



RESOLUTION

REGIONAL COMMITTEE FOR THE
EASTERN MEDITERRANEAN

EM/RC53/R.12
September 2006

Fifty-third Session

Agenda item 17

**Draft regional guidelines on stability testing of active substances
and pharmaceutical products**

The Regional Committee,

Having reviewed the draft regional guidelines on stability testing of active substances and pharmaceutical products¹;

Recalling Regional Committee resolution EM/RC/45/R.10 GATT agreement—its impact on health and EM/RC47/R.7 The implications of GATT and WTO agreements;

Recalling the role of WHO as the international standard-setting organization with respect to biologicals, pharmaceuticals and similar products;

1. **ADOPTS** the regional guidelines on stability testing of active substances and pharmaceutical products following the inclusion of the comments made by Member States as appropriate;
2. **REQUESTS** Member States to revise the requirements of drug registration to be consistent with these guidelines;
3. **REQUESTS** the Director-General to revise the global WHO stability guidelines taking into consideration the regional guidelines;
4. **REQUESTS** the Regional Director to continue efforts in the area of harmonization in other technical registration requirements, particularly those related to biogenerics and other biotechnology products.

¹ Document EM/RC53/12