AMR draft proposals

Stimulating the development of new antibiotics, and preserving them once developed, requires a global response. However, the EU can take the practical lead unilaterally on some urgent issues and make proposals for others to be taken forward in global foras.

Measures with a global effect that can be taken forward by EU alone:

- 1. Setting up of a pipeline database for all new antibiotics in development worldwide. The database will be used to identify "priority antibiotics" that are subject to dedicated use in humans (see 2) and new incentives (below). Possible ownership: EMA and or ECDC. The work can build on the ESKAPE list as well as JPIAMR priorities and the "urgent threat" definition by CDC. The "priority antibiotics" criteria could be agreed at an expert conference, possibly organised with WHO.
- 2. Development of a global charter to dedicate priority antibiotics for development and use only in humans. Taking the opportunity of the review of the veterinary medicines legislation, building on the principles of OneHealth, and acknowledging the need for new antibiotics in both humans and animals, pharmaceutical companies and public sector research funders should be invited to sign the charter. As the number of developers is relatively limited, it is feasible for the EU to take the lead, including at the global level.

Measures that require a global agreement and action:

- Development of a global charter, or an international law instrument (e.g. convention or protocol), securing prudent use (stewardship) of new priority antibiotics. The instrument should bind countries to implement plans for controlled use and monitoring of resistance. For example, the regional offices of WHO could be given a role to coordinate country-specific or regional plans.
- 2. Development of a global charter with the pharmaceutical industry to ensure global access to new priority antibiotics at affordable prices. Companies should be invited to apply differential (tiered) pricing based on the GDP of countries. Companies should commit not to promote new priority

- antibiotics and to agree with government agencies (or WHO regional offices, cf 3 above) the appropriate education of prescribers.
- 3. Agreement in G20 (alt G7/G8) to set up financial "pull" incentives to stimulate the development of new priority antibiotics. Being complementary to existing "push" incentives (e.g. from BARDA, IMI, IDFF) the size of the incentives should be set to further compensate for the R&D expenditure and the risks associated. The design of incentives could differ between countries, such as through a transferable right (modelled on the priority review voucher in the US) or an advanced purchase commitment ("virtual stockpiling"). For the latter, the new Joint Procurement Agreement could be used for "innovation procurement" for the EU.