Health Technology Review	
Technology Ref.:	HTA-24043
Technology Name/Version/Model:	Digital Therapeutics Edupression-V5
Approvals by International Bodies:	Diga in Germany EU-CE certified
Company name:	SOFY GmbH - Austria
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Short Description of the Technology:	– Technology is an intelligent and evidence-based digital health application for depression. The solution is based on psychoeducation, psychotherapy and measurement-based care to improve symptoms and foster patient empowerment. It can be used as a monotherapy or in combination with drug or talk therapy. – dupression.com® is an evidence-based self-help program that was developed for the treatment of mild to moderate unipolar depression. It is based on two core foundations, psychoeducation with elements of cognitive behavior therapy (CBT) and a mood chart. Both foundations are registered as a medical product. As such, detailed risk management documentation includes probability and severity of adverse events. Moreover, detailed strategies such as warnings were implemented in the software and documented accordingly. – It can be used on a PC as well as on mobile devices (browser, App) at any time. – A patient-relevant structural and procedural improvement of the DiGA edupression.com® was proven through a clinically significant improvement in health literacy and in particular depression literacy using a clinical trial (eFICASY study). – In the clinical trial, the patients' current depression competence was recorded several times using the depression competence scale (D-Lit), which assesses the level of depression competence. – An increase in depression competence within the 3-month study period was considered an improvement. – A randomized, controlled clinical study in mild to moderate unipolar depressive patients (eFICASY study). – Patients between the ages of 18 and 65 years with a current Mild or moderate depressive episode in the presence of unipolar depression (depressive episode, recurrent depressive disorder). – Access to standard care and DiGA edupression.com

	Primary endpoint: – Change in the severity of depressive symptoms, measured using Patient Health Questionnaire-9(PHQ-9). **Secondary endpoints:** – Change in depression-related health literacy, measured using the Depression Literacy Questionnaire (D-Lit) – Change in health-related quality of life, measured using the short version of the World Health Organization Quality of Life (WHOQOL-BREF) – Change in cognitive and emotional perception of illness, measured using the Brief Illness Perception Questionnaire (B-IPQ) – The edupression.com® system is not suitable for patients with bipolar depression, psychotic symptoms, or suicidal ideation.

Health Technology Assessment Team Recommendation:	**Approval for the English version. If an Arabic version to be released, this need a validation study to be submitted before the release**

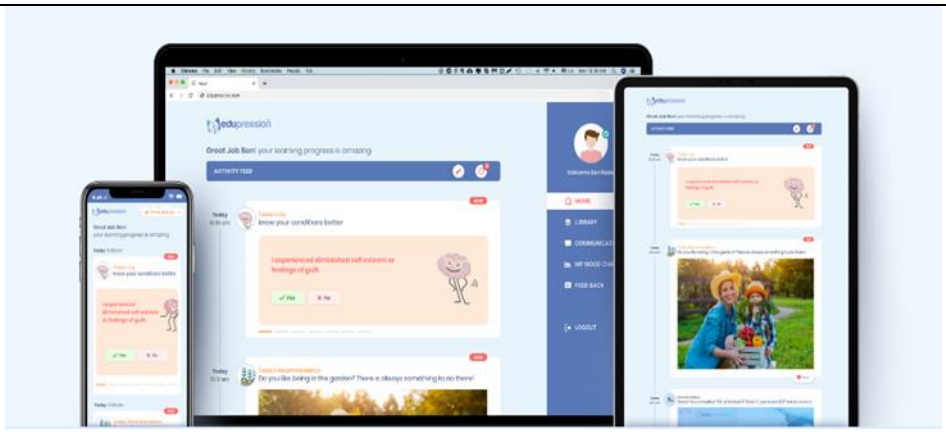
Summary of Review:

The technology is an intelligent and evidence-based digital health application for depression. The solution is based on psychoeducation, psychotherapy and measurement-based care to improve symptoms and foster patient empowerment.

We recommend **approval with limitation of using this technology** for Market entry with the following conditions:

1. Approval for the English app. If an Arabic version is to be released, this needs a validation study to be submitted before the release.
2. The technology should be performed by psychotherapists.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request

Technology Image



Population, setting and intended user for Technology "Digital Therapeutics Edupression-V5"

- **Population/ Intended User;**
  - Age from 18- 60
- **To be performed by:**
  - psychotherapists
- **Clinical Setting:**
  - Hospital, Psychotherapy centers
- **Condition of use:**
  - use digital therapy programs as monotherapy for mild depression and as adjunct therapy for moderate to severe depression.
- **Exclusion criteria:**
  - The use of edupression.com® is therefore not indicated in the presence of suicidal thoughts or bipolar disorder or psychotic symptoms in the context of schizophrenia, a severe depressive episode with psychotic symptoms, a schizoaffective disorder, delusional disorder, or other disorders with psychotic symptoms.
  - patients who are unable to follow the online psychoeducation offerings for various reasons (e.g. intellectual disability, alcohol or drug intoxication, visual impairment, etc.).
  - edupression.com® is also not suitable for patients who cannot use a digital device such as a computer/tablet/smartphone or who do not have the necessary language skills, which may apply to some geriatric patient groups or patients with a Native language that does not exist in the language range of edupression.com® or has a lack of foreign language skills applies.