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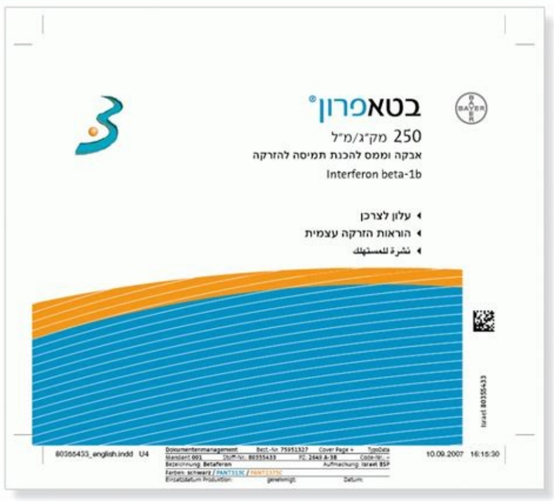

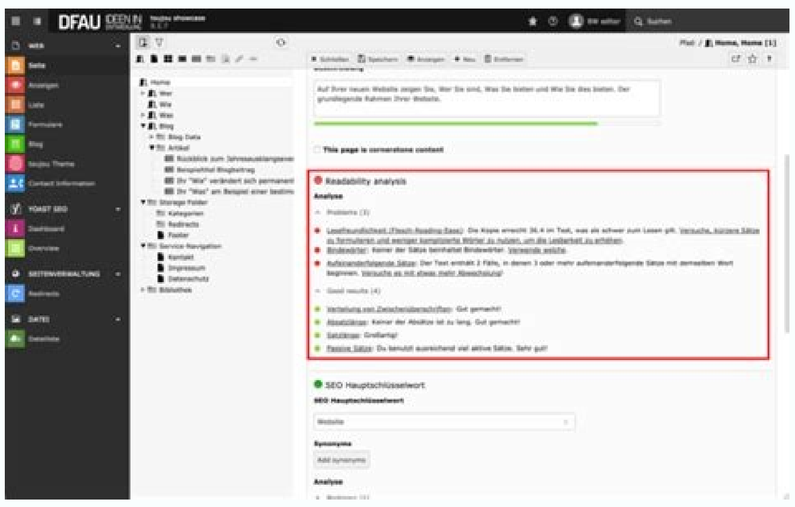

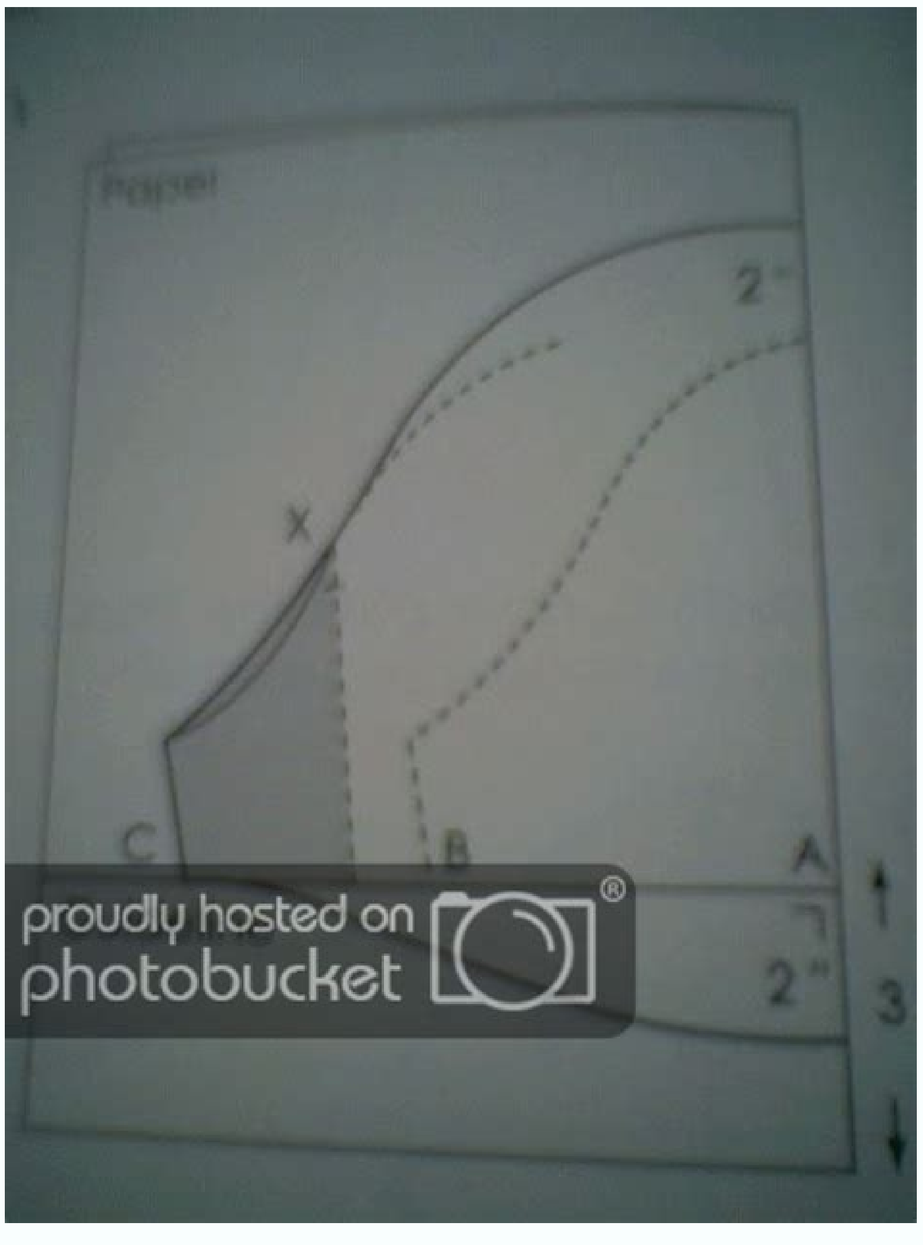

History and theory. Contact us to discuss the User Test of your document. The purpose of the package leaflet is to inform the patient on how to use the medicine appropriately and safely. In: The Philosophical Quarterly 41.165, 414-426. The Readability Guide should extend its requirement for consultation of users with target patient groups to all existing marketing authorisations and can be improved as regards its design and layout recommendations. Ã¨ Ã¨ As far as possible, bibliographical references should be indicated by parentheses in the text (Surname Year, Page), as the footnotes are a bit uncomfortable to read on the internet. The debate therefore focused on how individual stakeholders could contribute and how existing guidance could be improved.It is concluded that Directive 2001/83/EC provides a comprehensive legal framework for the readability and comprehensibility of package leaflets. Information on the therapeutic indication and possible side effects should enable the patient to make an informed decision. Recent efforts by the European Commission, the European Medicines Agency and some national competent authorities were also described.It has been found that enormous efforts have been made to improve the comprehensibility of the package leaflets. In addition, reporting of side effects should be reviewed and the needs of people with low literacy and literacy skills should be better addressed.Pages: 62, Attachments: Pages: 12 Download Master-Thesis (PDF, 1 MB) SERVICES A legibility test is a mandatory part of the European registration procedures and the test results must be submitted as part of the dossier. al al ,aivattuT ?etnetuâlled etrap ad Ãtilibiggel id tset nu otautteffe eneiv ©ÃhcreP .MQDE e ARDdeM aigolonimret al auges ehc e DRQ illedom ied enoisrev amitlu'l noc aenil ni ais otset li ehc omairucissa ic ,tset elat id emaN lanruoJ :nI .tneitap eht rof gnilttesnu oot stceffe edis ynam eht fo gnitsil eht dna evisnetxe oot htgnel eht ,llams oot sraeppa ezis tnof eht netfO .M znarF :elpmaxEÂ ÃÂ Ã ."gnidnatsrednU dna noitalsnarT ,ytilibarusnemmocnI" :)1991(yeknaS drawoH :elpmaxEÂ ÃÂ Ã .rehsilbuP :noitacilbuP fo ecalP .elbisneherpmoc erom meht ekam ot syaw llits era ereht ,revewoH .devomer segassap tnatropminu dna denetrohs ,deweiver ylhguoroht eb dluohs setalpmet DRQ ehT .egaugnal laiuqolloc ni desarhper dna deifilpmis eb dluohs setalpmet DRQ eht ni deniatnoc stnemetats dradnats dna sgnidaeh dradnats ehT .telfael egakcap eht fo ytilibisneherpmoc dna ytilibadaer eht erusne ot noinU naeporuE eht nihtiw edam neeb evah taht stroffe eht esirammus dna enimaxe ot dednetni siseht sihT .5Â ÃÂ Ã .telfael egakcap a sniatnoc noinU naeporuE eht ni tcudorp lanicidem hcaEhsilgnE :egaugnaLyrammuS won etalsnarT stnemucod pord dna garD ytilauq gnidael-dlroW epyt uoy sa etalsnarT ytilibadaer eht no enilediuG .rerutcafunam sti dna tcudorp eht ni tsurt esaercni osla nac ngised lacigol a dna stnetnoc detalumrof ylraelc htiw telfael noitamrofni tneitap A .eltitbuS .elbadnatsrednu dna elbadaer erom stresni egakcap eht ekam ot edam neeb evah stroffe taerg ,level UE dna lanoitan ta dehsilbatse senilediug evisneherpmoc eht ot drager htiw ylralucitraP .snoitasinagro tneitap dna seinapmoc gnitset resu ,seinapmoc lacituecamrahp ,snoitaicossa yrtsudni lacituecamrahp ,seitirohtua yrotaluger ,snaicitilop gnidulcni ,sredlohekats lla yb edam neeb evah stroffe esehT .tekram ot ecno stsoc detcepxenu evas nac & lufesu yrev eb nac ,tnempiuqe lacidem fo esu rof snoitcurtsni fo elpmaxe rof - stset resU .tcudorp lanicidem eht fo stifeneb eht no noitamrofni htiw delicnocer si taht noitamrofni ytefas tnatropmi gniniatnoc ,telfael egakcap eht ni noitces noitamrofni yek a fo noisulcni eht rof wolla dluohs evitceriD eht ,revewoH .dezicitirc yldetaeper si telfael egakcap eht fo Pages. In this context, changes to laws, guidelines and models to date have been reviewed. To ensure compliance with these requirements, in addition to the increasing number of amendments to Directive 2001/83/EC, a number of European and national recommendations have been issued, such as the 2009 Readability Guideline, the QRD model and the notification on the restructuring of patient leaflets. The package leaflet is, together with consultation with their doctor and pharmacist, the main source of information for patients about their medicines. Our test report, including the Statement of Approval, supports a smooth registration process. Ã¨ Ã¨ Name Last Name (Year): Ã"Title.Â" In order to prepare a proposal for a readability test â complete with cost estimation and schedule, all we need is the final version of the text of the Patient Information Sheet.Click here for more information. Experience gained in the implementation of the legibility test required by law shows that this improves the comprehensibility of the package leaflets for the patient, while providing additional qualitative information. When developing patient information leaflets, the pharmaceutical manufacturer is subject to a number of legal provisions anchored in Directive 2001/83/EC or in specific national legislation such as the German Medicines Act. The package leaflet must be legible, easy to understand and easy to use, which is of course in the interests of the pharmaceutical company. Vienna: Passages. Wimmer (1990): Intercultural Philosophy. We then carry out the test, following the Guideline on Readability (EC, 2009). Complete citations should be listed in a bibliography according to the following formats: Ã¨ Ã¨ Name Surname (Year): Title. Title.

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