



OFFICE of the DEPUTY PRIME MINISTER
MINISTRY for HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH CIRCULAR 84/2017

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Attention All: Consultant Psychiatrists
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

RE: Revision in the White Blood Cell Count Monitoring schedule for patients on Clozapine.

Clozapine is an atypical antipsychotic used for treatment resistant schizophrenia. The drug is subject to strict monitoring requirements because it is associated with serious side effects such as neutropenia, agranulocytosis, seizures, myocarditis and cardiomyopathy.

The Summary of Product Characteristics of Clozapine states that blood monitoring should be carried out in accordance with national-specific official recommendations.

The blood monitoring of Clozapine to manage the risk of agranulocytosis associated with clozapine is being revised as follows:

- **At least weekly for the first 18 weeks of treatment.**
- **At least at 2 week intervals between weeks 18 and 52.**
- **After 1 year of treatment with stable neutrophil counts, patients may be monitored at least at 4 week intervals.**
- **Monitoring must continue throughout treatment and for at least 4 weeks after discontinuation.**

All other current arrangements for the prescribing and dispensing of Clozapine remain in place.

Clozapine should be prescribed by consultant psychiatrists as per criteria set out in the Medicine Protocol. Its use should be limited to patients who have initially normal leukocyte findings (white blood cell count $\geq 3500/\text{mm}^3$ ($3.5 \times 10^9/\text{l}$), and ANC $\geq 2000/\text{mm}^3$ ($\geq 2.0 \times 10^9/\text{l}$).

For more detailed prescribing information, warnings and contraindications please refer to the Summary of Product Characteristics.

For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer