Medicines & Healthcare products
Regulatory Agency

Appendix 1 – Symptom checkers

Independent software intended for use by lay users. The user manually enters details/symptoms and the software algorithm matches these with conditions. There are many on the market, some using AI chatbots to interact with the user.

Outputs can include:
- A list of all matching conditions, likely conditions, most likely condition etc.
- An indication of seriousness – e.g. 'Red flag'.
- Recommended treatments.
- Triage 'signposting' of next steps, e.g. visit GP, go to A&E.

Examples that may be devices include:
- Software intended to output a subset of those medical conditions that match the input symptoms.
- Software that indicates the likelihood of a match.
- Software that provides treatment recommendations for listed conditions, e.g. first aid treatment.
- Software that offers filters by red flag/severity/probability of a match.

Examples that are unlikely to be devices include:
- Software that offers only reference information about the conditions listed.
- Software intended to list all matching conditions that fit the symptoms input where the order is independent of likelihood, e.g. in alphabetical order.
- Software that only signposts the user to suitable care e.g. see your GP, go to A&E.

Symptom checker devices will be class I unless considered to 'allow direct diagnosis', in which case they will be class IIa.

A device is considered to "allow direct diagnosis" when
    it provides the diagnosis of the disease or condition by itself,
    it provides decisive information for making a diagnosis, or
    claims are made that it can perform as, or support the function of, a clinician in performing diagnostic tasks.
For devices intended to be used by lay users, provision of an indicative diagnosis may be enough to imply that the device is allowing direct diagnosis.

Indicative words and phrases:

Triage
Self assessment
Medical Information
Health Information
Working diagnosis
Differential diagnosis