

EAHP SURVEY

The future potential of electronic product information (ePI)





Executive Summary

The move toward digitalisation of healthcare in Europe has been accelerated as a result of the pandemic and one aspect of digitalisation is the move towards the availability of electronic patient leaflets. The aim of the electronic product information project (ePI project) is the expansion of access to information on medicines and to facilitate access to the most up to date regulator-approved information. This report summarises the outcome of a survey conducted by the European Association of Hospital Pharmacists (EAHP). The survey was designed to analyse the use of (electronic) patient leaflets and the future potential of electronic product information (ePI) and targeted hospital pharmacists. The survey collected information on both the use of printed package leaflets and the prevalence of the application of product information in a digital format. The future use of ePI in European hospitals was also looked at. The project was carried out in cooperation with representatives of the pharmaceutical industry's Inter-Association Task Force (IATF) composed of Efpia (European Federation of Pharmaceutical Industries and Associations), Medicines for Europe and AESGP (Association of the European Self-Care Industry) for electronic product information (ePI).

The ePI survey was available in English and 20 other European languages covering the majority of EAHP's membership. The survey ran from the 10th of March to the 30th of April 2021. In this period, the third wave of the SARS-CoV2 pandemic was increasing the number of hospital patients and straining the healthcare systems. Many hospital pharmacists across Europe were involved in tending to these patients. Their duties in the hospitals impacted their participation in the survey and as a result the response rate to the ePI survey. However, with 534 responding hospital pharmacists in 36 countries, the feedback received is still considered representative of the views of hospital pharmacists.

Hospital pharmacists were asked by the ePI survey to provide feedback to 22 questions contained in 5 different sections. Statistical information on the background of the respondents was gathered by the introductory questions, while the remaining questions focused on the current use of patient information in the hospital setting by healthcare professionals and patients. In this regard, both the use of the package leaflets and digital product information was looked at. Participating hospital pharmacists shared their views and impressions about the behaviour of other healthcare professionals and patients, in particular on how, why, how frequently and in which format both of these groups are using product information. The final sections of the survey analysed the benefits and potential challenges in providing ePI in the hospital setting for both patients and healthcare professionals.

The answers presented in this report after the statistical questions are grouped into three categories focusing on structural questions, healthcare professional related questions and patient-related questions.

Overall, the results of the survey highlight that in the majority of cases an electronic/digital version of the leaflet is already used by the healthcare professionals in the hospital setting.

However, it is also reported that the majority of patients currently do not receive patient leaflets in the hospital setting.

A large majority of the respondents see the potential of the future ePI to facilitate easier and faster access to the product information for both healthcare professionals and patients. Attention should be spent on the ePI implementation. According to the hospital pharmacists who have responded, the implementation should take into account the current inadequate IT infrastructure in hospitals as well as the very broad structural preconditions of hospitals in Europe regarding the technical equipment to use ePI in daily routine.



The results of the survey highlight that:

• 78% of the responding hospital pharmacists indicate the digital product information is already used in their hospital or throughout their country

About the use of the product information by healthcare professionals in the hospital setting

- Respondents reported that 48% of nurses and 39% of hospital pharmacists regularly use the package leaflet in the hospital setting, followed by physicians (23%)
- For the purpose of this consultation, 59% of the responding hospital pharmacists indicate that the digital version of the package leaflet is used, alone (35%) or together with the paper version (24%)
- The hospital pharmacists (93%) are using most regularly the digital format of the product information followed by the physicians (71%) and the nurses (43%)
- A large majority of the responding hospital pharmacists see the potential of the digital format of the product information (94%) and ePI (91%) to support faster and easier access for healthcare professionals

About the use of the product information by patients in the hospital setting

- 55% of the responding hospital pharmacists point out that patients don't receive the package leaflet and 21% indicate that they share some specific information in the package leaflet orally with the patients
- A large majority of the responding hospital pharmacists see the potential of digital product information (61%) and ePI (82%) to facilitate the access of the patient to product information in the hospital setting

It should be underlined that the feedback about the healthcare professional and patient perspective was only collected from hospital pharmacists. Therefore, the results about the presumed behaviour of both healthcare professionals and patients are always the opinion of the hospital pharmacists, answering the survey.



Statistical questions

The first three questions of the survey asked respondents about their origin as well as the type and size of the hospital they worked in.

I work in... (question 1)

534 hospital pharmacists from EAHP's 35 member countries and Cyprus participated in the survey. Besides, 3 responses were received from hospital pharmacists practising outside of Europe and 2 from European countries, other than Cyprus, not part of EAHP's membership. The answers presented in the report only took into account the feedback received from EAHP's member countries and Cyprus. It should be noted that not all respondents provided feedback to all questions.

Country	Number of hospital pharmacists	Number of responses	Country	Number of hospital pharmacists	Number of responses
Austria	442	6	Lithuania	112	2
Belgium	1.344	55	Luxembourg	45	7
Bosnia and	75	0	Malta	90	5
Herzegovina					
Bulgaria	300	1	Montenegro	14	4
Croatia	132	34	Netherlands	552	3
Cyprus	No data	1	North Macedonia	55	1
Czech Republic	884	15	Norway	605	1
Denmark	600	2	Poland	2.000	11
Estonia	74	2	Portugal	1.000	52
Finland	700	0	Romania	1.025	3
France	6.000	16	Serbia	200	15
Germany	2.382	150	Slovakia	160	17
Greece	291	16	Slovenia	151	5
Hungary	502	50	Spain	3470	3
Iceland	37	6	Sweden	800	7
Ireland	450	4	Switzerland	460	1
Italy	3.500	1	Turkey	1.256	31
Latvia	100	6	United	8.700	1
			Kingdom		
			Total	38.508	534

 Table 1 - Number of responses by hospital pharmacists to question 1 'I work in...'.

Although, when contrasting the number of responses with the number of hospital pharmacists across EAHP's membership, the level of responses seems low. It aligns, however, with the experiences made by EAHP for other surveys. With 719 replies the European Statements of Hospital Pharmacy Survey Results for 2018 received a similar level of responses.¹ Also, one needs to factor in that many hospital pharmacists were working on addressing the third wave of the COVID-19 pandemic while EAHP's ePI survey was running. Thus, in light of these external factors and the similarity to the previous survey response rates,

¹ Amann S, Underhill J, Horák P, et al, EAHP European Statements Survey 2018, focusing on Section 1: Introductory Statements and Governance, Section 3: Production and Compounding, and Section 4: Clinical Pharmacy Services, European Journal of Hospital Pharmacy Published Online First: 02 December 2019. doi: 10.1136/ejhpharm-2019-002028.



the feedback received can be considered representative of the current views of hospital pharmacists given the circumstances.



My hospital is a... (question 2)

The survey respondents that replied to question 2 could choose between different types of hospitals. Those that did not identify with any of the options offered could select 'other' and provide additional details on the scope of the clinical activities in their hospital. 55% (N=290/529) of respondents indicated that they were working at a general hospital, while 27% (N=145) practised at a teaching or university hospital. 3% (N=18) of respondents came from psychiatric hospitals and 2% (N=14) from oncology hospitals. 1% practised at geriatric (N=7), paediatric (N=7) and traumatology hospitals (N=5), while 5 respondents did not want to share information about the type of hospital that they work in. The remaining 8% (N=44) chose the option 'other'. The background of this group was very diverse ranging from hospital pharmacists working at specialised hospitals, clinical networks to those sharing the full name of their institution.



How many beds are served by your hospital? (question 3)

Figure 2 - Percentage of responses by hospital pharmacists to question 3 'How many beds are served by your hospital?'.

Figure 1 - Percentage of responses by hospital pharmacists to question 2 'My hospital is a...'.



The replies to question 3 – focusing on the number of beds served by a hospital – showed that the respondents worked at hospitals of different sizes. A small minority practised at a hospital with fewer than 100 beds (6% (N=30), while more than half of the respondents (55% | N=294) worked at larger hospitals with over 500 or more than 1.000 beds.

Structural questions

This section provides an overview of the feedback collected from respondents through the six structural questions (questions 10, 15, 19, 20, 21 and 22) that were asked. The questions looked at the use of the digital format, the challenges for accessing digital product information, trusted sources including their impact on the supplementation of the product information at the hospital level, views on those that should be responsible for the content of the ePI and suggestions for improving the content and use of ePI.



Is the digital format of the product information already used in your hospital or country? (question 10)

Figure 3 - Percentage of responses by hospital pharmacists to question 10 'Is the digital format of the product information already used in your hospital or country?'.

78% of respondents specified in relation to question 10 that the digital format of the product information is already used. Out of these 44% (N=209/473) use the digital format in the hospital, while 34% (N=160) of respondents mentioned that this format is used throughout their entire country. 20% (N=95) of respondents stated that the digital format is not yet used, while 2% (N=9) ticked 'other'. Those opting for 'other' could either not provide feedback or indicated that digital information is not always available.

What are the current challenges in accessing the digital product information? (question 15)

The challenges that impede access to digital product information were analysed by question 15. 327 respondents shared feedback on this question. The five most common answers included lack of means to work with digital information (referred to by the survey participants frequently as 'accessibility') (N=80), education, knowledge and digital health literacy of patients (N=54), lack of tools and/or staff (N=38), insufficient IT and/or infrastructure at the hospital (N=32) and lack of access to available digital information (referred to by the survey participants frequently as 'availability') (N=30). Some specific challenges are listed below:

"Access to IT, particularly for poorer families or in resource-limited settings. Willingness to make the effort to ensure access." – United Kingdom



"Enough computers on the right places and/or television with special programs. Decisions of management (CEO's) of hospitals on giving priority to ICT department to implement." – Netherlands

"The access for the patient during his/her stay in the hospital and afterwards, for elderly people with no access to the internet" – Belgium

"Education of patients and health care staff." - Croatia

"On the EMA website is very difficult to access product information for health care workers who do not regularly access it" – Ireland

Which trusted source of ePI would you and your colleagues use as your primary reference for the ePI? (question 19)



Figure 4 - *Percentage of responses by hospital pharmacists to question 19 'Which trusted source of ePI would you and your colleagues use as your primary reference for the ePI?'.*

Question 19 gathered insights on the trusted sources of ePI that would be used as a primary reference. 42% (N=174/415) of respondents pointed towards their local health authority. 27% (N=110) named compendium from pharmaceutical industry associations and 23% (N=95) the internet. Those respondents opting for the latter mainly mentioned the websites of their national medicines agency and the European Medicines Agency. A handful also referred to the websites of manufacturers or other types of databases that were also mentioned in relation to question 7. 9% (N=36) opted for 'other'. Those choosing 'other' also named website of national competent authorities or existing databases offered either by authorities, healthcare professional organisations or commercial providers.

Would the trusted source of the product information have an impact on the supplementation of the product information at the hospital level? (question 20)

Figure 5 - Percentage of responses by hospital pharmacists to question 20 'Would the trusted source of the product information have an impact on the supplementation of the product information at the hospital level?'.

The impact that trusted sources of the product information could have on the supplementation of the product information at the hospital level was analysed by question 20. 54% (N=225/419) of respondents did not see any impact, while 46 % (N=194) did. Feedback in relation to those choosing to tick the option 'yes' touched on accessibility, more supplementary information and the possibility of having the information updated in real-time.

Who do you think is responsible for the content of the ePI? (question 21)

383 respondents provided feedback to question 21 inquiring about who they consider responsible for the content of the ePI. Almost half (N=175) referred to European or national competent authorities. Another large group (N=142) named manufacturers, oftentimes after approval of the information by the national authority. 39 respondents mentioned pharmacists and other professional associations.

In general, what suggestions do you have as to how to improve either the use or the content of ePI? (question 22)

The final question of the survey asked for suggestions for improving either the use or the content of ePI. 232 free text responses were provided in relation to question 22. There was a lot of variation in the responses. Some indicated that they had no additional feedback. Others referred to the searchability of information. Communication about the advantages of ePI was mentioned as means to improve use as well as patient education in relation to health literacy. Another factor that influences usability is the need for better IT infrastructure in hospitals to fully utilise ePI.

"I support the further use of ePI." – Sweden

"In our case, we need to strengthen the IT infrastructure in order to support such a project." – Malta

"Barcodes on the primary package should give easy access to the ePI." – Denmark

"For the use, it is important that local authorities share the ePI on their internet sites. The content must, as always be reviewed by authorities before publication." – Portugal

"It is a good idea since it offers quick access and is ecological. On the other hand, it is still difficult to make it available to patients." – Luxembourg

"It would be nice if ePI would highlight the respective changes to the previous version in colour -information on the divisibility of solid dosage forms - if it is necessary to print ePI, this should be possible without further formatting processes." – Germany

Healthcare professional related questions

This section presents the views and perceptions of hospitals pharmacists about the use of package leaflets by healthcare professionals, the reasons why and how frequently they are consulted and in which format (questions, 4, 5, 6 and 8). In relation to the digital format of the product information the type of healthcare professional using it, the trusted sources and its benefits are being looked at (questions 7, 11 and 13). With a view to the future, question 17 explored the potential of ePI for healthcare professionals.

Are package leaflets regularly being used by healthcare workers in the hospital you work in as compared to the summary of product characteristics (SmPC)? (question 4)

Figure 6 - Percentage of responses by hospital pharmacists to question 4 'Are package leaflets regularly being used by healthcare workers in the hospital you work in as compared to the summary of product characteristics (SmPC)?'.

The fourth question looked at the perception of hospital pharmacists in relation to the use of package leaflets by healthcare professionals working in their hospitals. Multiple options could be selected. Almost half of the responding hospital pharmacists (48% | N=254/533) indicated that nurses regularly work with the package leaflets, while 23% (N=124) opted for physicians and 3% (N=15) for others. Trainees, students

and technicians were the healthcare professionals mentioned in the category 'others'. 39% (N=206) of responding pharmacists indicated that hospital pharmacists were the second-largest group of healthcare professionals using the package leaflets. By contrast, 29% (N=154) of responding hospital pharmacists indicated that they only use the summary of product characteristics (SmPC). 36 responding hospital pharmacists (7%) stated that the package leaflet is not used by any of the professionals listed or by others working in the hospital.

For which reason is the package leaflet consulted by the healthcare workers (including you) in the hospitals? (question 5)

Figure 7 - Percentage of responses by hospital pharmacists to question 5 'For which reason is the package leaflet consulted by the healthcare workers (including you) in the hospitals?'.

Question 5 looked at the reasons why, according to the responding hospital pharmacists, healthcare workers consult the package leaflet. The most common reason for consulting the package leaflet was to check the directions for preparations and administration (73% | N=385/525). 43% (N=226) of the respondents reported that the package leaflet was consulted to check for possible problems or side effects. The next most common use of the package leaflet was as an information source to respond to queries from nurses (42% | N=221), physicians (36% | N=190) and other healthcare professionals (29% | N=150). It was reported to be given to patients upon request for information by only 33% (N=171) of respondents. Those choosing the option 'other' (7% | N=39) either never or rarely used the package leaflet or remarked that only the SmPC is used.

When the package leaflet is consulted by the different healthcare workers, which format is used? (question 6)

For question 6 respondents had again the choice to tick all options that apply. 41% (N=216/525) of respondents informed that healthcare professionals in their working environment exclusively use the paper version of the patient leaflet, while 35% (N=182) shared that only the digital version was used. The remaining 24% (N=127) indicated that healthcare workers refer to both the digital and the paper version of the package leaflet.

Figure 8 - Percentage of responses by hospital pharmacists to question 6 'When the package leaflet is consulted by the different healthcare workers, which format is used?'.

When breaking down the information by type of hospital – looking at responses received by hospital pharmacists working at general hospitals and teaching hospitals – a similar division can be observed. In general hospitals 41% (N=116/282) use the paper version and 33% (N=94) the digital version. 26% (N=72) of respondents working at general hospitals used both. For teaching hospitals, the numbers are a bit closer with 37% (N=52/142) using the paper version, 38% (N=54) the digital version and 25% (N=35) opting for both.

If the digital package leaflet is consulted, from which trusted source is it? (question 7)

Question 7 was a free text question looking at the sources that are being used by hospital pharmacists to access the digital version of the package leaflet. 414 respondents answered this question. Out of these 38% (N=157) respondents stated that information from the competent authorities at the national level is their trusted source, while 7% (N=30) referred to the European Medicines Agency. Specific websites like www.cbip.be, www.fachinfo.de or www.beipackzettel.de were named by 7% (N=30) respondents. 7% (N=29) referred to AiDKlinik[®] and 21 to manufacturers. The remaining 36% (N=147) respondents listed different healthcare professional organisations, including chambers of pharmacy, mobile applications, the internet and national databases, including for example databases of the Czech State Institute for Drug Control (SÚKL), the Hungarian National Institute of Pharmacy and Nutrition (OGYEI) and the National Authority of Medicines and Health Products in Portugal (INFRAMED).

How frequently are you consulting package leaflets? (question 8)

The frequency with which package leaflets are being consulted by hospital pharmacists was looked at by question 8. 27% (N=143/523) of respondents consulted them on a weekly basis, while 24% (N=126) did so daily. Every six months or longer was chosen by 20% (N=103) of respondents. 15% (N=80) indicated that they consulted the package leaflets monthly. Those opting for the field 'other' (14% | N=71) stated that they use the leaflets rarely or whenever necessary. In summary, it can be said that just over 50% of respondents consult the package leaflet at least weekly (24% of respondents selected the option 'daily', 27% of respondents selected the option 'weekly').

Figure 9 - Percentage of responses by hospital pharmacists to question 8 'How frequently are you consulting package leaflets?'.

When looking at the size of the hospital, it could be observed that most consulted the package leaflet weekly (25% (N=7/28) of respondents working at a hospital with fewer than 100 beds, 31% (N=63/206) of respondents working at a hospital with 101 to 500 beds and 26% (N=41/157) of respondents working at a hospital with 100 to 500 beds consulting package leaflets on a daily basis (30% | N=40/132) ranked before consulting them weekly. Conclusions could not be drawn based on the dataset on the frequency of consulting the package leaflet based on hospital size.

Which healthcare workers regularly use the digital format of the product information in your country? (question 11)

Figure 10 - Percentage of responses by hospital pharmacists to question 11 'Which healthcare workers regularly use the digital format of the product information in your country?'.

For question 11, looking at the healthcare workers that regularly use the digital format of the product information, respondents could select multiple options. The overwhelming majority (93% | N=440/474) named hospital pharmacists as professionals working mostly with the digital format of the product information. Physicians (71% | N=337) and nurses (43% | N=206) ranked in second and third place. A small group opted for neither of these three professions (5% | N=26). 3% (N=14) of respondents ticked the field 'other'. Those respondents opting for 'other' referred to technicians, other healthcare professionals and community pharmacists as healthcare workers using the digital format of the product information. One also underlined that no feedback could be given for the whole country.

Do you think that the use of the digital format of the product information in hospitals facilitates access to product information by the different healthcare workers? (question 13)

Figure 11 - Percentage of responses by hospital pharmacists to question 13 'Do you think that the use of the digital format of the product information in hospitals facilitates access to product information by the different healthcare workers?'.

The benefits that the digital format of the product information in hospitals could bring for healthcare workers was evaluated by question 13. Compared to the previous question focusing on patients, a very large majority of respondents (94% | N=437/467) viewed the digital format of the product information as very useful for healthcare workers. Those that supported their response with further feedback (N=265) underlined the possibility to gain faster and easier access to information and the importance of integrating electronic information into existing hospital systems. 6% (N=30) of respondents did not see any particular benefits, especially since insufficient IT infrastructures hamper the use of digital product information in their hospitals.

Do you think that the use of the ePI in hospitals could facilitate access to product information and the sharing of the product information with the different healthcare workers in the hospital? (question 17)

The benefits of ePI for healthcare workers were assessed by question 17. Similarly to question 13 on the benefits of the digital format of the product information, also a large majority of respondents (91% | N=403/441) saw the potential of ePI for healthcare workers. Also, in relation to this question mainly easier and faster access for the users were referred to. The 9% (N=38) of respondents that did not see any benefits

of ePI stressed that the digital information is already available in their in-house systems, that it might be too complicated to implement and that IT equipment for making ePI a reality is lacking.

Figure 12 - Percentage of responses by hospital pharmacists to question 17 'Do you think that the use of the ePI in hospitals could facilitate access to product information and the sharing of the product information with the different healthcare workers in the hospital?'.

Patient-related questions

This section looks at the patient perspective, in particular, how package leaflets reach patients and if the digital format could be useful for them (questions 9 and 12). In addition, information on already existing projects is being collected, benefits are being considered and technical conditions necessary for making ePI accessible for patients are being explored (questions 14, 16 and 18).

How do printed package leaflets regularly reach patients in your hospital? (question 9)

Figure 13 - Percentage of responses by hospital pharmacists to question 9 'How do printed package leaflets regularly reach patients in your hospital?'.

For question 9 looking at how patients in the hospital are provided with the patient leaflets, 55% (N=288/519) of respondents pointed out that patients do not receive them. Patient-specific information contained in the leaflet was orally shared with patients by 21% (N=110) of respondents. 14% (N=72) directly gave the leaflet to the patient. 9% (N=49) of respondents selected the option 'other'. Some opting for 'other' indicated that they could not provide feedback, that the handing out of package leaflet only concerns outpatients or that this is already handled digitally due to the system used in their hospital.

The picture looked similar when analysing the responses in relation to the size of the hospital. For all hospital sizes, most respondents indicated that the package leaflets were not received by the patient, followed by the provision of patient-specific information orally and handing the leaflet to the patient. The preferred method of communication in hospitals with less than 500 beds seemed to be direct communication with patients.

Do you think that the use of the digital format of the product information in hospitals facilitates access to product information for patients? (question 12)

Figure 14 - Percentage of responses by hospital pharmacists to question 12 'Do you think that the use of the digital format of the product information in hospitals facilitates access to product information for patients?'.

Question 12 assessed the usefulness of the digital format of the product information in hospitals. 61% (N= 284/464) of respondents deemed that the digital format would facilitate access to product information for patients. Out of those 164 respondents provided additional clarifications in form of comments. In their responses, the large majority touched on the possibility to gain faster and easier access to information. 39% (N=180) of respondents did not see any benefit. 14% (N=66) of this group specifically underlined that the current hospital infrastructures didn't allow access to digital information for patients. Digital health literacy was referred to by 10% (N=48) since digital information might not be the right format for some patient groups, like the elderly.

Are you aware of any concrete examples or projects that show how patients already benefit from digital product information (access to the mother language labelling, easy access to readable format, ... benefits which are foreseen with the future ePI)? (question 14)

Question 14 looked at concrete examples and projects that show how patients already benefit from digital product information. 91% (N=428/468) of respondents were not in possession of such information. The

remaining 9% (N=40) referred for example to unit dose barcoding used in their hospital, the ePI project in Belgium and systems created in their own hospitals using electronic information.

Figure 15 - Percentage of responses by hospital pharmacists to question 14 'Are you aware of any concrete examples or projects that show how patients already benefit from digital product information (access to the mother language labelling, easy access to readable format, ... benefits which are foreseen with the future ePI)?'.

Do you think that providing ePI in hospitals to patients – i.e. by providing a link via QR-code on unitdose medication offering ePI in digital services for patients – could facilitate access to product information and the sharing of the product information with patients? (question 16)

Figure 16 - Percentage of responses by hospital pharmacists to question 16 'Do you think that providing ePI in hospitals to patients – i.e. by providing a link via QR-code on unit-dose medication offering ePI in digital services for patients – could facilitate access to product information and the sharing of the product information with patients?'.

Question 16 inquired about the benefits that ePI could provide to patients in hospitals. 82% (N=360/439) saw the potential of ePI for facilitating access to product information and the sharing of the product information with patients. The 196 respondents that decided to provide additional feedback mentioned the digital literacy of young patients, better accessibility and the possibility for patients to obtain information linked to their health via their smartphones. 18% (N=79) of respondents remained cautious.

For half of them (9% | N=41), ePI would only provide limited benefits, especially since its use could pose difficulties for some patient groups, like the elderly population. The other half (9% | N=38) stressed the importance of having the information provided by the healthcare professional.

Some technical conditions might be necessary, to make ePI accessible for patients. Which of the following are available in your hospital? (question 18)

Figure 17 - Percentage of responses by hospital pharmacists to question 18 'Some technical conditions might be necessary, to make ePI accessible for patients. Which of the following are available in your hospital?'.

The technical conditions needed for making ePI accessible for patients were looked at by question 18. Respondents were asked to identify different means available in their hospital via which ePI could be made accessible. 69% (N=279/404) of respondents referred to open WIFI access for patients, while 30% (N=121) mentioned the integration of prescribing software. 20% (N=79) pointed to 'other' means, 16% (N=66) to screens with internet access at each bed and 13% (N=53) to QR code readers for patients without mobile devices. The large majority opting for 'other' (N=61/79) stressed that no means are available in their hospitals to make ePI accessible for patients.

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