

Have medication safety alerts reflected on the use of JAK inhibitors? – Retrospective nationwide register-based study in 2017–2023

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Introduction

The use of JAK inhibitors in rheumatic diseases and ulcerative colitis has become more common. In Finland, four JAK inhibitors have been included to reimbursement scheme since 2017: baricitinib, filgotinib, tofacitinib and upadacitinib. However, adverse effects of these medicines have raised concerns¹. Medication safety alerts related to tofacitinib were first published in 2019 and interpreted as a class effect in 2022.

Aim

The aim was to study the use of JAK inhibitors in Finland before and after the publication of medication safety alerts. Furthermore, the use according to certain demographic (age) or disease-specific factors (e.g. coronary heart disease) that have been acknowledged as risk factors were studied.

Method

Retrospective nationwide register study on all the patients receiving reimbursements and initiating treatment on JAK inhibitors

Figure 1. JAK inhibitor use of patients with rheumatic disease or ulcerative colitis in Finland 2017–2023

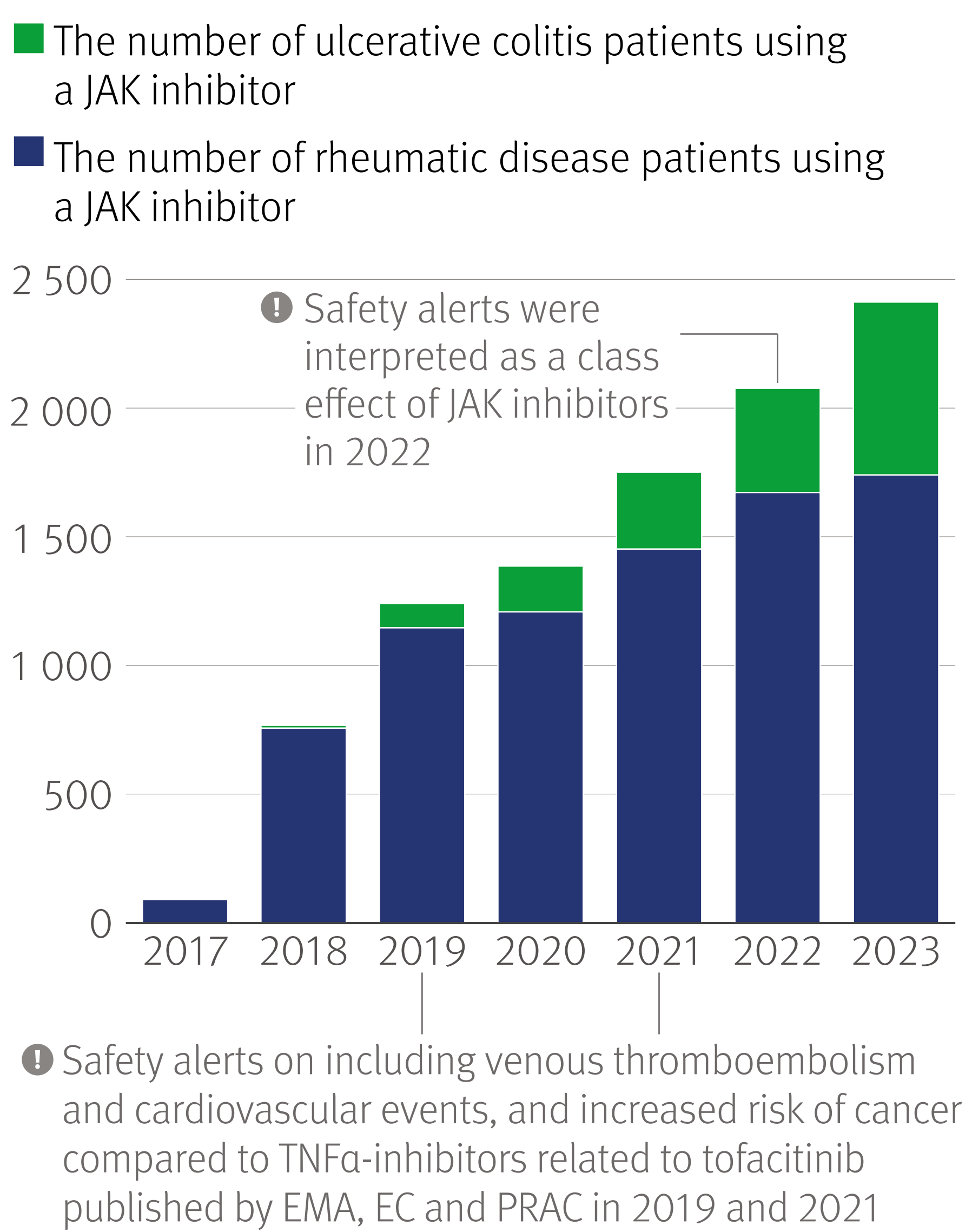
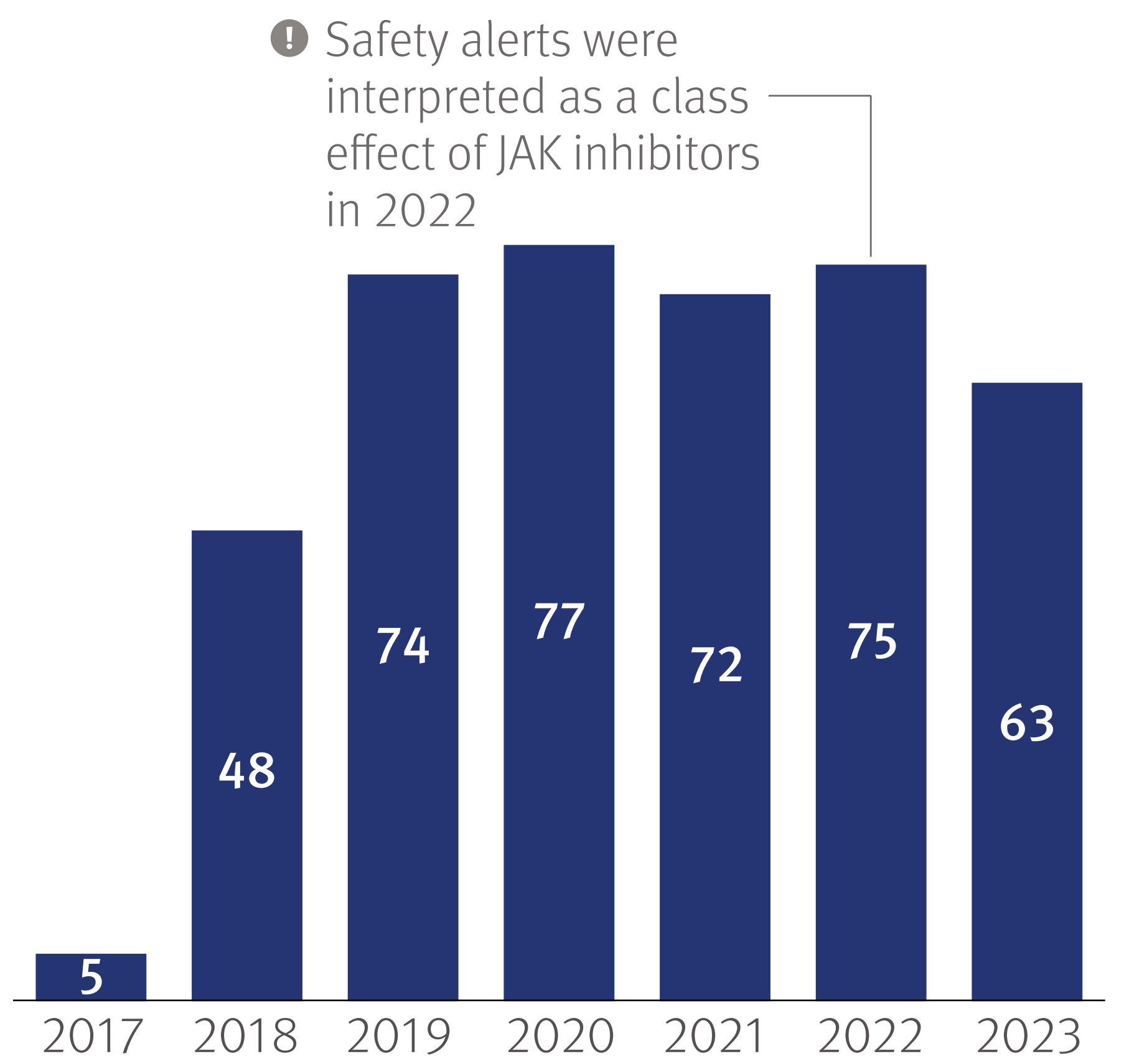


Figure 2. JAK inhibitor initiations of patients with coronary heart disease, the most severe risk factor according to European Medicines Agency (EMA), in Finland 2017–2023



in Finland during 2017–2023. Data were collected from the Dispensations reimbursable under the National Health Insurance (NHI) Scheme register maintained by Kela in February 2024. Medication safety alerts were collected from the EMA webpages. Data were analyzed with descriptive statistics and by appropriate statistical methods.

Results

The annual number of patients initiating JAK inhibitor treatment increased from 94 patients in 2017 to 722 patients in 2023. Cumulative number of patients receiving reim-

bursements of JAK inhibitors increased from 94 patients in 2017 to 2 428 patients in 2023, indicating that treatment initiations were 29.7% of all use (Figure 1). The most commonly used JAK inhibitors were tofacitinib and baricitinib. The median age of patients has decreased from 53 years in 2017 to 39 years in 2023. This change was mainly driven by proportional increase of ulcerative colitis patients (no users in 2017 vs. 27.7 % in 2023) who are younger (median age of 39 years in 2023), while median age of rheumatic disease patients (all users in 2017 vs. 71.7 % of in 2023) slightly increased during observation period (52.5 years in 2017 vs. 57 years in 2023). The absolute number of JAK inhibitor initiators with coronary heart disease, the most severe risk factor according to EMA, has first increased (5 patients, 5.3% of all initiations in 2017 vs. 77 patients, 5.7% in 2020), but then decreased from 2021 onwards (72 patients, 4.2% in 2021 vs. 63 patients, 2.6% in 2023) (Figure 2).

Conclusions

The absolute number of patients receiving JAK inhibitors in Finland has increased over 20-fold during the observation period. The use of JAK inhibitors has proportionally shifted towards younger ulcerative colitis patients. However, prescribing for patients with high risk due to their coronary heart disease seems to have decreased after the medication safety alerts.

Key points

- In Finland the use of JAK inhibitors has increased over 20-fold in 2017–2023, shifting towards younger patients.
- Medication safety alerts regarding the JAK inhibitor use published by the European Medicines Agency (EMA), European Commission (EC) and Pharmacovigilance Risk Assessment Committee (PRAC) have raised concerns.
- Prescribing for patients with high risk due to their coronary heart disease in Finland seems to have decreased after the medication safety alerts.

References

1 European Medicines Agency 2024. <https://www.ema.europa.eu/en/medicines/human/referrals/ianus-kinase-inhibitors-jaki>

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