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BAGSO statement on the introduction of digital patient information leaflets by the European Union

Preliminary remarks

With the proposal for a Directive of the European Parliament and of the Council on the establishment of a Union Code relating to medicinal products for human use (2023/0132 COD)¹, the European Commission plans to give Member States the choice between printed package leaflets, electronic product information or a combination of both. This is stated in Art. 63 para. 3:

‘Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient’s right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.’

As the umbrella organisation for senior citizens' organisations, BAGSO comments on this proposal from the perspective of older persons.

Evaluation

Pursue a complementary approach

BAGSO currently considers the planned option of a combination of printed and electronic patient information leaflets to be essential. Although digital package leaflets (in an enhanced form) are to be welcomed in principle, BAGSO demands that an analogue (paper) version must continue to be available, at least for a longer transitional period. Patient information leaflets are essential for the safe intake of medication and must always be accessible to all patients. A short-term switch to a

¹ Cf. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52023PC0192>

solely digital version would exclude people without internet access from accessing the package leaflet and thus jeopardise patient safety. It is currently estimated that around seven million people aged 60 and over in Germany do not have digital access. People with low digital skills – which often include older people – are also highly unlikely to be able to use the digital patient information leaflet. However, it is older persons in particular who regularly take medicines: 9 out of 10 people aged 65 and over were treated with medicines in 2022; many take several medicines a day.² It can be assumed that the development of digital skills in the population, especially in the older generations, will continue for years to come. In this regard, BAGSO calls for the possibilities of digitalisation to be made accessible and usable for everyone: It is the responsibility of the state to guarantee its citizens access to digital services and offerings. In addition to the expansion of the broadband network and the provision of free internet access, this particularly refers to educational programmes such as learning and digital experience centres at community level.³

After an appropriately long transition period, the printed package leaflet should be actively offered in pharmacies, not only at the request or enquiry of patients ('print-on-demand'), who often do not even know that they are entitled to such benefits. In this regard, BAGSO criticises the fact that the proposed provision in Art. 63 para. 3 is too vague, as it is not clear against whom the patient's entitlement to a free printout is directed. In BAGSO's view, the assumption of costs for printouts must be regulated; it is conceivable that the pharmaceutical industry could assume the costs. Before the paper package leaflet expires, BAGSO believes that an information campaign is needed to explain the transition to the target group and draw attention to the right to a printout.

Further developing digital patient information leaflets

From BAGSO's point of view, digital patient information leaflets have many advantages. Information can be accessed more quickly and in a more targeted manner thanks to a search function, for example, and changes to previous package leaflets can be identified more quickly on the manufacturers' websites. In addition,

² Cf. BARMER Drug report 2023 (in German):
<https://www.barmer.de/resource/blob/1241248/8e2483171c80ba878809dfdac7ccdb8e/arzneimittelreport-2023-data.pdf>

³ Cf. BAGSO Position paper "Older People in a digital world" 2020.
https://www.bagso.de/fileadmin/user_upload/bagso/06_Veroeffentlichungen/2020/BAGSO_Position_Paper_Older_persons_in_a_digital_world.pdf

digital patient information leaflets can be made more accessible and are available regardless of time and place. To fully exploit the potential of digitalisation, BAGSO recommends that paper package leaflets should not simply be digitised, but that the following further development options should be considered:

According to Art. 63 para. 2 of the proposed EU Directive, the package leaflet should be 'written and designed in a clear and understandable way.' In terms of user-friendliness, BAGSO sees potential for improvement compared to the status quo, e.g. better readability (font type and size), the use of plain language and the creation of shorter leaflets by focussing on the most important information. It is conceivable to offer digital patient information leaflets for specific target groups (e.g. children/adolescents, pregnant women/breastfeeding mothers, older people), for instance, to draw attention to specificities regarding dosage and tolerability. In addition, a digital patient information leaflet opens the possibility of linking to further (independent, verified) health information, including the use of audio-visual media.

Online portals that list the digital package leaflets must be available in every country. Digital accessibility must be considered from the outset when creating digital patient information leaflets and online portals. Regarding the introduction of the electronic patient record (ePA) in Germany, it makes sense to link the electronic medication treatment plan with the digital patient information leaflets.



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BAGSO – The voice of older people

BAGSO, the German National Association of Senior Citizens' Organisations, represents the interests of older generations in Germany. It stands up for active, healthy and self-determined ageing in social security. BAGSO is an umbrella organisation of more than 120 civil society organisations that are run by or work for older people.

In a colourful and diverse society, BAGSO promotes a differentiated image of old age. This includes both the various opportunities arising from longer lives as well as times of vulnerability and the need for care. BAGSO calls on politicians, society and businesses to offer conditions that allow for a good and dignified life in older age – in Germany, Europe and worldwide.