

HUMAN MEDICINES

RESEARCH & DEVELOPMENT



551
requests for
scientific advice
& protocol
assistance

11
applications for
parallel
scientific advice
with HTA bodies



29
recommendations
on advanced
therapy
classifications

91
positive opinions
on paediatric
investigation
plans

196
orphan
designations
recommended

AUTHORISATION

new active substances **41**

positive opinions **82**

Highlights

17 orphan
medicines

1 stem cell
therapy

1 paediatric
use

SAFETY MONITORING

471

periodic safety
update reports
assessed

18

referral
procedures
started

1.1 MILLION

adverse reaction
reports received

2030
signals
reviewed

34
signals
validated

7
changes to
product
information