, quality sections are reviewed by the quality team. Comments and corrections are made “within the IT system” so that all changes are made in the same document and there is no need to email the documents back and forth.

They use and rely quite much on already approved texts, ie. on originator text translations in case of generic; or in case of Swedish translations on those approved by MPA. They largely use ‘compare’ function of word.

If the quality of the texts is low, they do not revise them but request for a new, good quality translations. Minor errors, such as typos, alone are not considered worth of request for amendments.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.3 about any other measures including certified translations:

- In FR signed "translation compliance commitment" from the applicant that he has performed a high quality translation with respect to CMDh recommandations on translations and without deleting / adding something is required. Of course with regards to patent issues, there can be some deletions but this should be flagged by using tracked changes and justification. As a consequence, only some parts of SmPC and PIL are review by dedicated assessors (for example sections 4.1 to 4.4 and sections 8 of SmPC + legal status and corresponding information in the PIL). Depending on the products, some specific review can also be performed for the labelling or other sections of SmP/PIL.

- In ES, IT, NL and PT a certified translation is required, but the entire translation is also reviewed by the assessors.

- In LV two assessors are involved in the review of PI translations – a quality assessor for quality information and a clinical assessor – for clinical and nonclinical information.

Results of the CMDh Survey on the PI translation

Results

Answers on question n.3 about any other measure including certified translations:

- In principle SE follows the BPG on high quality translations and it is possible to ask the Applicant to submit improved national PI if it has unacceptably low quality. SE has also a detailed guidance on its external web-page to guide the Applicant before they submit the material for assessment. For example, there is a check list for the Applicant to follow and this in particular seems to be used by the applicants. They also created some nano-lecturers for the Applicants in fields the assessors usually commented on, as a preventative/educational work towards the industry. These can also be found on their external web-page (however, they are in Swedish).
- Also IT has published a Guidance on the AIFA website aimed to guide the Applicants before the submission of the national PI.

Answers on question n.4 about any specific waivers to the PI national translation requirements:

-In AT, DK, IS, NL, NO, PT, SE, SI the translation is not checked in case the product is not marketed.

Results of the CMDh Survey on the PI translation

Summary

- 15 Member States use dual monitor and some MSs use «compare word functions».
- 16 MSs have no experience with AI (DE, IT and RO are planning/available to test its use).
- In ES and NO AI tools have been tried but the results are not as expected for the time being or the project is on hold.
- SE has no AI solutions at present for the translational work, but it is working on developing technical solutions to aid in the assessment of mock up/artwork similarities. SE is also working on developing a tool that will aid in the assessment of product name. The intention is that both these solutions will be used as an aid for the manual assessment.
- If the translation has poor quality, many MSs (10) send it back and ask the company for a new translation.
- In case of huge workload to check translation, some MSs (4) use external experts.
- Some MSs don't check the entire translated PI documents because *Declaration of conformity of translations* or Translation compliance commitment are requested (only some sections are checked). In other MSs a certified translation is required, however the entire translation is also reviewed by the assessors.

Results of the CMDh Survey on the PI translation

Summary

- DE has no digital measure to streamline the translations but in BfArM a specific template is requested. The national texts are to be inserted into the “Bescheidmaske”, which is made available on the BfArM homepage. Submissions without a “Bescheidmaske” will be rejected unprocessed. The „Bescheidmaske“ ensures that the national product information is available in a structured form.
- Some MSs published Guidances aimed to guide the Applicants before the submission of the national PI.
- In 8 MSs the translation is not checked in case the product is not marketed.

Future expectations

Making unique efficient AI tools available in all MSs (and EMA too) aimed to simplify the assessment of National Product information (and even Names and Mock up) could reduce the NCAs’ workload and harmonise the approaches in the assessment.

After having received the results of the Survey , in IT we have started a project to set up a dedicated group of assessors exclusively dedicated to check translations; we could be involved in AI projects too.

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Thank you

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